



Date: 24 June 2025

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.

Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

Attn: The Board of Directors

Dear Sirs

Cloudbreak Pharma Inc. (the "Company") – Listing on the Main Board of The Stock Exchange of Hong Kong Limited

We refer to the prospectus of the Company dated 24 June 2025 (the "**Prospectus**") in connection with the global offering and proposed listing of its shares on the Main Board of The Stock Exchange of Hong Kong Limited.

We hereby give our consent and confirm that we have not withdrawn our consent to the issue of the Prospectus with the inclusion therein of our name, our opinion and/or report in the form and context in which they respectively appear in the Prospectus.

We also consent to this letter, our opinion and report referred to above being made available on display as described in the Prospectus.

Yours faithfully,

For and on behalf of
CCB International Capital Limited



Name: Calvin Chan
Title: Managing Director

Date: 24 June 2025

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.

Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

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We also consent to this letter, our opinion and report referred to above being made available on display as described in the Prospectus.

Yours faithfully,

For and on behalf of

Huatai Financial Holdings (Hong Kong) Limited



Name: Marcus Woo

Title: Managing Director

Date: 24 June 2015

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Lippo Centre Tower 1
89 Queensway
Hong Kong

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We hereby give our consent and confirm that we have not withdrawn our consent to the issue of the Prospectus with the inclusion therein of our name, our opinion and/or report in the form and context in which they respectively appear in the Prospectus.

We also consent to this letter, our opinion and report referred to above being made available on display as described in the Prospectus.

Yours faithfully,
For and on behalf of
Frost & Sullivan Limited



Name: Charles Lau
Title: Executive Director

Date: 24 June 2015

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.

Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

Attn: The Board of Directors

Dear Sirs

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We refer to the prospectus of the Company dated 24 June 2015 (the "**Prospectus**") in connection with the global offering and proposed listing of its shares on the Main Board of The Stock Exchange of Hong Kong Limited.

We hereby give our consent and confirm that we have not withdrawn our consent to the issue of the Prospectus with the inclusion therein of our name, our opinion and/or report in the form and context in which they respectively appear in the Prospectus.

We also consent to this letter, our opinion and report referred to above being made available on display as described in the Prospectus.

Yours faithfully,
For and on behalf of
Haiwen & Partners



Name: TANG Jiangshan
Title: Partner

HARNEYS

Harney Westwood & Riegels
3501 The Center
99 Queen's Road Central
Hong Kong
Tel: +852 5806 7800
Fax: +852 5806 7810

24 June 2025

raymond.ng@harneys.com
+852 5806 7883
013070-0184-RLN

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.
Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

Attn: The Board of Directors

Dear Sir or Madam

Consent to the issue of the Prospectus of Cloudbreak Pharma Inc. (the *Company*) in connection with the Proposed Listing and Global Offering

We refer to the prospectus of the Company dated 24 June 2025 (the ***Prospectus***) in connection with the Company's proposed global offering and the proposed listing of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the ***Stock Exchange***).

We hereby give our consent, and confirm we have not withdrawn our consent, to the issue of the Prospectus, with the inclusion therein of our summaries of the constitution of the Company and Cayman Islands companies law, the texts of which are set out in Appendix III to the Prospectus, and all references thereto and to our names, opinions and qualifications, in the form and context in which they respectively appear in the Prospectus.

We also hereby give our consent to (i) this letter being released to the Registrar of Companies in Hong Kong and the Stock Exchange for the purpose of the registration of the Prospectus, and (ii) a copy of the documents referred to the above, our letter of advice in respect of certain aspects of Cayman Islands companies law referred to in Appendix III of the Prospectus and a copy of this letter being made available for public inspection as described in Appendix V to the Prospectus.

The British Virgin Islands is Harneys Hong Kong office's main jurisdiction of practice.
Jersey legal services are provided through a referral arrangement with Harneys (Jersey) which is an independently owned and controlled Jersey law firm.
Resident Partners: M Chu | JP Engwirda | Y Fan | S Gray | P Kay | MW Kwok | IN Mann | R Ng
ATC Ridgers | PJ Sephton
612635712.1

Anguilla | Bermuda | British Virgin Islands | Cayman Islands
Cyprus | Hong Kong | Jersey | London | Luxembourg
Montevideo | São Paulo | Shanghai | Singapore
harneys.com

Yours faithfully

Harney Westwood & Riegels

Harney Westwood & Riegels

Date: 24 June 2015

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.
Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

Attn: The Board of Directors

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Cloudbreak Pharma Inc. (the "Company") – Listing on the Main Board of The Stock Exchange of Hong Kong Limited

We refer to the prospectus of the Company dated 24 June 2015 (the "**Prospectus**") in connection with the global offering and proposed listing of its shares on the Main Board of The Stock Exchange of Hong Kong Limited.

We hereby give our consent and confirm that we have not withdrawn our consent to the issue of the Prospectus with the inclusion therein of our name and our opinion in the form and context in which they respectively appear in the Prospectus.

We also consent to this letter, our opinion referred to above being made available on display as described in the Prospectus.

Yours faithfully,
For and on behalf of

Jun He Law Offices P.C.

Jun He Law Offices P.C.

Date: 24 June 2015

PRIVATE AND CONFIDENTIAL

Cloudbreak Pharma Inc.
Unit 2308, 23/F
Lippo Centre Tower 1
89 Queensway
Hong Kong

Attn: The Board of Directors

Dear Sirs

Cloudbreak Pharma Inc. (the "Company") – Listing on the Main Board of The Stock Exchange of Hong Kong Limited

We refer to the prospectus of the Company dated 24 June 2015 (the "**Prospectus**") in connection with the global offering and proposed listing of its shares on the Main Board of The Stock Exchange of Hong Kong Limited.

We hereby give our consent and confirm that we have not withdrawn our consent to the issue of the Prospectus with the inclusion therein of our name and our opinion in the form and context in which they respectively appear in the Prospectus.

We also consent to this letter, our opinion referred to above being made available on display as described in the Prospectus.



Yours faithfully,
For and on behalf of

A red circular stamp with a five-pointed star in the center. The text around the star is in Chinese characters: "上海分所" (Shanghai Branch Office) at the top and "JunHe LLP" at the bottom.

JunHe LLP Shanghai Office





羅兵咸永道

The Directors
Cloudbreak Pharma Inc.
Unit 2308, 23/F,
Lippo Centre Tower 1,
89 Queensway,
Admiralty,
Hong Kong

24 June 2025

Dear Sirs,

We refer to the prospectus dated 24 June 2025 in connection with the proposed initial listing of shares of Cloudbreak Pharma Inc. (the "Company") on the Main Board of The Stock Exchange of Hong Kong Limited (the "Prospectus"), a copy of which is attached and initialled by us on its front cover for the purpose of identification.

Our engagement to prepare this letter has been performed in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants.

We hereby consent to the inclusion of our accountant's report and our report on unaudited pro forma financial information, both dated 24 June 2025, in the Prospectus, and the references to our name in the form and context in which they are included.

Yours faithfully,



PricewaterhouseCoopers
Certified Public Accountants
Hong Kong



拨康视云™
Cloudbreak Pharma

Cloudbreak Pharma Inc.

撥康視雲製藥有限公司*

(Incorporated in the Cayman Islands with limited liability)
Stock Code: 2592

* For identification purpose only

GLOBAL OFFERING

Joint Sponsors, Overall Coordinators, Joint Global Coordinators, Joint Bookrunners and Joint Lead Managers
(In alphabetical order)



Joint Global Coordinators, Joint Bookrunners and Joint Lead Managers
(In alphabetical order)



IMPORTANT

If you are in any doubt about any of the contents of this prospectus, you should seek independent professional advice.



拔康视云™
Cloudbreak Pharma

CLOUDBREAK PHARMA INC.

撥康視雲製藥有限公司*

(Incorporated in the Cayman Islands with limited liability)

GLOBAL OFFERING

Number of Offer Shares under the Global Offering : 60,582,000 Shares
Number of Hong Kong Offer Shares : 6,058,500 Shares (subject to reallocation)
Number of International Offer Shares : 54,523,500 Shares (subject to reallocation)
Offer Price : HK\$10.10 per Share plus brokerage of 1.0%,
SFC transaction levy of 0.0027%, Stock
Exchange trading fee of 0.00565% and
AFRC transaction levy of 0.00015%
(payable in full on application in Hong
Kong dollars and subject to refund)
Nominal Value : US\$0.0001 per Share
Stock Code : 2592

Joint Sponsors, Overall Coordinators, Joint Global Coordinators,
Joint Bookrunners and Joint Lead Managers
(In alphabetical order)



Joint Global Coordinators, Joint Bookrunners and Joint Lead Managers
(In alphabetical order)



Joint Bookrunners and Joint Lead Managers



Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this prospectus, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this prospectus.

A copy of this prospectus, having attached thereto the documents specified in "Documents Delivered to the Registrar of Companies and Available for Inspection" in Appendix V to this prospectus, has been registered by the Registrar of Companies in Hong Kong as required by section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong). The Securities and Futures Commission and the Registrar of Companies in Hong Kong take no responsibility for the contents of this prospectus or any other document referred to above.

The Offer Price will be HK\$10.10. Investors applying for the Hong Kong Offer Shares may be required to pay, on application (subject to application channels), the Offer Price of HK\$10.10 for each Share together with a brokerage of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015%.

The Overall Coordinators (for themselves and on behalf of the Underwriters) with the consent of our Company, may reduce the number of Offer Shares and/or the Offer Price below that stated in this prospectus (which is HK\$10.10 per Offer Share) at any time prior to the morning of the last day for lodging applications under the Hong Kong Public Offering. In such a case, notices of the reduction in the number of Offer Shares and/or the Offer Price will be published on our website at www.cloudbreakpharma.com not later than the morning of the last day for lodging applications under the Hong Kong Public Offering. Such notice will also be available at the website of the Stock Exchange at www.hkex.com.hk. Further details are set out in "Structure of the Global Offering" and "How to Apply for Hong Kong Offer Shares" in this prospectus.

Prior to making an investment decision, prospective investors should consider carefully all of the information set out in this prospectus, including the risk factors set out in "Risk Factors" in this prospectus. The obligations of the Hong Kong Underwriters under the Hong Kong Underwriting Agreement to subscribe for, and to procure subscribers for, the Hong Kong Offer Shares, are subject to termination by the Overall Coordinators (for themselves and on behalf of the Underwriters) if certain events shall occur prior to 8:00 a.m. on the day that trading in the Shares commences on the Stock Exchange. Such grounds are set out in "Underwriting" in this prospectus. It is important that you refer to that section for further details.

The Offer Shares have not been and will not be registered under the U.S. Securities Act or any state securities law in the United States and may be offered and sold only outside the United States in offshore transactions in accordance with Regulation S.

ATTENTION

We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide printed copies of this prospectus to the public in relation to the Hong Kong Public Offering.

This prospectus is available at the websites of the Stock Exchange (www.hkexnews.hk) and our Company (www.cloudbreakpharma.com). If you require a printed copy of this prospectus, you may download and print from the website addresses above.

* For identification purpose only

24 June 2025

IMPORTANT

IMPORTANT NOTICE TO INVESTORS: FULLY ELECTRONIC APPLICATION PROCESS

We have adopted a fully electronic application process for the Hong Kong Public Offer. We will not provide printed copies of this prospectus to the public in relation to the Hong Kong Public Offer.

This prospectus is available at the website of the Hong Kong Stock Exchange at www.hkexnews.hk under the “HKEXnews > New Listings > New Listing Information” section, and our website at www.cloudbreakpharma.com. If you require a printed copy of this prospectus, you may download and print from the website addresses above.

To apply for Hong Kong Offer Shares, you may use one of the following application channels:

Application Channel	Platform	Target Investors	Application Time
HK eIPO White Form service.	www.hkeipo.hk ;	Investors who would like to receive a physical Share certificate. Hong Kong Offer Shares successfully applied for will be allotted and issued in your own name.	From 9:00 a.m. on Tuesday, 24 June 2025 to 11:30 a.m. on Friday, 27 June 2025, Hong Kong time. The latest time for completing full payment of application monies will be 12:00 noon on Friday, 27 June 2025, Hong Kong time.
HKSCC EIPO channel	Your broker or custodian who is a HKSCC Participant will submit an EIPO application on your behalf through HKSCC’s FINI system in accordance with your instruction	Investors who would <u>not</u> like to receive a physical Share certificate. Hong Kong Offer Shares successfully applied for will be allotted and issued in the name of HKSCC Nominees, deposited directly into CCASS and credited to your designated HKSCC Participant’s stock account.	Contact your broker or custodian for the earliest and latest time for giving such instructions, as this may vary by broker or custodian.

We will not provide any physical channels to accept any application for the Hong Kong Offer Shares by the public. The contents of the electronic version of this prospectus are identical to the printed document as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

If you are an **intermediary, broker or agent**, please remind your customers, clients or principals, as applicable, that this prospectus is available online at the website addresses above.

See “How to Apply for Hong Kong Offer Shares” for further details on the procedures through which you can apply for the Hong Kong Offer Shares electronically.

IMPORTANT

Your application through the **HK eIPO White Form** service or the HKSCC EIPO channel must be for a minimum of 500 Hong Kong Offer Shares and in one of the numbers set out in the table. If you are applying through the **HK eIPO White Form** service, you may refer to the table below for the amount payable for the number of Shares you have selected. You must pay the respective amount payable on application in full upon application for Hong Kong Offer Shares. If you are applying through the HKSCC EIPO channel, you are required to prefund your application based on the amount specified by your broker or custodian, as determined based on the applicable laws and regulations in Hong Kong.

No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment
	HK\$		HK\$		HK\$		HK\$
500	5,100.94	7,000	71,413.01	50,000	510,092.93	700,000	7,141,300.96
1,000	10,201.86	8,000	81,614.87	60,000	612,111.51	800,000	8,161,486.80
1,500	15,302.79	9,000	91,816.73	70,000	714,130.10	900,000	9,181,672.66
2,000	20,403.72	10,000	102,018.59	80,000	816,148.68	1,000,000	10,201,858.50
2,500	25,504.65	15,000	153,027.88	90,000	918,167.26	2,000,000	20,403,717.00
3,000	30,605.58	20,000	204,037.16	100,000	1,020,185.86	3,029,000 ⁽¹⁾	30,901,429.40
3,500	35,706.50	25,000	255,046.47	200,000	2,040,371.70		
4,000	40,807.43	30,000	306,055.75	300,000	3,060,557.56		
4,500	45,908.37	35,000	357,065.04	400,000	4,080,743.40		
5,000	51,009.29	40,000	408,074.35	500,000	5,100,929.26		
6,000	61,211.15	45,000	459,083.63	600,000	6,121,115.10		

Notes:

- (1) Maximum number of Hong Kong Offer Shares you may apply for and this is approximately 50% of the Hong Kong Offer Shares initially offered.
- (2) The amount payable is inclusive of brokerage, SFC transaction levy, the Stock Exchange trading fee and AFRC transaction levy. If your application is successful, brokerage will be paid to the Exchange Participants (as defined in the Listing Rules) or to the **HK eIPO White Form** Service Provider (for applications made through the application channel of the **HK eIPO White Form** service) while the SFC transaction levy, the Stock Exchange trading fee and the AFRC transaction levy will be paid to the SFC, the Stock Exchange and the AFRC, respectively.

No application for any other number of the Hong Kong Offer Shares will be considered and any such application is liable to be rejected.

EXPECTED TIMETABLE⁽¹⁾

If there is any change in the following expected timetable of the Hong Kong Public Offering, we will issue an announcement in Hong Kong to be published on the websites of the Stock Exchange at www.hkexnews.hk and our Company at www.cloudbreakpharma.com.

Hong Kong Public Offering commences 9:00 a.m. on Tuesday, 24 June 2025

Latest time to complete electronic applications
under the **HK eIPO White Form** service through
the designated website at www.hkeipo.hk⁽²⁾ 11:30 a.m. on Friday, 27 June 2025

Application lists open⁽³⁾ 11:45 a.m. on Friday, 27 June 2025

Latest time for (a) completing payment of **HK eIPO White Form**
applications by effecting internet banking transfer(s) or
PPS payment transfer(s) and (b) giving
electronic application instructions to HKSCC⁽⁴⁾ 12:00 noon on
Friday, 27 June 2025

If you are instructing your **broker** or **custodian** who is a HKSCC Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you are advised to contact your **broker** or **custodian** for the latest time for giving such instructions which may be different from the latest time as stated above.

Application lists close⁽³⁾ 12:00 noon on Friday, 27 June 2025

Announcement of Offer Price, the level of applications in the Hong Kong Public Offering; the indication of level of interest in the International Offering; and the basis of allocation of the Hong Kong Offer Shares to be published on our website at www.cloudbreakpharma.com⁽⁵⁾ and the website of the Stock Exchange at www.hkexnews.hk
on or before Wednesday, 2 July 2025

The results of allocations in the Hong Kong Public Offering (with successful applicants' identification document numbers, where appropriate) to be available through a variety of channels, including:

- in the announcement to be posted on our website
and the website of the Stock Exchange
at www.cloudbreakpharma.com
and www.hkexnews.hk, respectively Wednesday, 2 July 2025

EXPECTED TIMETABLE⁽¹⁾

- Results of allocations in the Hong Kong Public Offering will be available at “Allotment Results” page at www.tricor.com.hk/ipo/result and www.hkeipo.hk/IPOResult with a “search by ID” function from 11:00 p.m. on Wednesday, 2 July 2025
- from the allocation results telephone enquiry line by calling +852 3691 8488 between 9:00 a.m. and 6:00 p.m. from Thursday, 3 July 2025

Share certificates in respect of wholly or partially successful applications pursuant to the Hong Kong Public Offering to be dispatched or deposited into CCASS on or before⁽⁶⁾⁽⁸⁾ Wednesday, 2 July 2025

HK eIPO White Form e-Auto Refund payment instructions/refund cheque in respect of wholly or partially unsuccessful applications pursuant to the Hong Kong Public Offering to be dispatched on or before⁽⁷⁾⁽⁸⁾ Thursday, 3 July 2025

Dealings in Shares on the Hong Kong Stock Exchange expected to commence at 9:00 a.m. on Thursday, 3 July 2025

Notes:

- (1) All dates and times refer to Hong Kong local dates and times, except as otherwise stated. Details of the structure of the Global Offering, including conditions of the Hong Kong Public Offering, are set forth in “Structure of the Global Offering” in this prospectus.
- (2) If you have already submitted your application through the designated website at www.hkeipo.hk and obtained an application reference number from the designated website prior to 11:30 a.m., you will be permitted to continue the application process (by completing payment of application monies) until 12:00 noon on the last day for submitting applications, when the application lists close. You will not be permitted to submit your application through the designated website at www.hkeipo.hk after 11:30 a.m. on the last day for submitting applications.
- (3) If there is/are a tropical cyclone warning signal number 8 or above, or a “black” rainstorm warning and/or Extreme Conditions, collectively (“**Bad Weather Signals**”) in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon on Friday, 27 June 2025, the application lists will not open or close on that day. See “How to Apply for Hong Kong Offer Shares – E. Bad Weather Arrangements” for details.
- (4) Applicants who apply for the Hong Kong Offer Shares by giving **electronic application instructions** to HKSCC should refer to “How to Apply for Hong Kong Offer Shares – A. Application for Hong Kong Offer Shares – 2. Application Channels” for details.
- (5) None of the website or any of the information contained on the website forms part of this prospectus.

EXPECTED TIMETABLE⁽¹⁾

- (6) The Share certificates will only become valid evidence of title provided that the Global Offering has become unconditional in all respects and neither of the Hong Kong Underwriting Agreement nor the International Underwriting Agreement is terminated in accordance with its respective terms prior to 8:00 a.m. on the Listing Date. The Listing Date is expected to be on or about Thursday, 3 July 2025. Investors who trade the Shares on the basis of publicly available allocation details prior to the receipt of Share certificates or prior to the Share certificates becoming valid evidence of title do so entirely at their own risk.
- (7) e-Auto Refund payment instructions/refund cheque will be issued in respect of wholly or partially unsuccessful applications. Part of the applicant's identification document number, or, if the application is made by joint applicants, part of the identification document number of the first-named applicant, provided by the applicant(s) may be printed on the refund cheque, if any. Such data would also be transferred to a third party for refund purposes. Banks may require verification of an applicant's identification document number before encashment of the refund cheque. Inaccurate completion of an applicant's identification document number may invalidate or delay encashment of the refund cheque.
- (8) Applicants who have applied through the **HK eIPO White Form** service for 1,000,000 or more Hong Kong Offer Shares may collect any Share certificates in person from our Hong Kong Share Registrar, Tricor Investor Services Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong from 9:00 a.m. to 1:00 p.m. on Thursday, 3 July 2025 or such other date as notified by us as the date of collection of Share certificates. Applicants being individuals who are eligible for personal collection may not authorise any other person to collect on their behalf. If you are a corporate applicant which is eligible for personal collection, your authorised representative must bear a letter of authorisation from your corporation stamped with your corporation's chop. Both individuals and authorised representatives must produce evidence of identity acceptable to our Hong Kong Share Registrar at the time of collection.

Applicants who have applied for Hong Kong Offer Shares through the HKSCC EIPO channel should refer to "How to Apply for Hong Kong Offer Shares – D. Despatch/Collection of Share Certificates and Refund of Application Monies" in this prospectus.

Applicants who have applied through the **HK eIPO White Form** service and paid their applications monies through single bank accounts may have refund monies (if any) dispatched to the bank account in the form of e-Auto Refund payment instructions. Applicants who have applied through the **HK eIPO White Form** service and paid their application monies through multiple bank accounts may have refund monies (if any) dispatched to the address as specified in their application instructions in the form of refund cheque in favour of the applicant (or, in the case of joint applications, the first-named applicant) by ordinary post at their own risk.

Share certificates and/or refund cheque for applicants who have applied for less than 1,000,000 Hong Kong Offer Shares and any uncollected Share certificates will be dispatched by ordinary post, at the applicants' risk, to the addresses specified in the relevant applications.

Further information is set out in "How to Apply for Hong Kong Offer Shares – D. Despatch/Collection of Share Certificates and Refund of Application Monies" in this prospectus.

EXPECTED TIMETABLE⁽¹⁾

The above expected timetable is a summary only. For details of the structure of the Global Offering, including its conditions, and the procedures for applications for Hong Kong Offer Shares, see “Structure of the Global Offering” and “How to Apply for Hong Kong Offer Shares” for details, respectively.

If the Global Offering does not become unconditional or is terminated in accordance with its terms, the Global Offering will not proceed. In such a case, the Company will publish an announcement as soon as practicable thereafter.

Publication of this prospectus into any jurisdiction other than Hong Kong may be restricted by law. Persons who come into possession of this prospectus (including, without limitation, agents, custodians, nominees and trustees) should inform themselves of, and observe, any such restrictions. Any failure to comply with such restrictions may constitute a violation of the securities laws of any such jurisdiction.

CONTENTS

IMPORTANT NOTICE TO INVESTORS

This prospectus is issued by us solely in connection with the Hong Kong Public Offering and does not constitute an offer to sell or a solicitation of an offer to buy any security other than the Hong Kong Offer Shares offered by this prospectus pursuant to the Hong Kong Public Offering. This prospectus may not be used for the purpose of, and does not constitute, an offer or a solicitation of an offer to subscribe for or buy, any security in any other jurisdiction or in any other circumstances. No action has been taken to permit a public offering of the Offer Shares or the publication of this prospectus in any jurisdiction other than Hong Kong. The publication of this prospectus and the offering and sale of the Offer Shares in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions pursuant to registration with or authorisation by the relevant securities regulatory authorities or an exemption therefrom.

You should rely only on the information contained in this prospectus to make your investment decision. We have not authorised anyone to provide you with information that is different from what is contained in this prospectus. Any information or representation not made in this prospectus must not be relied on by you as having been authorised by us, the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Capital Market Intermediaries, the Underwriters, any of our or their respective directors, officers or representatives, or any other person or party involved in the Global Offering.

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SUMMARY

This summary aims to give you an overview of the information contained in this prospectus. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to invest in the Offer Shares.

*There are risks associated with any investment. Some of the particular risks in investing in the Offer Shares are set out in the section headed “Risk Factors” in this prospectus. You should read that section carefully before you decide to invest in the Offer Shares. **In particular, we are a biotechnology company seeking to list on the Main Board under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules.** There are unique challenges, risks and uncertainties associated with investing in companies such as ours. Your investment decision should be made in light of these considerations.*

OVERVIEW

We are a clinical-stage ophthalmology biotechnology company dedicated to the development of various treatments. Ophthalmology is a branch of medical science dealing with the structure, function and diseases of the eyes. Our history traces back to 2015 upon the establishment of our Group. We have two Core Products, CBT-001 and CBT-009, both of which are being proprietarily developed. Our Core Product CBT-001 is indicated for the treatment of pterygium (a benign proliferative ocular surface disease), and we have commenced phase 3 multi-regional clinical trial (“MRCT”) in the United States and China in June 2022 and September 2023 respectively for it. Our Core Product CBT-009 is indicated for the treatment of juvenile myopia (myopia in children and adolescents aged 5 to 19), and we have completed the phase 1/2 clinical trial in January 2023 and submitted the investigational new drug (“IND”) application to the United States Food and Drug Administration (“FDA”) in July 2024 for it. Our other drug candidates are in relatively earlier development stage, including two other clinical-stage drug candidates, which are CBT-006 and CBT-004, and four pre-clinical stage drug candidates, which are CBT-007, CBT-199, CBT-145, and CBT-011.

However, the market potential for these Core Products might be limited and the market opportunities may be smaller than expected, because of unfavourable factors including but not limited to, inaccurate estimations on target patient populations, penetration in and/ or difficulty in accessing the medical community and patients. See “Risk Factors – Risks Relating to the Development, Clinical Trials and Regulatory Approval of Our Drug Candidates – The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised” for details.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ANY OF OUR DRUG CANDIDATES SUCCESSFULLY.

All of our four clinical-stage drug candidates have adopted the 505(b)(2) regulatory pathway. The 505(b)(2) regulatory pathway is applicable to modified new drugs that were developed based on previously approved reference drugs with modifications in dosage forms, routes of administration, formulation and/or new indications.

OUR PIPELINE OF DRUG CANDIDATES

We have established a pipeline of drug candidates covering major anterior and posterior ophthalmic diseases, with four clinical-stage drug candidates and four pre-clinical stage candidates, each as described in more detail below. All of the drug candidates in our pipeline are proprietary developed. See “Business – Our Pipeline of Drug Candidates” for details. The following chart summarises our pipeline of drug candidates as of the Latest Practicable Date:

Drug candidate	Mechanism	Indication	Commercial rights	Formulation	Pre-clinical	Phase 1	Phase 2	Phase 3	Relevant authority for clinical trial ⁽¹⁾	Competent authority and regulatory pathway ⁽¹⁾	Current status/upcoming milestones
Clinical-stage Drug Candidates	CBT-001 ⁽⁶⁾	MKI (VEGFRs, PDGFRs, FGFRs)	Prevention of pterygium progression and reduction of conjunctival hyperaemia	Global ⁽⁵⁾	Emulsion ⁽⁶⁾	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽²⁾			FDA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 2.2 and Class 2.4 ⁽⁵⁾)	- U.S.: commenced ph 3 MRCT in Jun 2022; expect to complete in June 2026 - China: commenced ph 3 MRCT in Sept 2023; expect to complete in June 2026 - New Zealand, Australia and India: commenced additional trials as part of global ph 3 MRCT
	CBT-009 ⁽⁸⁾⁽⁷⁾	Muscarinic receptor antagonist	Juvenile myopia	Global	Eye drop	Ph 1/2 combined and completed in Australia			TGA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 2.2 and Class 2.4 ⁽⁸⁾)	- U.S.: obtained the IND approval in Sept 2024; expect to commence ph 3 ⁽⁸⁾ - China: commenced toxicity study on juvenile animals in Feb 2025 and expect to submit IND application in third quarter of 2025
	CBT-006 ⁽⁹⁾	Cholesterol dissolving agent	MGD associated DED	Global	Eye drop	Ph 1 in U.S. expected to be directly commenced based on ph 1/2 results in Australia under the 505(b)(2) pathway ⁽⁹⁾			FDA	- U.S.: completed ph 2 in May 2022 - HK: expect to commence additional clinical research by end of 2025	
	CBT-004 ⁽¹⁰⁾	MKI (VEGFRs, PDGFRs)	Vascularised pinguecula	Global	Emulsion	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽⁶⁾			FDA	- U.S.: completed ph 2 in May 2025 - China: NMPA/chemical drugs application (Class 2.2 ⁽⁹⁾)	
Pre-clinical Stage Drug Candidates	CBT-007 ⁽¹¹⁾	MKI (PDGFRs, VEGFRs, FGFRs, PGFRs, TGF-β)	Glaucoma	Global	Eye drop						- U.S.: intend to submit IND in third quarter of 2025
	CBT-199 ⁽¹²⁾	Muscarinic cholinergic receptor agonist	Presbyopia	Global	Eye drop						- Australia: intend to submit IND in second quarter of 2025
	CBT-145 ⁽¹³⁾	Undisclosed	Presbyopia	Global	Eye drop						- As a back-up project for CBT-199; the IND application to be determined based on the progress of CBT-199
	CBT-011 ⁽¹⁴⁾	Antibody-drug synergism (“ADS”)	Diabetic macular edema (“DME”)/ age-related macular degeneration	Global	Eye drop						- U.S.: intend to submit IND by the end of 2025

* Denotes our Core Products

■ represents the clinical trials we have conducted/ we are conducting

■ represents the development phase of a drug candidate that was exempted from clinical trials

SUMMARY

Notes:

- (1) The jurisdiction of conducting clinical trials may differ from the jurisdiction where regulatory approval and commercialisation is pursued. We intend to obtain regulatory approval for and pursue commercialisation of our drug candidates primarily in the United States and China.
- (2) The clinical trials for a drug candidate before it is approved to be commercialised in the United States are generally conducted in three sequential phases, known as phase 1, phase 2 and phase 3. However, not all drug candidates are required to complete each of the three phases. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the “**FDCA**”) provides that FDA may rely on data not developed by the applicant for approval of a new drug application (“**NDA**”), even if this data was for a drug approved for a different indication. Under the 505(b)(2) pathway, we are able to utilise validated molecules or compounds with well-established safety and efficacy profiles currently applied in other therapeutic areas and develop them into novel ophthalmic drugs with new indications, dosage forms, routes of administration and formulation. All of our clinical-stage drug candidates have been approved by the FDA to adopt the 505(b)(2) pathway, and we were or will be able to skip the phase 1 clinical trial for them and directly proceed with the phase 2 clinical trial in the United States (for CBT-009, we will be able to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising the clinical trial results of phase 1/2 clinical trial in Australia).
- (3) The classification refers to the new drug classification under the Requirements for Registration Classification and Application Dossiers of Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA in 2020. “New drug” refers to new chemical entities or improved new forms of known chemical entities that have never been marketed anywhere in the world, namely Class 1, 2 and 5.1. Class 1 is classified as innovative new drugs which have never been marketed within or outside China. Class 2.2 is classified as new drugs the preparation of which uses new dosage form (including the new drug delivery system, new prescription process or administration route of known active ingredients), and which also have an obvious clinical advantage. Class 2.4 is classified as new drugs the preparation of which uses known active ingredients but with new indications. See “Industry Overview – Drug Application Pathways in the United States and China – Drug Application Pathways in China” for details.
- (4) For CBT-001, we submitted the IND application in the United States in December 2016, and the FDA did not raise any objection against proceeding with phase 2 clinical trial during the 30-day review period of the IND application. The phase 2 clinical trial was completed in April 2018. The FDA agreed that the CBT-001 could proceed to phase 3 MRCT in the end-of-phase-2 meeting (the “**EOP2 Meeting**”) with the FDA in May 2019. Further, after reviewing the data from phase 2 clinical trial in the United States and conducting a pre-IND meeting with us in March 2020, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China in March 2023. We commenced phase 3 MRCT in the United States and China in June 2022 and September 2023, respectively. We expect to complete phase 3 MRCT in the United States and China in June 2026. We have also commenced additional clinical trials in New Zealand, Australia and India as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. In May 2025, we completed the patient recruitment across all five jurisdictions and recruited 660 patients in total. We plan to submit an NDA to the FDA and the NMPA upon the completion of global phase 3 MRCT. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Clinical Development Plan” for details. The reference drug for CBT-001 under the 505(b)(2) pathway is Nintedanib (Ofev®).
- (5) We entered into a commercialisation licensing arrangement with Grand Pharma, pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in Greater China. Notwithstanding the above, we retain the right of applying for the NDA and expect to be the market authorisation holder of CBT-001. In addition, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand,

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Malaysia, Singapore, the Philippines and Indonesia (the “Territory”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan” for details.

- (6) CBT-001 was designed in the form of eye drop (solution) in phase 2 clinical trial and was reformed into ophthalmic emulsion in phase 3 MRCT.
- (7) For CBT-009, the phase 1/2 clinical trial was completed in January 2023. On 21 September 2023, we received the FDA’s preliminary comments on our pre-IND application, approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular toxicity study to support phase 3 clinical trial, and received an approval letter from the FDA in September 2024 stating that it had no objection to us proceeding with phase 3 clinical trial. We have commenced the toxicity study on juvenile animals in China in February 2025 and expect to submit IND application to the NMPA in the third quarter of 2025. We plan to commence phase 3 clinical trial in the United States and China simultaneously, after the toxicity study in China is completed. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009 – Clinical Development Plan” for details. The reference drug for CBT-009 under the 505(b)(2) pathway is atropine.
- (8) Notwithstanding the fact that we have made the pre-IND application to the FDA in July 2023 for CBT-009 and received its preliminary comments in September 2023, we made the IND application to the FDA in July 2024, one year after the pre-IND application, because it took around one year to prepare for and complete a GLP ocular toxicity study. The study was proposed by us and agreed by the FDA. It was conducted to support the phase 3 clinical trial of CBT-009 and has been completed in June 2024.
- (9) For CBT-006, we expect to commence additional clinical research in Hong Kong by the end of 2025. We may hold an EOP2 meeting with the FDA or a pre-IND meeting with the NMPA depending on the combined clinical results of the phase 2 clinical trial in the United States and additional clinical research in Hong Kong. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-006 – Clinical Development Plan” for details. The reference drugs for CBT-006 under the 505(b)(2) pathway are Mitozytrex, Sporanox, Dexacort, Vibativ® and Perindopril Erbumin.
- (10) For CBT-004, we obtained the IND approval from the FDA in February 2021, and since then, our R&D team has developed an improved formulation to enable higher doses of CBT-004. Consequently, we decided to conduct additional formulation stability and GLP ocular toxicity studies in rabbits and dogs, which is the reason of the time gap between the IND approval and the IND amendment. The IND amendment was submitted in September 2023 to amend our previous IND submission and phase 2 clinical trial protocol. We completed phase 2 clinical trial in May 2025. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-004 – Clinical Development Plan” for details. The reference drug for CBT-004 under the 505(b)(2) pathway is Inlyta (axitinib).
- (11) For CBT-007, we intend to submit the IND application to the FDA and/or other regulatory authorities in the third quarter of 2025 depending on the results of our ongoing pre-clinical research. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-007 – Near-term Plans” for details. CBT-007 will adopt the 505(b)(2) pathway and its reference drug is Stivarga (an oral prescription anticancer drug approved by the FDA for patients with metastatic colorectal cancer, gastrointestinal stromal tumor, and hepatocellular carcinoma).
- (12) For CBT-199, we intend to submit the IND application to the HREC in the second quarter of 2025 depending on the results of our ongoing pre-clinical research. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-199 – Near-term Plans” for details. CBT-199 is expected to adopt the 505(b)(1) pathway.

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- (13) For CBT-145, as a back-up project for CBT-199, the IND application is to be determined based on the progress of CBT-199. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-145 – Near-term Plans” for details. CBT-145 is expected to adopt the 505(b)(1) pathway.
- (14) For CBT-011, we intend to submit the IND application to the FDA and/or other regulatory authorities by the end of 2025 depending on the results of our ongoing pre-clinical research. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-011 – Near-term Plans” for details. CBT-011 is expected to adopt the 505(b)(1) pathway.

Clinical-stage Drug Candidates

Core Products

Our Core Product CBT-001 is a potential first-in-class drug therapy using multi-kinase inhibitor targeting platelet-derived growth factor receptors (“**PDGFRs**”), fibroblast growth factor receptors (“**FGFRs**”) and vascular endothelial growth factor receptors (“**VEGFRs**”), and is indicated for the prevention of pterygium progression and reduction of conjunctival hyperaemia. It is expected to be able to address moderate to severe pterygium. According to the F&S Report, there is currently no approved drug therapy for the treatment of pterygium globally, and the current existing treatment option for pterygium is surgical excision. CBT-001 is expected to be the first drug therapy globally for the treatment of pterygium, and to potentially reduce or postpone the need for surgical excision via early non-invasive treatment to control pterygium progression, once approved. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001” for details.

According to the F&S Report, the global market size of pterygium drug therapies is expected to reach US\$178.3 million in 2028 and US\$1,786.8 million in 2033, representing a CAGR of 58.6%. However, the market size of pterygium drug therapies globally is expected to remain nil till 2027, and may be relatively limited in the subsequent few years, as CBT-001, an expected first-in-class drug therapy globally, will require a period of time for education for healthcare professionals and expansion of patient acceptance, following its regulatory approvals. The market size of pterygium drug therapies is estimated based on certain assumptions, including but not limited to (i) the expected prevalence of pterygium; (ii) the expected diagnosis and treatment rate of pterygium, estimated based on current diagnosis and treatment rate of surgery and anti-inflammatory drugs; (iii) the estimated annual price of CBT-001; and (iv) that three drug candidates (CBT-001, AG-86893 and RMP-A03) indicated for pterygium are expected to be approved and launched in 2027, 2029 and 2036, respectively. See “Industry Overview – Pterygium – Market Size of Pterygium Drug Therapies” for details of the forecasted market size of drug therapies in 2027 to 2033 in the United States, China, and rest of the world, respectively, as well as detailed discussion on such assumptions. As of the Latest Practicable Date, there were three clinical-stage drug candidates indicated for pterygium and reduction of conjunctival hyperaemia globally, among which two were in phase 2 clinical trial stage and one was in phase 3 clinical trial stage, being CBT-001. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Market Opportunity and Competition” for details.

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Our Core Product CBT-009 is an ophthalmic formulation of atropine indicated for the treatment of juvenile myopia. We believe CBT-009 can make improvements on the current standard of care for juvenile myopia. Based on CBT-009's clinical trial and formulation stability results, CBT-009 is expected to improve patient tolerability, safety and product stability as compared with existing aqueous-based formulations based on pre-clinical and clinical studies conducted by us. See "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009" for details.

According to the F&S Report, the global market size of juvenile myopia drug therapies increased from US\$72.8 million in 2019 to US\$90.2 million in 2023, with a CAGR of 5.5%. It is expected to reach US\$858.3 million in 2028 and US\$3,697.0 million in 2033, representing a CAGR of 56.9% from 2023 to 2028 and 33.9% from 2028 to 2033, respectively. However, the market size of juvenile myopia drug therapies in China remained low at US\$5.2 million in 2023, and is expected to be relatively limited in the subsequent few years. The market size of juvenile myopia drug therapies is estimated based on certain assumptions, including but not limited to (i) the expected prevalence of juvenile myopia; (ii) the expected diagnosis and treatment rate of juvenile myopia, estimated based on current diagnosis and treatment rate; and (iii) the estimated annual costs per treatment. See "Industry Overview – Juvenile Myopia – Market Size of Juvenile Myopia Drug Therapies" for details of the forecasted market size of drug therapies in 2027 to 2033 in the United States, China, and rest of the world, respectively, as well as detailed discussion on such assumptions. There is currently no approved atropine drug therapy for the treatment of juvenile myopia in the United States. As of the Latest Practicable Date, Eikance 0.01% eye drop approved by the Australia Therapeutic Goods Administration was the first available prescription for children aged between four and 14 years old as a treatment option to slow down the progression of myopia. In addition to Eikance, Xingqi Meioupin 0.01% eye drop was approved by the NMPA in China in March 2024 for children aged between six and 12 years old as a treatment option to slow down the progression of myopia. In December 2024 and June 2025, Ryjusea 0.025% eye drop was approved in Japan and in the EU for children aged between five and 15 years old as a treatment option to slow down the progression of myopia. Eikance, Xinqi Meioupin and Ryjusea are aqueous-based eye drops which offer effective hydration and easier distribution evenly across the ocular surface, as well as good tolerance by patients and easy application without causing discomfort or stinging. CBT-009 is the only clinical-stage drug candidate that adopts non-aqueous formulation. In addition to the comparable efficacy in mitigating myopia that CBT-009 can provide as compared to other aqueous-based formulation, it is expected to further improve patient tolerability, safety and product stability as compared with existing aqueous-based formulations based on pre-clinical and clinical studies conducted by us or our contract research organisations ("CROs"). See "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009 – Market Opportunity and Competition" for details.

Other Clinical-stage Drug Candidates

Our clinical-stage drug candidate CBT-006 is a potential first-in-class drug candidate indicated for the treatment of meibomian gland dysfunction ("MGD") associated dry eye disease ("DED"). None of the launched products or drug candidates indicated for MGD associated DED use the same active ingredient as CBT-006 does. CBT-006 uses cyclodextrin

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as the active ingredient while other drugs use perfluorohexyloctane, selenium disulfide or lotilaner. CBT-006, once approved, is expected to become a first-in-class product treating MGD associated DED, by dissolving cholesterol and other lipids deposited at the orifice of meibomian glands and thus improve meibum quality and the health of meibomian gland. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-006” for details.

According to the F&S Report, MGD is a contributing factor in 70% to 86% of DED cases globally. Globally, the patient population of MGD associated DED reached 843.6 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 885.7 million in 2028 and 922.5 million in 2033, respectively, representing a CAGR of 1.0% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively. There is a wide range of treatment options for DED. Among them, Miebo™ (perfluorohexyloctane ophthalmic solution), indicated for the treatment of the signs and symptoms of DED and approved by the FDA on 18 May 2023, was the first and only FDA-approved drug therapy for DED that directly targets tear evaporation, which is often led by MGD by forming a monolayer at the air-liquid interface of the tear film to reduce evaporation, as of the Latest Practicable Date. On the same date, there were six clinical-stage drug candidates indicated for MGD associated DED globally, all of which were in phase 3 clinical trial stage, phase 2 clinical trial stage or the NDA stage, including CBT-006. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-006 – Market Opportunity and Competition” for details.

Our clinical-stage drug candidate CBT-004 is a potential first-in-class ophthalmic drug using multi-kinase inhibitor targeting VEGFRs and PDGFRs, and is indicated for the treatment of vascularised pinguecula. According to the F&S Report, there is currently no approved drug therapy for the treatment of vascularised pinguecula globally, and the current existing treatment options, including lubricating eye drops and off-label use of non-steroidal anti-inflammatory drugs or steroid eye drops, are insufficient to fulfil the clinical needs due to safety concerns and lack of efficacy. CBT-004 is expected to have advantages over the current standard of care for which can only temporarily alleviate symptoms of pinguecula. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-004” for details.

According to the F&S Report, the global market size of vascularised pinguecula drug therapies is expected to reach US\$1,539.3 million in 2033. As of the Latest Practicable Date, CBT-004 was the only clinical-stage drug therapy indicated for vascularised pinguecula globally. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-004 – Market Opportunity and Competition” for details.

Our Pre-clinical Stage Drug Candidates

In addition to our four clinical-stage drug candidates, our pipeline also includes four pre-clinical stage drug candidates, namely, CBT-007, developed for improving success rate of glaucoma filtration surgery, CBT-199 and CBT-145, a new formulation and a new chemical entity indicated for the treatment of presbyopia, and CBT-011, an ADS conjugate

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indicated for the treatment of diabetic macular edema (“DME”), a disease with retinal thickening caused by the accumulation of intraretinal fluid. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates” for details.

OUR STRENGTHS

We believe the following strengths have contributed to our success:

- An innovation-driven ophthalmology biotechnology company with proprietary technology platforms;
- Proprietary-developed pipeline covering major ophthalmic diseases with unmet medical needs and significant market potential;
- Unique innovation model enabling cost-effective drug development;
- Proprietary technology platforms purposefully built for development of ophthalmic therapies;
- Manufacturing facilities and commercialisation channel laying foundation for near-term commercialisation opportunities; and
- Visionary leadership team with rich industry experience and strong scientific expertise.

OUR STRATEGIES

We plan to pursue the following strategies to achieve our business goals:

- Accelerate clinical development of our pipeline of drug candidates in global markets;
- Continue to enhance our R&D capabilities to develop technology platform and modalities that support our pipeline expansion;
- Pursue diversified and tailored commercialisation strategies for our drug candidates; and
- Scale up our organisation to build an international platform.

ADDRESSABLE MARKETS AND COMPETITIVE LANDSCAPE OF OUR DRUG CANDIDATES

The global market size of ophthalmic drugs increased from US\$33.7 billion in 2019 to US\$39.6 billion in 2023, with a CAGR of 4.1%. It is expected to reach US\$53.0 billion in 2028 and US\$70.3 billion in 2033, representing a CAGR of 6.0% from 2023 to 2028 and 5.8% from 2028 to 2033, respectively.

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The pharmaceutical and biotechnology industries are highly competitive and subject to rapid changes. While we believe that our pipeline of drug candidates in clinical and pre-clinical trial stages, R&D capabilities, technology platforms and leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications as our drug candidates are indicated for, in particular in the fields of ophthalmology. Any drug candidates that we successfully develop and commercialise will compete both with existing drugs and with any new drugs that may become available in the future. In addition, as multiple prevention methods and alternative treatment options exist for the targeted indications of our drug candidates, and some of the indications are not contagious and may not lead to serious vision impairment depending on the patients' own condition, the market opportunities for our drug candidates may be smaller than anticipated. See "Risk Factor – Risks relating to the Development, Clinical Trials and Regulatory Approval of our Drug Candidates – The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised" for details of the relevant risks.

See the market opportunities and competitions of CBT-001, CBT-009, CBT-006 and CBT-004 respectively in "– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates" in this section, and in each of the sub-sections headed "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Market Opportunity and Competition" respectively.

RESEARCH AND DEVELOPMENT

We believe R&D is essential to the success of our ophthalmic drug candidates throughout different development stages, and we have established a pipeline of drug candidates covering major anterior and posterior ophthalmic diseases. All of the drug candidates in our pipeline are proprietarily developed, and we believe they have the potential to address unmet medical needs in the global ophthalmic drug market. For the years ended 31 December 2022, 2023 and 2024, our R&D expenses amounted to US\$15.3 million, US\$27.5 million and US\$37.9 million, respectively. For the same years, our clinical research expenses for our Core Products CBT-001 and CBT-009 amounted to US\$7.6 million, US\$8.9 million and US\$19.8 million, representing 49.4%, 32.3% and 52.2% of our R&D expenses in 2022, 2023 and 2024, respectively, and 31.2%, 22.9% and 41.8% of our total operating costs in 2022, 2023 and 2024, respectively.

We have built strong R&D capabilities to capture the potential in the global ophthalmic pharmaceutical market. We carry out in-house drug discovery and development led by senior scientists who have accumulated decades of pharmaceutical R&D and entrepreneurship experience in global ophthalmology giants and renowned research institutions, including our founder and CEO, Dr. Ni Jinsong, and members of our scientific advisory board. As of 31 December 2022, 2023 and 2024, and the Latest Practicable Date, we had 15, 17, 17 and 20 employees in charge of R&D activities, respectively. Among the 20 employees in charge of R&D activities as of the Latest Practicable Date, five members are from our senior management and 15 members are from our R&D department, and seven of them hold a master's degree or higher including five with doctor's degrees. Except for the chief

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operations director who is responsible for managing researchers and facilitating the execution of research activities, all the R&D team members majored in fields related to pharmacy, chemistry and health care, and seven of them have more than ten years of work experience in the pharmaceutical or ophthalmology industry. We have three R&D centres located in the United States and China, and conduct clinical trials in strategically selected regions worldwide, with a view to maximising the long-term commercial potential of our future products across the global market.

We have developed two proprietary technology platforms, namely, multi-kinase inhibitor (“**MKI**”) and antibody-drug synergism (“**ADS**”) platforms, designed for developing drug candidates targeting anterior and posterior ophthalmic diseases, respectively. Each of MKI platform and ADS platform targets the development of small molecule drugs and conjugates between an antibody and a small molecule drug, respectively. The combination of our two technology platforms offers comprehensive solutions to cover a wide range of ophthalmic diseases. Each of our MKI and ADS platforms is a platform for developing drug candidates targeting anterior and posterior ophthalmic diseases, respectively. For details of our technology platforms, see “Business – Our Strengths – Proprietary Technology Platforms Purposefully Built for Development of Ophthalmic Therapies” and “Business – Research and Development – Overview” in this prospectus.

In addition to our proprietary discovery and development of drug candidates in-house, we also outsource certain R&D work to third-party CROs and contract development and manufacturing organisations (“**CDMOs**”) which we consider to be cost-efficient and in line with market practice. Depending on the complexity and workload of a specific trial, we outsource all non-clinical studies (which require facilities to conduct studies on animals) and certain clinical work to qualified CROs, which provide us with a suite of logistics execution and operation services to assist us in implementing and managing clinical trials in accordance with agreed trial design and under our supervision. We are responsible for designing the protocol for clinical trials including efficacy and safety endpoints and measurements, and we monitor all the clinical work outsourced. Prior to May 2023 before our pilot production facility in Suzhou was put into use, we outsourced all drug product manufacturing work (which needs to comply with good manufacturing practice (“**GMP**”) requirements) to qualified CDMOs.

We have also adopted a drug development model that adopts multiple R&D pathways, including using drug re-purposing to obtain an NDA under the 505(b)(2) pathway, as well as using new chemical entities or new biologics. We believe our drug development model enables more predictable and sustainable discovery and development of novel and effective ophthalmic drugs. See “Business – Research and Development” for further details of our R&D centres, R&D team and in-house R&D activates, R&D pathways, drug development processes, and collaboration with CROs and CDMOs.

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MANUFACTURING

We have built a pilot production facility located in Suzhou New District (蘇州高新技術產業開發區), a specially designated region for technological and industrial development. Our pilot production facility has a total GFA of 1,226.43 sq.m, and was designed and built with a view to complying with GMP standards in the United States, China and EU, which will be able to support our global clinical trials and global commercialisation of our future products. We also plan to build a sizeable commercial production facility in Suzhou based on our clinical development progress and commercialisation needs that meets various quality standards set by relevant regulatory authorities globally, including GMP, to prepare for the anticipated commercialisation of our drug candidates.

We have a dedicated manufacturing team which possesses the qualifications and techniques required in various stages of the manufacturing process. Our manufacturing team is led by Dr. John Qiu, a Project Management Professional (“PMP”) certificate holder with extensive experience in project management related roles including serving as an operational leader in certain multinational companies. As of 31 December 2024, our manufacturing and quality control and quality assurance function was led by 17 key personnel divided into five functional units. During the Track Record Period, we have also engaged certain qualified third parties as CDMOs to provide manufacture services for our clinical trials for CBT-001 in the United States.

We have established a quality management system for the manufacturing of our drug candidates to facilitate the progress of our clinical trials. See “Business – Manufacturing” for further details of our pilot production facility in Suzhou, our manufacturing team and collaboration with CDMOs, and our quality management system.

COMMERCIALISATION

Our preparation for commercialisation in the near-term will be focused on our most advanced Core Product, CBT-001, assuming that we obtain the regulatory approvals in the United States and China. In the United States, we plan to maintain close relationship with principal investigators (“PIs”) to support our phase 3 MRCT and raise awareness on pterygium and associated treatment options among eye care professionals (“ECPs”) by educating key opinion leaders (“KOLs”) and clinicians as part of our pre-launch market education efforts for CBT-001. Once approved, we plan to commercialise CBT-001 in the United States via paralleled direct-to-consumer campaign and ECP education campaign, and pursue third-party reimbursement from government and private insurance providers to cover the costs for CBT-001. We may also seek collaboration with leading pharmaceutical companies for the manufacturing and commercialisation of CBT-001 in the United States. In Greater China, we entered into a commercialisation licensing arrangement with Grand Pharma in April 2020, pursuant to which Grand Pharma was granted an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001. Notwithstanding the above, we retain the right of applying for the NDA and expect to be the market authorisation holder of CBT-001. In Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “Territory”), we entered into a license agreement with Santen in August 2024, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and

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commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in the Territory; and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan” for details.

We plan to conduct similar market education activities in preparation for the commercialisation of CBT-009 once its phase 3 clinical trial commences. Our goal is to educate ECPs prior to the regulatory approval of CBT-009 and to commercialise CBT-009 as a safe and effective pharmacotherapy for juvenile myopia. In advance of CBT-009’s full commercial launch, we plan to raise the awareness of juvenile myopia through educating KOLs and eye care clinicians at academic medical centers and private practices in the United States by presenting the phase 1/2 clinical data and scientific data of CBT-009 and communicating the epidemiology and diagnosis rate data at major eye care conferences. We will also gather insights via our ongoing marketing research assessments to understand the unmet medical needs from patients, ECPs and leading national insurance payers. Once approved, we plan to commercialise CBT-009 in the United States and China via direct-to-consumer campaign and ECP education campaigns working closely with KOLs and professional associations.

We will also gradually build and expand our own sales and marketing team in anticipation of the launch of our future products, and our efforts will be in line with the progress of the clinical trial development plan for our pipeline of drug candidates. See “Business – Commercialisation” for details.

Pricing Strategies

For our Core Product CBT-001, the targeted indication of which had no approved drug therapy globally as of the Latest Practicable Date, we plan to price it competitively with existing therapies which are used off-label, so that we can provide a cost-effective option for the treatment of its targeted indications. Currently, there is no approved drug therapy for the treatment of pterygium globally, and the existing treatment option for pterygium is surgical excision, which costs between chargemaster (a comprehensive list of hospitals’ products, procedures and services) price of US\$5,000 and US\$10,000 per procedure in the United States, excluding post-surgical follow-up visits, and approximately RMB3,000 in China. Whilst there are therapies currently used off-label to alleviate certain symptoms of pterygium, these therapies do not directly address the disease pathogenesis and cost approximately US\$600 for monthly supply. Once approved, CBT-001 is expected to be the first drug therapy globally for the treatment of pterygium. We plan to price CBT-001 competitively with existing therapies which are used off-label to alleviate certain symptoms of pterygium. At this pricing level, we believe CBT-001 will offer a better alternative than the current off-label therapies and surgical excision, and will be a more cost-effective option for the treatment of pterygium.

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For our Core Product CBT-009, we have considered the pricing of alternative treatment options indicated for myopia. Currently, orthokeratology is a procedure that can be used to help improve refractive errors due to corneal abnormalities by fitting contact lenses overnight with the cost running as high as US\$4,000 depending on the cost for examination, contact lens fitting, and the degree of refractive correction needed. Surgical options for myopia include laser-assisted in situ keratomileusis, photorefractive keratectomy, or implantation of an aphakic intraocular lens. However, these procedures are not indicated for patients under 18 years of age. In addition, the costs of refractive surgery can be high. For example, the average cost of LASIK eye surgery for both eyes is US\$4,400 in the United States and ranges from RMB4,000 to RMB6,000 in China. Whilst there are pharmaceuticals currently used off-label to alleviate certain symptoms of myopia, these therapies do not directly address the disease pathogenesis and cost approximately US\$55.0 for monthly supply. We plan to price CBT-009 competitively with approved drugs indicated for myopia. It is anticipated that CBT-009 with a longer shelf life of two years or more and a higher comfort level could be priced at US\$75.0 to US\$100 (average wholesale price per month) direct to the pharmacies and eye doctor offices for distribution, which will be accepted by parents for their children to prevent the progression of myopia. At this pricing level, we believe CBT-009 will offer a better alternative than the current off-label therapies for juvenile myopia, and will be a more cost effective option. We are still in consideration of the pricing of CBT-009 in China. Subject to various affecting factors, we currently plan to price CBT-009 to be higher than atropine sulphate from Shenyang Xinqi (not included in the National Reimbursement Drug List; the annual cost per patient of which is at RMB3,625) by approximately 50% upon commercialisation, as CBT-009 potentially has better tolerability and longer shelf-life.

Drug candidates under development indicated for pterygium and juvenile myopia respectively, as well as approved drug therapies for juvenile myopia, contribute to a competitive landscape for CBT-001 and CBT-009. As our potential competitors commercialise their drug candidates after obtaining regulatory approvals, we anticipate facing substantial pricing pressure and increased competition. Such situation may impact our market position and pricing power, potentially affecting the adoption rates of our two Core Products. See “Risk Factors – Risks Relating to the Development, Clinical Trials and Regulatory Approval of Our Drug Candidates – The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised”.

See detailed pricing strategies of CBT-001, CBT-009, CBT-006 and CBT-004 respectively in each of the sub-sections headed “Business – Clinical-stage Drug Candidates – Pricing Strategies”.

SUPPLIERS AND RAW MATERIALS

During the Track Record Period, our suppliers primarily included (i) service providers such as CROs and CDMOs, and (ii) suppliers of raw materials and consumables for clinical trials.

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For the years ended 31 December 2022, 2023, and 2024, our purchases from our five largest suppliers were US\$7.9 million, US\$8.1 million, US\$18.4 million, respectively, in each year accounted for 67.4%, 72.2% and 83.4% of our total purchases for the respective year. The purchases from our largest supplier were US\$5.1 million, US\$5.6 million, US\$14.0 million in each year in the Track Record Period, respectively, in each year accounted for 44.0%, 50.2% and 63.5% of our total purchases for the respective year. See “Business – Suppliers and Raw Materials” for details.

INTELLECTUAL PROPERTY

As a clinical-stage ophthalmology biotechnology company, we attach great importance in maintaining and protecting our intellectual property rights. Our chief patent officer, Elizabeth Capan, is in charge of our overall intellectual property strategy development and execution, patent application and prosecutions. We have filed a number of patent applications for our drug candidates and our proprietary technology platforms in various jurisdictions, and expect to rely on a combination of patents, trade secrets, trademarks and other intellectual property rights, as well as employee and third-party confidentiality agreements, to safeguard our intellectual properties. As of the Latest Practicable Date, we had 60 granted patents and 168 pending patent applications worldwide, and among them, we had 45 granted patents and 64 pending patent applications worldwide for our Core Product CBT-001, as well as two granted patent and 23 pending patent applications worldwide for our Core Product CBT-009. In addition, we attach great importance to maintaining sufficient intellectual property protection for our proprietary-developed MKI and ADS platforms. As of the Latest Practicable Date, we had 55 granted patents and 88 pending applications relating to individual compounds and drug candidates developed using our MKI and ADS platforms worldwide. See “Business – Intellectual Property – Overview” and “Statutory and General Information – B. Further Information about the Business of our Group – 2. Intellectual property rights” set out in Appendix IV to this prospectus for details.

KEY RISK FACTORS

We are a biotechnology company seeking to list on the Main Board under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, including: (i) the market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised; (ii) our success in the foreseeable future significantly depends on the successful completion of clinical trials, obtaining of regulatory approvals and commercialisation of our drug candidates. Unfavourable results from clinical trials, any delays or failure in obtaining regulatory approvals or unsuccessful commercialisation of our drug candidates could delay or otherwise impair our ability to generate revenue and materially harm our prospects; (iii) the research and development of our drug candidates involves a lengthy and expensive process with no assured outcome. We may not achieve favourable results for our drug candidates in clinical trials, and results of earlier studies and trials may not be predictive of future trial results; (iv) our drug candidates are subject to extensive regulation, and we cannot assure you any of our drug candidates will receive regulatory approvals; (v) we are a pre-revenue biotechnology company. We incurred net losses since our inception and throughout the Track Record

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Period, and we may continue to incur losses in the near future and may not achieve or maintain profitability. You may lose all or substantially all of your investment if our business fails; (vi) we had negative cash flow from operating activities throughout the Track Record Period and we will likely need substantial additional funding for our drug development programmes and commercialisation efforts, which may not be available on acceptable terms to us, or at all; and (vii) we had net current liabilities during the Track Record Period, which expose us to liquidity risk, and such position may continue or recur after the Listing. See the section headed “Risk Factors” in this prospectus for detailed discussion of these and other risks.

SUMMARY OF HISTORICAL FINANCIAL INFORMATION

The following tables set forth selected financial data from our consolidated financial information for the Track Record Period, extracted from the Accountant’s Report set out in Appendix I to this prospectus. The selected financial data sets forth below should be read together with section our consolidated financial statements and the related notes, as well as the section headed “Financial Information” in this prospectus.

Results of Operations

The following table sets forth a summary of our consolidated profit or loss and other comprehensive loss for the years indicated derived from our consolidated statements of comprehensive income set out in the Accountant’s Report included in Appendix I to this prospectus:

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	For the year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Revenue	–	–	10,000
Other income	471	880	214
Other gains, net	718	674	645
General and administrative expenses	(8,912)	(11,277)	(9,489)
Research and development expenses	<u>(15,290)</u>	<u>(27,492)</u>	<u>(37,946)</u>
Operating loss	(23,013)	(37,215)	(36,576)
Finance income, net	1,571	3,597	2,002
Change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments	<u>(45,314)</u>	<u>(95,777)</u>	<u>(63,723)</u>
Loss before income tax	(66,756)	(129,395)	(98,297)
Income tax expenses	<u>(82)</u>	<u>(23)</u>	<u>(833)</u>
Loss for the year attributable to:			
– Owners of the Company	<u>(66,838)</u>	<u>(129,418)</u>	<u>(99,130)</u>
Loss for the year	<u>(66,838)</u>	<u>(129,418)</u>	<u>(99,130)</u>
Total comprehensive loss for the year	<u>(72,953)</u>	<u>(131,201)</u>	<u>(100,020)</u>

We have incurred net loss during the Track Record Period. Our loss for the year was US\$66.8 million, US\$129.4 million and US\$99.1 million for the years ended 31 December 2022, 2023 and 2024, respectively. Substantially all our losses during the Track Record Period were resulted from our general and administrative expenses, R&D expenses and change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments, representing the losses on the convertible redeemable preferred shares, derivative financial instruments in connection with the Preferred Shares we issued to our Pre-IPO Investors, other financial liabilities in connection with warrants granted in connection with the Pre-IPO Investment. The increase in our loss for the year from 2022 to 2023 reflected our business expansion and the progress of the clinical development of our drug candidates, which incurred more costs on general and administrative as well as R&D matters. The decrease in our loss for the year from 2023 to 2024 primarily reflected change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments.

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Our results of operations during the Track Record Period were primarily driven by our general and administrative expense and R&D expenses. Our general and administrative expenses decreased by US\$1.8 million, or 15.9%, from US\$11.3 million in 2023 to US\$9.5 million in 2024, primarily as a result of (i) a US\$2.2 million decrease in employee benefit expenses, which is primarily led by a US\$0.9 million decrease in staff costs mainly resulting from less bonus paid to our employees compared to that in 2023, and a US\$1.3 million decrease in share-based compensation under the Series C Equity Incentive Arrangement which was issued pursuant to the schedule, and (ii) a US\$0.6 million decrease in listing expenses in relation to the preparation of our proposed Listing, reflecting the progress made by each professional party, partially offset by a US\$0.7 million increase in legal and professional fees paid to counsels and other professional agencies in relation to our financing and business development activities. Our general and administrative expenses increased by US\$2.4 million, or 26.5%, from US\$8.9 million in 2022 to US\$11.3 million in 2023, primarily as a result of (i) a US\$2.9 million increase in employee benefit expenses, consisting of a US\$2.5 million increase in staff costs as we recruited additional employees, including senior officers, to support our business expansion and increased compensation level for existing employees, and a US\$0.4 million increase in share-based compensation under the Series C Equity Incentive Arrangement, and (ii) a US\$2.1 million increase in listing expenses in relation to the preparation of our proposed Listing, partially offset by a US\$3.3 million decrease in legal and professional fees paid to counsels and other professional agencies.

Our R&D expenses increased by US\$10.5 million, or 38.0%, from US\$27.5 million in 2023 to US\$37.9 million in 2024, primarily as a result of a US\$10.8 million increase in clinical research expenses primarily because of the expenses spent on phase 3 MRCT for CBT-001 in 2024, partially offset by a US\$0.7 million decrease in employee benefit expenses, primarily led by a US\$1.0 million decrease in relation to the share-based compensation under the Series C Equity Incentive Arrangement which was issued pursuant to the schedule. Our R&D expenses increased by US\$12.2 million, or 79.8%, from US\$15.3 million in 2022 to US\$27.5 million in 2023, primarily as a result of a US\$12.4 million increase in employee benefit expenses, consisting of (a) a US\$11.8 million increase mainly in relation to the share-based compensation under the Series C Equity Incentive Arrangement, and (b) a US\$0.5 million increase in staff costs due to the increased compensation level for our R&D personnel in 2023 as we recruited additional R&D staff to support the clinical development of our drug candidates.

See “Financial Information – Results of Operations” for details.

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Selected Balance Sheet Items

The following table sets forth a summary of our balance sheet items as of 31 December 2022, 2023 and 2024, derived from our consolidated statements of financial position set out in the Accountant's Report in Appendix I to this prospectus:

	As of 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Non-current assets	1,978	3,364	2,500
Current assets	<u>80,109</u>	<u>61,467</u>	<u>37,509</u>
Total assets	82,087	64,831	40,009
Non-current liability	548	228	209
Current liabilities	<u>226,703</u>	<u>327,397</u>	<u>391,346</u>
Total liabilities	227,251	327,625	391,555
Net current liabilities	(146,594)	(265,930)	(353,837)
Total deficit	(145,164)	(262,794)	(351,546)
Total deficit and liabilities	<u>82,087</u>	<u>64,831</u>	<u>40,009</u>

As of 31 December 2024, we maintained a net liabilities position, primarily due to the recognition of convertible redeemable preferred shares issued to investors as our liabilities. We had net liabilities of US\$145.2 million, US\$262.8 million and US\$351.5 million as of 31 December 2022, 2023 and 2024, respectively. The increase in our net liabilities as of 31 December 2023 to the amount as of 31 December 2024 was primarily due to the loss for the year of US\$99.1 million in 2024, partially offset by the recognition of equity-settled share-based payment of US\$11.3 million. The increase in our net liabilities as of 31 December 2022 to the amount as of 31 December 2023 was primarily due to (i) the loss for the year of US\$129.4 million in 2023, (ii) changes in fair value of convertible redeemable preferred shares due to own credit risk of US\$1.0 million, and (iii) currency translation differences of US\$0.8 million, partially offset by the recognition of equity-settled share-based payment of US\$13.6 million. See the Accountant's Report as set out in Appendix I to this prospectus for a detailed description of our statements of changes in equity.

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We expect our net liabilities position to improve significantly upon Listing, as we recorded US\$386.2 million in convertible redeemable preferred shares as liabilities as of 31 December 2024, which were attributable to the Preferred Shares we issued to our Pre-IPO Investors and contributed to our net liabilities position historically. Such Preferred Shares will be automatically converted into ordinary shares upon Listing, after which they will no longer be recorded as liabilities on our statement of financial position, and accordingly, we expect to turn from net liabilities to net assets position.

Our net current liabilities increased from US\$265.9 million as of 31 December 2023 to US\$353.8 million as of 31 December 2024, primarily due to (i) a US\$63.7 million increase in the fair value of the Preferred Shares we issued, (ii) a US\$17.8 million decrease in cash and cash equivalents as we have been utilising proceeds in our bank accounts to support our R&D activities and daily operation, and (iii) a US\$7.5 million decrease in short-term bank deposits as the proceeds are gradually utilised. Our net current liabilities increased from US\$146.6 million as of 31 December 2022 to US\$265.9 million as of 31 December 2023, primarily due to a US\$212.5 million increase in convertible redeemable preferred shares in connection with the issuance of Series C Preferred Shares in Series C Financing and the fair value changes in the Preferred Shares we issued, partially offset by (i) a US\$74.0 million decrease in other financial liabilities at fair value through profit or loss as the Series C Warrants were fully exercised by the relevant Pre-IPO Investors in January 2023, (ii) a US\$26.1 million decrease in trade and other payables primarily due to a US\$27.2 million decrease in receipt in advance from an investor in 2023, as the first tranche of investment amounts we received from a Series C Investor in December 2021 (as such Series C Investor and us had separately agreed that its consideration may be paid in two tranches in order to facilitate settlement) were initially recognised as trade and other payables, and (iii) a US\$11.8 million decrease in derivative financial instruments reflecting all outstanding warrants granted in connection with the Pre-IPO Investment were converted to Preferred Shares upon the exercise of conversion rights by Pre-IPO Investors.

We seek to improve our liquidity and net current liabilities as well as ensure our working capital sufficiency going forward by driving our operating cash flow and improving our net current liabilities position. We target to achieve positive operating cash flow in the future as we continue to enhance our R&D capabilities and accelerate clinical development of our drug candidates, improve cost efficiency, and to pursue diversified and tailored commercialisation strategies for our drug candidates. We will closely monitor the level of our working capital, particularly in view of our strategy to scale up our organisation to build an international platform.

See “Financial Information – Discussion of Selected Balance Sheet Items” for details.

Although we recorded net current liabilities and net liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including general, administrative and operating costs as well as R&D costs, for at least 12 months from the date of publication of this prospectus by using our cash and cash equivalents amounted to US\$34.9 million as of 31 December 2024, consisting of deposits with banks, cash at banks and cash on hand, and the estimated net proceeds from the Global Offering. As of 30 April 2025 and the Latest Practicable Date, we had unutilised banking facilities of US\$45.0 million and US\$45.0 million, respectively, and

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none of which were restricted. We do not anticipate any changes to the availability of bank financing to finance our operations in the future and net proceeds from the Global Offering. We estimate that we will receive net proceeds from the Global Offering of approximately HK\$522.2 million after deducting professional fees, underwriting commissions and other fees incurred in connection with the Global Offering at the Offer Price of HK\$10.10 per Offer Share.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, including R&D expenses, (ii) capital expenditures, and (iii) lease payments. As of 31 December 2024, we had cash and cash equivalents of US\$34.9 million. Assuming an average cash burn rate going forward of 1.4 times of the level in the 12 months ended 31 December 2024, which is primarily based on the prospective monthly cash burn rate in the 12 months ending 31 December 2025, we estimate that our cash and cash equivalents as of 31 December 2024 will be able to maintain our financial viability for approximately 11 months, or, if we also take into account the estimated net proceeds (based on the Offer Price of HK\$10.10) from the Global Offering, for approximately 32 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

See “Financial Information – Liquidity and Capital Resources” for details.

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Cash Flows

The following table sets forth a summary of our consolidated statements of cash flows for the years indicated:

	For the year ended		
	31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Cash used in operation	(19,835)	(22,586)	(25,480)
Income tax (paid)/refund	(215)	80	(1,042)
Net cash used in operating activities	(20,050)	(22,506)	(26,522)
Net cash (used in)/generated from investing activities	(29,818)	57,355	9,374
Net cash (used in)/generated from financing activities	(14,337)	2,052	(457)
Net (decrease)/increase in cash and cash equivalents	(64,205)	36,901	(17,605)
Cash and cash equivalents at beginning of the year	80,604	15,917	52,654
Exchange differences on cash and cash equivalents	(482)	(164)	(187)
Cash and cash equivalents at the end of the year	<u>15,917</u>	<u>52,654</u>	<u>34,862</u>

We experienced cash outflow from operating activities during the Track Record Period primarily because we incurred significant R&D and general and administrative expenses without generating revenue from product sales. Our operating cash flow will continue to be affected by our R&D and general and administrative expenses, and we expect to have cash outflow from operating activities for the foreseeable future as we further our pre-clinical R&D initiatives, continue the clinical development of, and seek regulatory approvals for, our drug candidates, launch commercialisation of our products if any of them receives regulatory approvals, and add personnel necessary to operate our business.

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Key Financial Ratios

The following table sets forth our key financial ratio as of the balance sheet dates indicated:

	As of 31 December		
	2022	2023	2024
Current ratio <i>(note)</i>	0.35	0.19	0.10

Note: current ratio represents current assets divided by current liabilities as of the same date.

GLOBAL OFFERING

This prospectus is published in connection with the Hong Kong Public Offering as part of the Global Offering. 60,582,000 Offer Shares will initially be made available under the Global Offering (subject to reallocation) comprising:

- (i) the Hong Kong Public Offering of initially 6,058,500 Shares (subject to reallocation) in Hong Kong as described in “Structure of the Global Offering – The Hong Kong Public Offering” in this prospectus; and
- (ii) the International Offering of initially 54,523,500 Shares (subject to reallocation) to be offered outside the United States (including to professional and institutional investors within Hong Kong) in offshore transactions in accordance with Regulation S as described in “Structure of the Global Offering – The International Offering” in this prospectus.

The Offer Shares will represent approximately 7.2% of the issued share capital of our Company immediately following the completion of the Global Offering, assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements.

OFFERING STATISTICS

The statistics in the following table are based on the assumptions that: (i) the Global Offering is completed and 60,582,000 Offer Shares are issued and sold in the Global Offering, and (ii) no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements:

	Based on an Offer Price of HK\$10.10
Market capitalisation of our Shares ⁽¹⁾	HK\$8,472.8 million
Unaudited pro forma adjusted net tangible assets per Share ⁽²⁾	HK\$1.02

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Notes:

- (1) The calculation of market capitalisation is based on 838,892,874 Shares expected to be in issue following completion of the Global Offering. This calculation is based on the Offer Price of HK\$10.10.
- (2) The unaudited pro forma adjusted net tangible asset per Share is calculated after making the adjustments referred to in the section headed “Unaudited Pro Forma Financial Information” set out in Appendix II to this prospectus and on the basis of a total of 836,667,874 Shares expected to be in issue (for the purpose of the unaudited pro forma financial information excluding the 2,225,000 Shares issued pursuant to RSUs that immediately become vested upon the Listing subject to potential lock-up period or according to the vesting schedule pursuant to the Equity Incentive Arrangements) following the completion of the Global Offering. This calculation is based on the Offer Price of HK\$10.10.

LISTING EXPENSES

Listing expenses represent professional fees, underwriting commissions and other fees incurred in connection with the Global Offering. At the Offer Price of HK\$10.10 per Offer Share, the listing expenses which are payable by us are estimated to amount in aggregate to be approximately US\$11.4 million (equivalent to approximately HK\$89.7 million), accounting for approximately 14.7% of the gross proceeds from the Global Offering.

The total listing expenses consist of (i) approximately US\$4.1 million underwriting fees (including underwriting commission, incentive fee, SFC transaction levy, Stock Exchange trading fee and AFRC transaction levy) and (ii) approximately US\$7.3 million non-underwriting fees mainly comprising (a) fees paid to legal adviser(s) and accountant(s) of approximately US\$4.4 million, and (b) other fees and expenses and fees paid to other professional parties of approximately US\$2.9 million. Among the total listing expenses, US\$2.1 million and US\$1.5 million was charged to our consolidated statements of comprehensive income for the year ended 31 December 2023 and 2024, respectively, and approximately US\$3.3 million is expected to be charged to profit or loss, and approximately US\$4.5 million directly attributable to the issue of the Shares is expected to be deducted from equity upon the completion of the Global Offering. Our total listing expenses are estimated to account for 14.7% of the gross proceeds of the Global Offering. The listing expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the Global Offering of approximately HK\$522.2 million after deducting professional fees, underwriting commissions and other fees incurred in connection with the Global Offering at the Offer Price of HK\$10.10 per Offer Share. We intend to use the net proceeds we receive from the Global Offering as follows:

- Approximately 62.4%, or HK\$325.9 million, will be used to fund the continuing clinical R&D activities including costs and expenses of our R&D staff and R&D activities as well as registration filings and post-approval studies of our Core Product, CBT-001;

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- Approximately 27.6%, or HK\$144.1 million, will be used to fund the continuing clinical R&D activities including costs and expenses of our R&D staff and R&D activities as well as registration filings of our Core Product, CBT-009;
- Approximately 5.5%, or HK\$28.7 million, will be used for funding the manufacturing facilities and commercialisation activities; and
- Approximately 4.5%, or HK\$23.5 million, will be used for working capital and other general corporate purposes.

To the extent that our actual net proceeds from the Global Offering differ from our estimate above, we intend to apply the actual net proceeds in the same proportion set out above. See “Future Plans and Use of Proceeds” for further details of our use of proceeds from the Global Offering.

DIVIDEND POLICY

We have not declared or paid any dividend during the Track Record Period. We do not currently have any dividend policy or fixed dividend payout ratio or intention to declare or pay any dividend in the near future. Any amount of dividends we pay will be at the discretion of our Directors and will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by our Company from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Directors. Any declaration and payment as well as the amount of dividends will also be subject to our constitutional documents and the relevant laws. See “Summary of the Constitution of the Company and the Cayman Companies Act” set out in Appendix III to this prospectus for details. As advised by our legal advisers as to Cayman Islands laws, although we experienced net loss during the Track Record Period, we will still be able to declare dividends out of our profits after all our historically accumulated losses have been made up for and the allocation of sufficient net profit to our statutory common reserve fund as described above. No dividend shall be declared or payable except out of our profits or share premium account lawfully available for distribution.

OUR SINGLE LARGEST SHAREHOLDERS

As of the Latest Practicable Date and immediately following the completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), our Company had and will have no controlling shareholder as defined under the Listing Rules. As of the Latest Practicable Date, Dr. Ni and Ms. Leng (spouse of Dr. Ni) were interested in an aggregate of 172,150,042 Ordinary Shares, representing approximately 22.18% of the total issued share capital of our Company. Dr. Ni and Ms. Leng’s interest in our Company comprised: (i) 157,992,705 Ordinary Shares representing approximately 20.36% held through Water Lily Consultants; (ii) 3,900,219 Ordinary Shares representing approximately 0.50% held through Ni Legacy Trust; (iii) 5,288,139 Ordinary Shares representing approximately 0.68% held through Ice Tree LLC; (iv) 3,624,970 Ordinary

SUMMARY

Shares representing approximately 0.47% held through Ice Tree Consultants; and (v) 1,344,009 Ordinary Shares representing approximately 0.17% held through Leng Legacy Trust. Immediately following completion of the Share Conversion and Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), Dr. Ni and Ms. Leng will be interested in an aggregate of 172,150,042 Shares, representing approximately 20.52% of the enlarged share capital of our Company. Accordingly, Dr. Ni, Ms. Leng, Water Lily Consultants, Ni Legacy Trust, Ice Tree LLC, Ice Tree Consultants and Leng Legacy Trust are our Single Largest Shareholders upon Listing. For details, please refer to “Relationship with our Single Largest Shareholders” in this prospectus.

PRE-IPO INVESTMENTS

We have had four rounds of Pre-IPO Investments, namely (i) the Series A Financing from which we raised approximately RMB10.0 million; (ii) Series B Financing from which we raised approximately US\$17.1 million in aggregate from the Series B-1 Financing and Series B-2 Financing; (iii) Series C Financing from which we raised approximately US\$127.0 million; and (iv) acquisition of Shares by Mok Ka Ying from CNCB (one of the original Series C Investors), for which none of the proceeds were received by our Company as no new Shares were issued. As of the Latest Practicable Date, approximately 85.3% of the net proceeds from the Pre-IPO Investments have been utilised by our Group, primarily for research and development of drug candidates and pipeline of our products, as well as general working capital and administrative expenses. A number of our Pre-IPO Investors are Sophisticated Investors who made meaningful investment in our Company, namely Skketch Shine, Design Time, Gaotejia, Grand Diamond and Dyee Evergreen (which its special purpose vehicle, De Hong Xin, will hold shares for the purpose of Dyee Evergreen’s overseas investment), and they will hold approximately 5.92%, 2.96%, 4.44%, 3.19% and 2.96% of the issued share capital of our Company immediately after the completion of the Global Offering (assuming all the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares have been converted to ordinary Shares on a 1:1 basis, that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), respectively. Yunxin Holdings, Yicun Holdings, Grand Diamond, Zhongyin Health, Skketch Shine, Gaotejia, Design Time, De Hong Xin, Hainan Efung, Shanghai Tianyi, Chuangdongfang Changhui, Yingke Zhi De Pu Ze, Yunwen, Jiangmen Efung, Jinhua Jinkai and Shanghai Yiyue are subject to a lock-up undertaking for a period commencing on the date of this prospectus and ending on the last day of six (6) months from the Listing Date. See “History, Development and Corporate Structure – Pre-IPO Investments” for further details regarding the key terms of these Pre-IPO Investments and the background of our Pre-IPO Investors.

SUMMARY

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, there has been no material adverse change in our financial, operational or trading positions or prospects since 31 December 2024, being the date of our consolidated financial statements as set forth in the Accountant's Report set out in Appendix I to this prospectus, and that no material unexpected or adverse changes have occurred since the date of the issue of the relevant regulatory approvals for our drug candidates.

Impact of COVID-19 Pandemic

The delay in the commencement of our phase 3 MRCT for CBT-001 in the United States was partially impacted by the COVID-19 pandemic. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Summary of Clinical Results – 1. On-going Phase 3 MRCT” and “Risk Factors – Risks Relating to Our Operations – Our business and operations could be adversely affected by the effects of natural disasters, health pandemics or epidemics and other outbreaks or other unforeseen catastrophic events, including the outbreak of COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations” for details on the impact of the COVID-19 pandemic on the commencement of our phase 3 MRCT in the United States for CBT-001. The CROs and CDMOs we engaged to support our clinical trials in the United States, China and Australia experienced complete or partial shutdown because of the COVID-19 pandemic, and the regulatory approval process in the United States, Australia and China were also adversely affected by the COVID-19 pandemic. The COVID-19 pandemic delayed the phase 3 MRCT for CBT-001 for over a year, because we could not inspect the clinical sites of CROs and CDMOs or proceed with the regulatory approval process during that period of time.

Notwithstanding the above, we commenced our phase 3 MRCT for CBT-001 in the United States in June 2022. Our ongoing operations as well as clinical and pre-clinical studies were no longer impacted by the COVID-19 pandemic as of the Latest Practicable Date. As of the Latest Practicable Date, the COVID-19 pandemic had not had any material adverse impact on our R&D activities, clinical development, daily operations or regulatory affairs and our operations in China. Given that the COVID-19 related prevention and control policies have largely been lifted since December 2022, our Directors are of the view that it is unlikely that the COVID-19 pandemic will have a material adverse impact on our business going forward.

Expected Net Loss

We expect to incur net loss for 2025 due to (i) the anticipated increase in staff costs associated with increase in share-based payment to be made, (ii) estimated listing expenses to be charged to profit or loss in connection with the Listing, (iii) anticipated increase in legal and professional fees and auditor fees for compliance purposes after the Listing, and (iv) that we expect no revenue to be generated in 2025. Our financial performance will be affected by the fair value change of convertible redeemable preference shares until the conversion into equity upon Listing.

SUMMARY

REGULATORY DEVELOPMENTS ON OVERSEAS LISTING

We have submitted a filing to the CSRC for the Global Offering and for the Listing of our Shares on the Stock Exchange on 4 December 2023. The CSRC issued the Notice of Filing on 10 December 2024 for the Global Offering and for the listing of the Shares on the Stock Exchange. As advised by our PRC Legal Advisers, our Company has completed all necessary filings with the CSRC for the proposed Listing of our Shares on the Stock Exchange.

DEFINITIONS

In this prospectus, unless the context otherwise requires, the following terms shall have the meanings set out below. Certain other terms are explained in “Glossary of Technical Terms” in this prospectus.

“2023 Equity Incentive Scheme”	the equity incentive scheme approved and adopted by our Company on 14 March 2025 as amended from time to time, for the benefit of any officer, employee, adviser or consultant of our Company or any of our subsidiaries, a summary of its principal terms is set out in “Statutory and General Information – D. Equity Incentive Arrangements – 3. 2023 Equity Incentive Scheme” in Appendix IV to this prospectus
“ADS Australia”	ADS Pharmaceuticals Pty Ltd, a company incorporated in New South Wales, Australia on 20 November 2020, and an indirect wholly owned subsidiary of our Company
“ADS USA”	ADS Therapeutics LLC, a limited liability company initially formed in Nevada, the United States on 16 January 2017 and later converted into a limited liability company in Delaware, the United States on 16 November 2020, and a wholly owned subsidiary of our Company
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council
“Allergan”	Allergan Inc., previously named as Allergan Plc., a pharmaceutical company and a subsidiary of AbbVie Inc. (AbbVie being a listed company on the New York Stock Exchange with stock code ABBV)
“Articles of Association” or “Articles”	the amended and restated articles of association of our Company conditionally adopted on 14 March 2025 and effective on the Listing Date, as amended from time to time, a summary of which is set out in “Summary of the Constitution of the Company and the Cayman Companies Act” set out in Appendix III to this prospectus
“associate(s)”	has the meaning ascribed to it under the Listing Rules

DEFINITIONS

“AU\$”	Australian dollar, the lawful currency of the Commonwealth of Australia
“Board” or “Board of Directors”	the board of directors of our Company
“Business Day”	a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
“BVI”	the British Virgin Islands
“CAGR”	compound annual growth rate
“Capital Market Intermediaries”	the capital market intermediaries participating in the Global Offering and has the meaning ascribed thereto under the Listing Rules
“Cayman Companies Act” or “Companies Act”	the Companies Act (As Revised) of the Cayman Islands (Chapter 22, Law 3 of 1961), as consolidated and revised from time to time
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CDE”	Center for Drug Evaluation of NMPA (國家藥監局藥審中心)
“CDER”	Center for Drug Evaluation and Research
“China”, “mainland China” or the “PRC”	the People’s Republic of China, excluding, for the purposes of this prospectus and for geographical reference only and except where the context requires otherwise, Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Class A Ordinary Shares”	the class A ordinary shares of our Company, with par value US\$0.0001 per share
“Class B Ordinary Shares”	the class B ordinary shares of our Company, with par value US\$0.0001 per share
“Class C Ordinary Shares”	the class C ordinary shares of our Company, with par value US\$0.0001 per share
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules

DEFINITIONS

“Cloudbreak BVI”	Cloudbreak Biotechnology Limited, a BVI business company incorporated in the BVI on 18 November 2019, and an indirect wholly owned subsidiary of our Company
“Cloudbreak Cayman”	Cloudbreak Pharmaceutical Inc., an exempted company incorporated in Cayman Islands on 1 November 2019, and a wholly owned subsidiary of our Company
“Cloudbreak Germany”	Cloudbreak Pharmaceutical GmbH, a company incorporated in Germany on 4 November 2021, and a wholly owned subsidiary of our Company
“Cloudbreak Guangzhou”	Cloudbreak Bio-Pharmaceutical Science and Technology (Guangzhou) Co., Ltd. (撥康視雲生物醫藥科技(廣州)有限公司) (formerly known as Boyun Bio-Pharmaceutical Science and Technology (Guangzhou) Co., Ltd. (撥雲生物醫藥科技(廣州)有限公司)), a company established in the PRC on 30 September 2018, and an indirect wholly owned subsidiary of our Company
“Cloudbreak HK”	Cloudbreak Therapeutics Limited, a company incorporated in Hong Kong on 28 November 2019, and an indirect wholly owned subsidiary of our Company
“Cloudbreak Pharma HK”	Cloudbreak Pharma (HK) Limited, a company incorporated in Hong Kong on 13 June 2022, and a wholly owned subsidiary of our Company
“Cloudbreak Suzhou”	Cloudbreak Bio-Pharmaceutical Science and Technology (Suzhou) Co., Ltd. (撥康視雲生物醫藥科技(蘇州)有限公司) (formerly known as Boyun Bio-Pharmaceutical Science and Technology (Suzhou) Co., Ltd. (撥雲生物醫藥科技(蘇州)有限公司)), a company established in the PRC on 27 September 2021, and an indirect wholly owned subsidiary of our Company
“Cloudbreak USA”	Cloudbreak Therapeutics LLC, a company incorporated in California, the United States on 14 September 2015, and a wholly owned subsidiary of our Company
“Cloudbreak Wenzhou”	Cloudbreak Bio-Pharmaceutical Science and Technology (Wenzhou) Co., Ltd. (撥康視雲生物醫藥科技(溫州)有限公司), a company established in the PRC on 11 June 2024, and an indirect wholly owned subsidiary of our Company

DEFINITIONS

“Cloudbreak Yixing”	Cloudbreak Bio-Pharmaceutical Science and Technology (Yixing) Co., Ltd. (撥康視雲生物醫藥科技(宜興)有限公司), a company established in the PRC on 5 September 2023, and an indirect wholly owned subsidiary of our Company
“Companies Ordinance”	the Companies Ordinance (Chapter 622) of Hong Kong, as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32) of Hong Kong, as amended, supplemented or otherwise modified from time to time
“Company”	Cloudbreak Pharma Inc., an exempted company incorporated under the laws of the Cayman Islands with limited liability on 20 November 2020
“Compliance Adviser”	Fosun International Capital Limited
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purposes of this prospectus, our Core Products refer to CBT-001 and CBT-009
“Corporate Governance Code”	Appendix C1 of the Listing Rules
“COVID-19”	an infectious disease caused by the most recently discovered coronavirus (severe acute respiratory syndrome coronavirus 2), first reported in December 2019
“CSRC”	the China Securities Regulatory Commission (中國證券監督管理委員會)
“Dinh Legacy Trust”	The Dinh Legacy Trust, a discretionary family trust established by Mr. Dinh for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Mr. Dinh’s family members and charities independent of Mr. Dinh
“Director(s)”	the directors of our Company, including all executive, non-executive and independent non-executive directors

DEFINITIONS

“Dr. Li”	Dr. Li Jun Zhi, our Non-executive Director and a co-founder of our Group
“Dr. Ni”	Dr. Ni Jinsong, the chairman of our Board, our Executive Director, chief executive officer, and a co-founder of our Group
“Dr. Yang”	Dr. Yang Rong, our Executive Director and chief scientific officer
“EIT LAW”	the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time
“EMA”	European Medicines Agency
“Equity Incentive Arrangements”	the Series B Equity Incentive Arrangement, Series C Equity Incentive Arrangement, and the 2023 Equity Incentive Scheme
“EU”	European Union
“Executive Director”	an executive director of our Company
“Extreme Conditions”	the occurrence of “extreme conditions” as announced by any government authority of Hong Kong due to serious disruption of public transport services, extensive flooding, major landslides, large-scale power outage or any other adverse conditions before Typhoon Signal No. 8 or above is replaced with Typhoon Signal No. 3 or below
“FDA”	the United States Food and Drug Administration
“FINI”	Fast Interface for New Issuance, an online platform operated by HKSCC that is mandatory for admission to trading and, where applicable, the collection and processing of specified information on subscription in and settlement for all new listings
“Frost & Sullivan”	Frost & Sullivan Limited, a global market research and consulting company, which is our industry consultant and an Independent Third Party
“Frost & Sullivan Report” or “F&S Report”	an independent market research report commissioned by us and prepared by Frost & Sullivan for the purpose of this prospectus
“Global Offering”	the Hong Kong Public Offering and the International Offering

DEFINITIONS

“Grand Pharma”	Grand Pharmaceutical (China) Co., Ltd. (遠大醫藥(中國)有限公司), a company established in the PRC on 24 February 1990 and an indirectly non-wholly owned subsidiary of Grand Pharma Group, our collaborator, one of our Pre-IPO Investors, and an Independent Third Party
“Grand Pharma Group”	Grand Pharmaceutical Group Limited (遠大醫藥集團有限公司), a company incorporated in Bermuda with limited liability and the shares of which are listed on the Main Board of the Stock Exchange (stock code: 512), one of the subsidiaries of which is our collaborator and one of our Pre-IPO Investors, and an Independent Third Party
“Greater China”	the PRC, Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Group” or “Our Group”	our Company and all of its subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of its present subsidiaries, the businesses operated by such subsidiaries or their predecessors (as the case may be)
“Guide for New Listing Applicants”	the Guide for New Listing Applicants published by Hong Kong Stock Exchange on 29 November 2023, which consolidated and enhanced all effective guidance letters and listing decisions related to New Listing (as defined under Chapter 1.01 of the Listing Rules), as to be amended from time to time
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“HK eIPO White Form”	the application for Hong Kong Offer Shares to be issued in the applicant’s own name, submitted online through the designated website at www.hkeipo.hk
“HK eIPO White Form Service Provider”	the HK eIPO White Form service provider designated by our Company as specified on the designated website at www.hkeipo.hk
“HKSCC”	Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited

DEFINITIONS

“HKSCC EIPO”	the application for the Hong Kong Offer Shares to be issued in the name of HKSCC Nominees and deposited directly into CCASS to be credited to your designated HKSCC Participant’s stock account through causing HKSCC Nominees to apply on your behalf, including by instructing your broker or custodian who is a HKSCC Participant to give electronic application instructions via HKSCC’s FINI system to apply for the Hong Kong Offer Shares on your behalf
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly owned subsidiary of HKSCC
“HKSCC Operational Procedures”	the Operational Procedures of HKSCC, containing the practices, procedures and administrative or other requirements relating to HKSCC’s services and the operations and functions of CCASS, FINI or any other platform, facility or system established, operated and/or otherwise provided by or through HKSCC, as from time to time in force
“HKSCC Participant”	a participant admitted to participate in CCASS as a direct clearing participant, a general clearing participant or a custodian participant
“HKSCC Rules”	the General Rules of HKSCC and as may be amended or modified from time to time and where the context so permits, shall include the Operational Procedures of HKSCC
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong Offer Shares”	the 6,058,500 Shares being initially offered by our Company for subscription at the Offer Price pursuant to the Hong Kong Public Offering (subject to reallocation as described “Structure of the Global Offering” in this prospectus)
“Hong Kong Public Offering”	the offer for subscription of the Hong Kong Offer Shares to the public in Hong Kong at the Offer Price, subject to and in accordance with the terms and conditions set out in this prospectus
“Hong Kong Share Register”	the register of members of our Shares maintained by the Hong Kong Share Registrar
“Hong Kong Share Registrar”	Tricor Investor Services Limited

DEFINITIONS

“Hong Kong Stock Exchange”	the Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“Hong Kong Underwriters”	the underwriters of the Hong Kong Public Offering whose names are set out in “Underwriting – Hong Kong Underwriters” in this prospectus
“Hong Kong Underwriting Agreement”	the underwriting agreement dated Monday, 23 June 2025 relating to the Hong Kong Public Offering entered into by our Company, Dr. Ni, Ms. Leng, Water Lily Consultants, Ice Tree LLC, Ice Tree Consultants, the Overall Coordinators, the Joint Global Coordinators and the Hong Kong Underwriters
“Ice Tree Consultants”	Ice Tree Consultants, Inc., a company incorporated under the laws of the State of California, USA on 19 January 2017, and is solely owned by Ms. Leng
“Ice Tree LLC”	Ice Tree, LLC, a limited liability company formed in the State of Nevada, USA on 5 February 2020, and is solely owned by Ms. Leng
“IFRS”	IFRS Accounting Standards, which include standards, amendments and interpretations promulgated by the International Accounting Standards Board and the International Accounting Standards and Interpretation issued by the International Accounting Standards Committee
“Independent Non-executive Director”	an independent non-executive director of our Company
“Independent Third Party(ies)”	party or parties that, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is or are not a connected person or connected persons of our Company within the meaning of the Listing Rules
“International Offer Shares”	the 54,523,500 Shares being initially offered for subscription under the International Offering, together, where relevant, subject to reallocation as described in “Structure of the Global Offering” in this prospectus
“International Offering”	the offer of the International Offer Shares at the Offer Price, outside the United States in offshore transactions in accordance with Regulation S or any other available exemption from registration under the U.S. Securities Act, as further described in “Structure of the Global Offering” in this prospectus

DEFINITIONS

“International Underwriters”	the group of international underwriters expected to enter into the International Underwriting Agreement relating to the International Offering
“International Underwriting Agreement”	the international underwriting agreement relating to the International Offering to be entered into by, among other parties, our Company, our Single Largest Shareholders, the Overall Coordinators, the Joint Global Coordinators and the International Underwriters on or about Monday, 30 June 2025
“Joint Bookrunners”	<i>(in alphabetical order with respective to (i) the Joint Sponsors, and (ii) the other Joint Bookrunners, respectively)</i> CCB International Capital Limited, Huatai Financial Holdings (Hong Kong) Limited, BOCI Asia Limited, BOCOM International Securities Limited, China Galaxy International Securities (Hong Kong) Co., Limited, China Industrial Securities International Capital Limited, CMBC Securities Company Limited, CMB International Capital Limited, First Shanghai Securities Limited, Fosun International Securities Limited, Huafu International Securities Limited, ICBC International Securities Limited, Livermore Holdings Limited, Patrons Securities Limited, Quam Securities Limited, Ruibang Securities Limited, Soliton Securities Limited, SPDB International Capital Limited, and uSMART Securities Limited
“Joint Global Coordinators”	<i>(in alphabetical order with respective to (i) the Joint Sponsors, and (ii) the other Joint Global Coordinators, respectively)</i> CCB International Capital Limited, Huatai Financial Holdings (Hong Kong) Limited, CMB International Capital Limited, and Quam Securities Limited
“Joint Lead Managers”	<i>(in alphabetical order with respective to (i) the Joint Sponsors, and (ii) the other Joint Lead Managers, respectively)</i> CCB International Capital Limited, Huatai Financial Holdings (Hong Kong) Limited, BOCI Asia Limited, BOCOM International Securities Limited, China Galaxy International Securities (Hong Kong) Co., Limited, China Industrial Securities International Capital Limited, CMBC Securities Company Limited, CMB International Capital Limited, First Shanghai Securities Limited, Fosun International Securities Limited, Huafu International Securities Limited, ICBC International Securities Limited, Livermore Holdings Limited, Patrons Securities Limited, Quam Securities Limited, Ruibang Securities Limited, Soliton Securities Limited, SPDB International Capital Limited, and uSMART Securities Limited

DEFINITIONS

“Joint Sponsors”	<i>(in alphabetical order)</i> CCB International Capital Limited and Huatai Financial Holdings (Hong Kong) Limited
“Latest Practicable Date”	18 June 2025, being the latest practicable date for the purpose of ascertaining certain information contained in this prospectus prior to its publication
“Leng Legacy Trust”	The Leng Legacy Trust, a discretionary family trust established by Ms. Leng for estate planning and controlled by her by virtue of being settlor and protector. The beneficiaries are Ms. Leng’s family members and charities independent of Ms. Leng
“Listing”	the listing of our Shares on the Main Board
“Listing Committee”	the listing committee of the Hong Kong Stock Exchange
“Listing Date”	the date, expected to be on or about Thursday, 3 July 2025, on which dealings in our Shares first commence on the Main Board
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time
“M&A Rules”	Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》), which were jointly promulgated by MOFCOM, the State Assets Supervision and Administration Commission, the STA, the SAIC, the CSRC, and the SAFE on 8 August 2006, and came into effect on 9 September 2006 and subsequently amended on 22 June 2009, as amended, supplemented or otherwise modified from time to time
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
“Memorandum and Articles of Association”	the Memorandum of Association and Articles of Association
“Memorandum” or “Memorandum of Association”	the amended and restated memorandum of association of our Company conditionally adopted on 14 March 2025 to take effect on the Listing Date, as amended from time to time, a summary of which is set out in “Summary of the Constitution of the Company and the Cayman Companies Act” in Appendix III to this prospectus

DEFINITIONS

“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“Mr. Dinh”	Mr. Van Son Dinh, our Executive Director, chief operating officer and a co-founder of our Group
“Ms. Leng”	Ms. Bing Leng, the spouse of Dr. Ni
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“Ni Legacy Trust”	The Ni Legacy Trust, a discretionary trust family established by Dr. Ni for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Dr. Ni’s family members and charities independent of Dr. Ni
“NMPA”	the National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration
“Non-executive Director”	a non-executive director of our Company
“NPC”	the National People’s Congress (全國人民代表大會)
“NRDL”	the National Reimbursement Drug List (國家醫保藥品目錄)
“Offer Price”	the final offer price per Offer Share (exclusive of brokerage fee of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015%) of HK\$10.10
“Offer Shares”	the Hong Kong Offer Shares and the International Offer Shares
“Ordinary Share(s)”	existing ordinary share(s) in the share capital of the Company, with par value US\$0.0001 per share, comprising Class A Ordinary Shares, Class B Ordinary Shares and Class C Ordinary Shares
“Overall Coordinators”	(<i>in alphabetical order</i>) CCB International Capital Limited and Huatai Financial Holdings (Hong Kong) Limited

DEFINITIONS

“PCT”	the Patent Cooperation Treaty, which assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions
“Post-IPO Equity Incentive Scheme”	the equity incentive scheme adopted by the Company on 14 March 2025, the principal terms of which are set out in “Statutory and General Information – D. Equity Incentive Arrangements – 4. Post-IPO Equity Incentive Scheme” in Appendix IV to this prospectus
“PRC Legal Advisers”	Haiwen & Partners, our legal advisers as to PRC law
“Pre-IPO Investor(s)”	the Series A Investor, the Series B Investors, and the Series C Investors
“Pre-IPO Investment”	the pre-IPO investments in our Company undertaken by the Pre-IPO Investors pursuant to the relevant investment or share purchase agreements, details of which are set out in “History, Development and Corporate Structure – Pre-IPO Investments” in this prospectus
“Preferred Share(s)”	preferred share(s) in the share capital of the Company, with par value US\$0.0001 per share, comprising Series A Preferred Shares, Series B Preferred Shares, and Series C Preferred Shares
“PTAB”	the Patent Trial and Appeal Board of the USPTO
“R&D”	research and development
“Regulation S”	Regulation S under the U.S. Securities Act
“Renminbi” or “RMB”	the lawful currency of the PRC
“RSU(s)”	restricted share unit(s)
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAIC”	the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)

DEFINITIONS

“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局), the successor of the SAIC
“Series A Financing”	the fundraising and investment into our Group by the Series A Investor, details of which are set out in “History, Development and Corporate Structure – Pre-IPO Investments – Series A Financing” in this prospectus
“Series A Investor”	holder of Series A Preferred Shares of our Company
“Series A Preferred Shares”	the Series A preferred shares of our Company, with par value US\$0.0001 per share
“Series B Equity Incentive Arrangement”	the equity incentive arrangements approved by Cloudbreak Cayman on 27 August 2020, and which were subsequently approved by our Company on 24 November 2021, for the benefit of any officer, employee, adviser or consultant of the Company or any of our subsidiaries, a summary of its principal terms is set out in “Statutory and General Information – D. Equity Incentive Arrangements – 1. Series B Equity Incentive Arrangement” in Appendix IV to this prospectus
“Series B Investors”	holders of Series B Preferred Shares of our Company
“Series B Preferred Shares”	the Series B preferred shares of our Company, with par value US\$0.0001 per share
“Series B Financing”	the Series B-1 Financing and the Series B-2 Financing
“Series B-1 Financing”	the fundraising and investment into our Group by Grand Diamond Limited, details of which are set out in “History, Development and Corporate Structure – Pre-IPO Investments – Series B-1 Financing” in this prospectus
“Series B-2 Financing”	the fundraising and investment into our Group by Yicun Holdings Limited and Zhongyin Health Holdings Limited, details of which are set out in “History, Development and Corporate Structure – Pre-IPO Investments – Series B-2 Financing” in this prospectus

DEFINITIONS

“Series C Equity Incentive Arrangement”	the equity incentive arrangement approved by our Company on 24 November 2021, for the benefit of any officer, employee, adviser or consultant of our Company or any of our subsidiaries, a summary of its principal terms is set out in “Statutory and General Information – D. Equity Incentive Arrangements – 2. Series C Equity Incentive Arrangement” in Appendix IV to this prospectus
“Series C Financing”	the fundraising and investment into our Group by the Series C Investors, details of which are set out in “History, Development and Corporate Structure – Pre-IPO Investments – Series C Financing” in this prospectus
“Series C Investors”	holders of Series C Preferred Shares of our Company
“Series C Preferred Shares”	the Series C preferred shares of our Company, with par value US\$0.0001 per share
“Series C Warrants”	the warrants to be issued by the Company to certain Series C Investors with respect to the subscription of certain number of Series C Preferred Shares in connection with the Series C Financing
“SFC”	the Securities and Futures Commission of Hong Kong
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Share Conversion”	the conversion of Ordinary Shares and Preferred Shares into Shares, details of which are set out in “History, Development and Corporate Structure – Share Conversion and Increase in Authorised Share Capital” in this prospectus
“Share(s)”	Ordinary Shares and Preferred Shares before Listing, or ordinary shares in the share capital of our Company, with par value US\$0.0001 per share after conversion of all Ordinary Shares and Preferred Shares upon Listing
“Shareholder(s)”	holder(s) of our Share(s)
“Single Largest Shareholders”	Dr. Ni, Ms. Leng, Water Lily Consultants, Ni Legacy Trust, Ice Tree LLC, Ice Tree Consultants and Leng Legacy Trust, who together are considered as a group of largest shareholders of our Company

DEFINITIONS

“Sophisticated Investor”	has the meaning ascribed to it under chapter 2.3 of Guide for New Listing Applicants issued by the Stock Exchange
“STA”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局)
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Stock Exchange”	the Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“subsidiary(ies)”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“Track Record Period”	the period comprising the three financial years ended 31 December 2022, 2023 and 2024
“Underwriters”	the Hong Kong Underwriters and the International Underwriters
“Underwriting Agreements”	the Hong Kong Underwriting Agreement and the International Underwriting Agreement
“USPTO”	the United States Patent and Trademark Office
“US\$” or “U.S. Dollars”	U.S. dollars, the lawful currency of the United States
“USA” or “U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. Securities Act”	United States Securities Act of 1933, as amended
“VD&TL”	VD&TL Capital, a company incorporated under the laws of the State of California, USA on 14 August 2018, and is wholly-owned by Mr. Dinh
“Water Lily Consultants”	Water Lily Consultants Inc., a company incorporated under the laws of the State of California, USA on 14 August 2018, and is wholly-owned by Dr. Ni
“YDD Consulting”	YDD Consulting, a corporation incorporated under the laws of the State of California, USA on 14 August 2018, and is wholly-owned by Dr. Yang
“%”	per cent

DEFINITIONS

In this prospectus, unless expressly stated or the context requires otherwise:

- *all information and data is at the Latest Practicable Date;*
- *certain amounts and percentage figures, including but not limited to, shareholdings and operating data, may have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them;*
- *references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous region; and*
- *the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including certain of our subsidiaries) have been included in this prospectus in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of company names and other terms from the Chinese language are provided for identification purposes only.*

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain terms used in this prospectus in connection with us and our business. Some of these may not correspond to standard industry definitions.

“active pharmaceutical ingredient” or “API”	active pharmaceutical ingredient, the substance in a pharmaceutical drug that is biologically active
“ADS” or “ADS platform”	antibody-drug synergism or antibody-drug synergism platform developed by our Company, an innovative technology developed by the Group to either improve the efficacy or extend the duration of drug effect for intravitreally administered drugs by involving conjugating an antibody drug with a small molecule drug, using a linker designed to be enzymatically hydrolysed in the vitreous humour in a controlled manner
“amblyopia”	reduced vision typically in one eye that results from the brain suppressing input from the affected eye due to unequal visual signals from each eye leading to poor development of visual acuity in the affected eye
“AMD”	age-related macular degeneration, a disease that causes damage to the macula and leads to progressive loss of central vision
“best-in-class”	the drug with the best clinical advantage within a drug class
“BLA”	biologic license application, an application for permission to introduce a biologic product into inter-state commerce
“CDMO”	contract development and manufacturing organisation, a company that provides comprehensive drug development and manufacturing services on for other companies on a contract basis
“CMC”	chemistry, manufacturing and controls, a process which mainly includes defining a drug product’s characteristics, formulation development and product testing to ensure that the product is safe, effective and consistent between batches
“CMO”	contract manufacturing organisation, a company that provides drug manufacturing services on a contract basis

GLOSSARY OF TECHNICAL TERMS

“CRO”	contract research organisation, a company that provides a range of professional research services on a contract basis
“cycloplegia”	paralysis of the ciliary muscle of the eye
“DME”	diabetic macular edema, a complication of diabetes wherein the patient loses the central vision to a certain degree due to accumulation of excess fluid in the extracellular space within retina’s macular
“diagnosis and treatment rate”	the percentage of patient population with disease that has been identified in healthcare institutions and received appropriate medical care or intervention method, no matter what kind of treatment method adopted
“double-masked clinical trial”	a type of clinical trial in which neither the participants nor the research team know which treatment a specific participant is receiving, which helps prevent bias or expectations from influencing the results of the study
“dry eye”	a condition associated with inadequate tear production and marked by redness, itching and burning of the eye
“DED”	dry eye disease, a multifactorial disease of the tear film, characterised by increased tear film osmolarity, ocular inflammation, deterioration of ocular surface and neurosensory abnormalities, can cause some ocular symptoms such as ocular discomfort and visual disturbance
“ECPs”	eye care professionals
“FGFRs”	fibroblast growth factor receptors, membrane-spanning proteins that are a subgroup of the family of tyrosine kinase receptor
“first-in-class”	a drug that uses a new and unique mechanism of action for treating a medical condition
“GCP”	good clinical practice, an international ethical and scientific quality standard developed by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use for designing, conducting, recording and reporting trials that involve the participation of human subjects

GLOSSARY OF TECHNICAL TERMS

“generic drug”	a drug that is chemically identical to an original drug and is generally available in the same strength and dosage forms as the original
“glaucoma”	a group of eye diseases that are usually characterised by progressive structural and functional changes of the optic nerve, leading to a typical appearance of the optic disc and visual field damage if untreated
“GLP”	good laboratory practice, a quality system of management controls for research laboratories and organisations to try to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical and pharmaceuticals non-clinical safety tests
“GMP”	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards
“ILD”	interstitial lung disease, a group of lung conditions that cause scarring or fibrosis of lung tissues
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials. Also known as clinical trial application, or CTA, in China
“Institutional Review Board” or “IRB”	national, regional or local board established to safeguard ethical conduct of research involving human subjects
“juvenile myopia”	myopia in children and adolescents aged 5 to 19 years old
“KOLs”	key opinion leaders, individuals or organisations who have expert product knowledge and influence in a particular field, and who are trusted by relevant interest groups and have significant effects on consumer behaviour
“mCNV”	myopic choroidal neovascularisation, a complication of myopia, which causes the creation of new blood vessels in the choroid, a vascular membrane of the eyeball

GLOSSARY OF TECHNICAL TERMS

“MGD”	meibomian gland dysfunction, a chronic diffuse abnormality of the meibomian glands, characterised by terminal duct obstruction along with qualitative or quantitative changes in the glandular secretion
“MRCT”	multi-regional clinical trial, a clinical trial that is conducted in different regions under a common trial design for simultaneous global new drug development
“MKI”	multi-kinase inhibitor
“MKI platform”	multi-kinase inhibitor platform, a technology platform that uses selective MKIs that target VEGFRs, and to a lesser extent, PDGFRs and FGFRs, for treating ocular indications involving abnormal angiogenesis or vascularity, current indications of interest of which include pterygium, pinguecula, and glaucoma filtration surgery
“mydriasis”	excessive or prolonged dilatation of the pupil of the eye
“NDA”	new drug application, an application through which the drug sponsor formally proposes that the relevant regulatory authority approve a new drug for sales and marketing
“off-label use”	medication which is being used in a manner not specified in the approved packaging label
“ophthalmology”	a branch of medical science dealing with the structure, functions and diseases of the eye
“OTC drugs” or “OTC products”	over-the-counter drugs or products, drugs or products that are sold directly to a consumer without a prescription
“PDGFRs”	platelet-derived growth factor receptors, cell surface tyrosine kinase receptors for members of the platelet-derived growth factor family
“penetration rate”	the percentage of the target patient population that has adopted or is using certain treatment method

GLOSSARY OF TECHNICAL TERMS

“phase 1 clinical trial”	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“phase 2 clinical trial”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“phase 3 clinical trial”	a study in which a drug is administered to an expanded patient population at geographically dispersed clinical trial sites to generate statistically sufficient data to evaluate the efficacy and safety of the drug for regulatory approval and to provide adequate information for the labelling of the product
“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs
“PI”	principal investigator, the scientist in charge an experiment or research report
“pinguecula”	a round, yellowish, elevated tissue that develops on the conjunctiva adjacent to the cornea
“pre-clinical research”	research that tests a drug candidate on non-human subjects to gather efficacy and safety information to decide whether the drug candidate is ready for clinical trials in human subjects
“presbyopia”	an eye condition where the patient has difficulty seeing near items clearly due to declines in refractive abilities of the lens
“pterygium”	a benign proliferative ocular surface disease characterised mainly by wing-shaped and fibrovascular growth of the limbal and conjunctival tissue over the adjacent cornea
“retina”	a thin layer of tissue that lines the back of the eye on the inside
“RVO”	retinal vein occlusion, a disease due to the blockage of the retinal vein which can lead to blurry vision or loss of vision

GLOSSARY OF TECHNICAL TERMS

“standard of care”	a treatment that is accepted and widely used by medical experts as a proper and standard treatment for a certain disease
“TEAE”	treatment-emergent adverse event, an undesirable event not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment
“translational science”	a process of accelerating and turning research discoveries into real-world applications that improves people’s health, such as diagnostics, treatments and cures
“VEGF”	vascular endothelial growth factor, a signal protein produced by cells that stimulates the formation of blood vessels
“VEGFRs”	vascular endothelial growth factor receptors, tyrosine kinase receptors responsible for binding with VEGF to initiate signal cascades that stimulate angiogenesis among other effects

FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that state our intentions, beliefs, expectations or predictions for the future that are, by their nature, subject to significant risks and uncertainties. These forward-looking statements include all statements in this prospectus that are not historical fact, including, without limitation, statements relating to:

- our expectations with respect to obtaining regulatory approvals, commencing commercial production and the ability to achieve market penetration of our drug candidates;
- our expectations or targets for the timing and likelihood of achieving milestones associated with our drug development programmes, including the commencement and completion, and the progress of our research and clinical trials, as well as the target timing of regulatory approvals and commercial launch of our product candidates;
- our expectations with respect to the potential clinical benefits and competitive positioning of our drug candidates and technology platforms;
- our ability to successfully commercialise our drug candidates;
- our existing and potential collaboration arrangement with business partners;
- our ability to attract and retain senior management and key employees;
- our strategies, business plans, objectives, prospects and goals and our ability to successfully implement our strategies, plans, objectives and goals;
- the market opportunities and competitive landscape of our product candidates and the indications they focus on;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- the future regulatory and operating environment in the United States, the PRC and other jurisdictions in which we may operate and our ability to comply with applicable regulations in the future;
- estimates of our costs, expenses, future revenues, capital expenditures and our needs for and ability to obtain additional financing; and
- the general political and economic conditions in the United States, the PRC and other jurisdictions in which we may operate.

FORWARD-LOOKING STATEMENTS

When used in this prospectus, the words “aim”, “anticipate”, “believe”, “could”, “estimate”, “expect”, “going forward”, “intend”, “may”, “ought to”, “plan”, “project”, “seek”, “should”, “will”, “would” and similar expressions, as they relate to us, are intended to identify a number of these forward-looking statements. Such statements reflect the current views of our management with respect to future events and are subject to certain risks, uncertainties and assumptions, including the risk factors described in this prospectus. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove to be incorrect, our results of operations and financial condition may be adversely affected and may vary materially from those described herein as anticipated, believed or expected. Accordingly, such statements are not a guarantee of future performance and you should not place undue reliance on such forward-looking information. Moreover, the inclusion of forward-looking statements should not be regarded as representations by us that our plans and objectives will be achieved or realised.

RISK FACTORS

You should carefully read and consider all of the information in this prospectus, including the risks and uncertainties described below, before making an investment in our Shares. Our business, financial condition, results of operations and/or the ability to meet our financial obligations could be materially and adversely affected by any of these risks and uncertainties. The trading price of our Shares could decline due to any of these risks (or such additional risks), and you may lose all or part of your investment. In particular, we are a biotechnology company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules.

There are unique challenges, risks and uncertainties associated with investing in companies such as ours, which may cause you to lose all or part of your investment. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-Looking Statements” in this prospectus.

RISKS RELATING TO THE DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR DRUG CANDIDATES

The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised.

We estimate the incidence and prevalence of target patient populations for particular ophthalmic diseases based on scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analyses, and we use such estimates in making decisions regarding our drug development strategy, including determining which drug candidates to focus our limited resources on in clinical or pre-clinical trials. These estimates may be inaccurate or based on imprecise data.

The total addressable market opportunity will depend on, among other things, the presence of multiple existing prevention methods and treatment options. For example, our Core Product CBT-001 and clinical-stage drug candidate CBT-004 are indicated for the treatment of pterygium and vascularised pinguecula, respectively. Although there is currently no approved drug therapy globally for the respective indications, off-label use of certain pharmaceuticals (such as artificial tears for both indications) for symptom relief is available for patients, and surgical excision is also commonly adopted for eligible patients. Moreover, our other Core Product CBT-009 is developed for treating juvenile myopia. However, given that there are also multiple existing prevention methods and/or treatment options indicated for juvenile myopia, including optical correction such as spectacle lenses and contact lenses, and pharmaceuticals such as atropine eye drops that might be manufactured by other market players in the future, the market potential for CBT-009, similarly to those of CBT-001 and CBT-004, may be limited, in which patients may choose those prevention methods and/or treatment options due to their high acceptance among patient populations. Increased competition from the approval and commercialisation of competing drug therapies and other treatment options may lead to a saturated market, potentially affecting our market share and

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pricing power. The entry of new competitors may compel us to reduce our prices to remain competitive, leading to pricing pressure that could impact our profit margins and overall financial performance.

Also, the targeted indications of some of our drug candidates, such as pterygium, juvenile myopia and pinguecula, are not contagious and may not lead to serious vision impairment if left untreated, depending on the patient's own condition. As a result, even though the number of patients of our targeted indications may be large, the actual addressable patients of our drug candidates may be limited and smaller than we expected.

In addition, the market size is dependent on the acceptance of the drug by the medical community and patient access, drug pricing, reimbursement and the availability of alternative treatments. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access. Furthermore, new studies may change the estimated incidence or prevalence of diseases, and the number of addressable patients for our drug candidates in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our drug candidates, because the potential target populations are smaller than expectation, we may never achieve profitability without obtaining regulatory approvals for additional indications. Also, the anticipated competition may slow the adoption of our drug candidates, as stakeholders, including healthcare professionals and patients, may gravitate toward newly available therapies or other treatment options, leading to a potential decline in market penetration for our offerings. Any of the above unfavourable developments could have a material adverse effect on our business, financial condition and results of operations.

Our success in the foreseeable future significantly depends on the successful completion of clinical trials, obtaining of regulatory approvals and commercialisation of our drug candidates. Unfavourable results from clinical trials, any delays or failure in obtaining regulatory approvals or unsuccessful commercialisation of our drug candidates could delay or otherwise impair our ability to generate revenue and materially harm our prospects.

We are heavily reliant on the successful completion of clinical trials, obtaining of regulatory approvals and commercialisation of our drug candidates, which are still in clinical or pre-clinical development. As of the Latest Practicable Date, we were developing four clinical-stage drug candidates and four pre-clinical stage drug candidates. Our two Core Products CBT-001 and CBT-009 are in more advanced clinical development stage, while other drug candidates are in relatively earlier stage. We have invested a significant amount of effort and financial resources in our existing drug candidates. However, the process to develop, obtain regulatory approvals for and commercialise drug candidates is long, complex and costly, with no assured outcome, and we may fail to complete our clinical trials, obtain regulatory approvals or successfully commercialise our drug candidates in accordance with the anticipated timeline due to risks described below and elsewhere in this prospectus. The successful development, obtaining of regulatory approvals and commercialisation of our drug candidates are subject to numerous factors, including:

- the ability to successfully enrol patients and complete clinical trials;

RISK FACTORS

- the performance by CROs, CDMOs, PIs, clinical study sites, hospitals or other third parties we may retain to conduct clinical trials, to carry out their duties to us in a manner that complies with our protocols and applicable laws and good clinical practice requirements imposed by the FDA, the NMPA, or other regulatory authorities and that protects the integrity of the resulting data;
- the ability to obtain sufficient supplies that may be necessary for use in clinical trials for evaluation of our drug candidates;
- the ability to obtain satisfactory efficacy and safety data from our ongoing clinical trials;
- the ability to demonstrate to the FDA, the NMPA or other comparable regulatory authorities that the clinical data of our drug candidates is able to meet the standards required for approval, or that certain phases of clinical trials can be waived by the FDA, the NMPA or other comparable regulatory authorities under the 505(b)(2) pathway or based on previous clinical trial results in other regions;
- the ability to develop sufficient commercial manufacturing capacity and successfully launch commercial sales of our drug candidates, if and when approved;
- the ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates, and ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- the ability to gain competitive advantage over other drug candidates and products of competitors; and
- the ability to continue maintaining an acceptable safety profile for our drug candidates following regulatory approvals, if and when received.

If we fail to obtain favourable clinical trial results, obtain regulatory approvals in accordance with our expected timeline or at all or to successfully commercialise our drug candidates, our ability to generate revenue would be delayed or otherwise impaired and our business and prospects will be materially and adversely affected.

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The research and development of our drug candidates involves a lengthy and expensive process with no assured outcome. We may not achieve favourable results for our drug candidates in clinical trials, and results of earlier studies and trials may not be predictive of future trial results. The overall timeline of clinical trials remains inherently uncertain as it might be affected by various uncontrollable factors.

Clinical trials are expensive and can take many years to complete, and outcomes are inherently uncertain. While our clinical trial expenses for products in development may be capitalised in accordance with our accounting policies, expenditure on clinical trials recorded in our consolidated statements of comprehensive income still constituted a significant portion of our R&D expenditure during the Track Record Period. For the years ended 31 December 2022, 2023 and 2024, our R&D expenses amounted to US\$15.3 million, US\$27.5 million and US\$37.9 million respectively.

Failure can occur at any time during the R&D process. Before obtaining regulatory approvals to market our drug candidates, we must conduct substantial pre-clinical research and extensive clinical trials to demonstrate their safety and efficacy in humans. The results of pre-clinical research and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. In some instances, there can be significant variability in safety or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may not be favourable and you may lose all or part of your investments in us if our R&D fails.

Even if the desirable results are achieved in clinical trials, the timeline of the R&D process might be affected by various uncontrollable factors. For example, the clinical trial design process necessitates a continuous testing and validation phase which introduce certain level of uncertainties to the overall duration of the trials. This complexity arises from the need to determine both the dosing period and follow-up period when patients are monitored for a specific duration after the last dose to assess the effect of the treatment, and provide useful guidance on dosing regime to future clinical use. The design of these periods involve multiple factors including the anticipated duration of the effect of the drug candidates and may need to be adjusted based on preliminary findings of the trials. Therefore, the overall timeline for clinical trials remains inherently uncertain.

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Our drug candidates are subject to extensive regulation, and we cannot assure you any of our drug candidates will receive regulatory approvals.

Our drug candidates and the activities associated with their development and commercialisation, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labelling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulations by the FDA, the NMPA or other comparable regulatory authorities. We are not permitted to market any of our drug candidates in the United States, the PRC and other jurisdictions unless and until we receive the respective regulatory approvals. Securing regulatory approvals normally requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. It may also require the submission of information regarding the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent us from obtaining regulatory approvals or limit or prevent their commercial use.

The process of obtaining regulatory approvals in the United States, the PRC and other jurisdictions is expensive, may take many years if additional clinical trials are required and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in or the enactment of additional laws, regulations or approval policies may cause delays in the approval process or rejection of an application. The FDA, the NMPA or other comparable regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies.

Our drug candidates could be delayed in receiving, or fail to receive, regulatory approvals for many reasons, including:

- our ability to successfully submit an IND or an NDA and obtain regulatory approvals for our drug candidates may involve inherent risks, take longer, or cost more than it would for a company with more experience in obtaining regulatory approvals, despite our experience in communication and consultation with regulatory authorities;
- we may not be able to reach an agreement with the FDA, the NMPA or other comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- we may fail to demonstrate to the satisfaction of the FDA, the NMPA or other comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;

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- our CROs, CDMOs, clinical study sites or investigators may fail to comply with the GCP requirements imposed by the FDA, the NMPA or other comparable regulatory authorities;
- our clinical trial results may fail to meet the level of statistical significance required by the FDA, the NMPA or other comparable regulatory authorities for approval;
- we may not be able to reach an agreement with the FDA, the NMPA or other comparable regulatory authorities regarding the interpretation of data from pre-clinical studies or clinical trials, or from clinical trial results of reference drugs when we develop our drug candidates under the 505(b)(2) pathway;
- we may not be able to collect sufficient data from clinical trials to support the submission of an IND or an NDA or other submission or to obtain regulatory approvals in the United States, the PRC or elsewhere;
- the FDA, the NMPA or other comparable regulatory authorities may refuse to approve the manufacturing processes for our clinical and commercial supplies; and
- changes in the approval policies or regulations of the FDA, the NMPA or other comparable regulatory authorities may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes which may have impact on the costs, timing or successful completion of a clinical trial. The process of obtaining regulatory approvals may also be prevented, limited or delayed as a result of policy changes.

In addition, even if we were to obtain the approval, regulatory authorities or policy changes may restrict the use of our drug candidates to a narrow population, or include warnings, precautions or contraindications for our drug candidates, or subject our products to burdensome post-approval study or risk management requirements. Regulatory authorities may also revoke the approval, may approve any of our drug candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labelling claims necessary or desirable for the successful commercialisation of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We aim to complete our global phase 3 MRCT for our most advanced drug candidate, CBT-001, in June 2026, and submit an NDA to the FDA and the NMPA upon the completion of global phase 3 MRCT. Such approval process is complicated and expensive and could involve additional trials and studies as a condition to receiving regulatory approvals. We may be unable to successfully and efficiently execute and complete any required additional trials or studies in a way that leads to an approval of CBT-001 in the United States or China, and we may require more time and incur greater costs than anticipated. Any such delays could impair our ability to generate revenue and materially harm our prospects.

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If we are unable to obtain approvals from the FDA, the NMPA or other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative drug candidates or new modified drug candidates, the time and cost we incur to obtain regulatory approvals may increase, and we may ultimately be unable to complete the development or commercialisation of our drug candidates.

The FDA, the NMPA or other comparable regulatory authorities have mechanisms in place for expedited review and approval for drug candidates that are innovative drug or new modified drug applications, provided that such drug or drug candidate has an apparent clinical value and are urgently needed, has clinically short supply, or may be used to prevent and treat diseases that seriously threaten life or seriously affect the quality of life, for which there have been no effective prevention or treatment methods or there is sufficient evidence to show obvious clinical advantages compared with the existing treatment methods or meets other expedited registration requirements. If we submit an application for our drug candidates under the expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted to us on a timely basis, or at all.

Furthermore, there can be no assurance that, after feedback from the regulatory authorities, we will continue to pursue or apply for expedited development, review or approval, even if we had initially decided to do so. A failure to obtain any form of expedited development, review or approval for our drug candidates, or withdrawal of any drug candidates, would result in a longer time period until commercialisation of such drug candidates, and thus increase the cost of development of such drug candidate and harm our competitive position in the market. In addition, even if we are able to use an expedited registration pathway, it may not lead to expedited approval of our drug candidates, or approval at all, in which case we may ultimately be unable to complete the development or commercialisation of our drug candidates.

We may not be successful in our efforts to identify or discover new drug candidates through our internal research and development, or in pursuing additional therapeutic opportunities through indication expansion, to build and maintain our product pipeline as desired.

Our efforts to develop new drug candidates, either through our internal R&D or in pursuing additional therapeutic opportunities through indication expansion require substantial technical, financial and human resources, and may fail for a number of reasons.

We intend to devote substantial resources to further develop potential first-in-class and best-in-class drugs to address ophthalmic diseases. We have developed our risk-balanced pipeline of drug candidates by adopting the optimal R&D pathway for each drug candidate, including focusing on the development of new indications, dosage forms and regimens, routes of administration and formulations on the approved reference drugs under the 505(b)(2) pathway as an innovative treatment option for certain ophthalmic diseases, as well as using new chemical entities or new biologics. Our R&D efforts may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

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- the research methodology used may not be successful in discovering new drug candidates or formulations or developing additional indications;
- there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs or make them unmarketable or unlikely to receive regulatory approvals; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates, develop suitable potential drug candidates through internal research programs, or at all. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful, which could materially adversely affect our future growth and prospects.

In addition, in the event that we decide to pursue licensing-in arrangements in the future, there is possibility that we may not be successful in developing additional drug candidates through licensing-in for a variety of reasons, including inability to identify appropriate drug candidates or reach agreement with the relevant counterparties or failure to successfully advance the development of the drug candidate as contemplated, which could materially adversely affect our future growth and prospects.

If we experience delays or difficulties in the enrolment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enrol a sufficient number of eligible patients to participate in these trials as required by the FDA, the NMPA, or other comparable regulatory authorities in various regions such as the United States, PRC and Australia we have conducted, or will conduct our clinical trials in.

We may experience difficulties in the enrolment of patients in our clinical trials, as patient enrolment is dependent on a number of factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;

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- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrolment in clinical trials;
- the patient referral practice of physicians;
- the ability to obtain and maintain patient consent;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, our clinical trials will likely compete with other clinical trials for drug candidates that are expected to be indicated for the same diseases as our drug candidates. The competition will reduce the number and types of patients available to us, because some patients who might have opted to enrol in our trials may instead opt to enrol in a trial conducted by one of our competitors. Because the number of qualified clinical trial sites is limited, we expect that some of our clinical trials may be conducted at the same clinical trial sites that some of our competitors use, which may reduce the number of patients available for our clinical trials at such clinical trial sites. Patient enrolment may also be delayed as a result of epidemics such as the COVID-19 pandemic, or similar events.

The inability to enrol a sufficient number of patients for our clinical trials for any of the above reasons would result in significant delays, increased drug development costs and could even require us to abandon one or more clinical trials altogether. Any of the above could result in a material adverse effect on our business, financial condition and results of operations.

Our drug candidates may cause undesirable side effects or have other properties that could result in delays or failure to receive regulatory approvals, or limitations on the commercial profile of an approved label, or otherwise lead to significant negative consequences on our ability to market and distribute our drug candidates or maintain market acceptance of such drugs if commercialised.

As with most pharmaceutical products, the use of our drugs could be associated with side effects or adverse events. Such side effects or other adverse events may be observed at any time, including in clinical trials or after a product is commercialised. It is not uncommon in the ophthalmology industry for drug candidates which showed promise in early stage to have later been found to cause side effects that prevented further development of the drug candidate or resulted in significant negative consequences if the drug has already been commercialised. Moreover, because clinical trials assess a sample of the potential patient population, when such trials are conducted with a limited number of patients and

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duration of exposure, rare and severe side effects of our drug candidates may only be uncovered when a significantly larger number of patients become exposed to the drug candidate.

A high and unacceptable severity and prevalence of these or other side effects arising in the course of our clinical trials could make us, whether voluntarily or at the determination of the FDA, the NMPA, or any other comparable regulatory authorities or otherwise, perform additional studies, delay, suspend or terminate clinical trials or cease further development of such drug candidate and withdraw it from any or all targeted indications. The drug-related side effects could also result in a more restrictive label, or affect patient recruitment, the ability or willingness of enrolled patients to complete the clinical trial, result in potential product liability claims or harm our reputation.

Even if we are able to proceed with continued development of a drug candidate, we cannot assure you that we will be able to resolve any product-related adverse effects to the satisfaction of the FDA, the NMPA, or any other comparable regulatory authorities in a timely manner or at all.

Additionally, even if one or more of our drug products or drug candidates receive the marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw or limit approvals of such products;
- regulatory authorities may require additional warnings, contra-indications or other restrictions on the labels of such products;
- regulatory authorities may require us to develop risk evaluation and remediation or mitigation plans, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, restricted distribution methods, patient registries and/or other elements to assure safe use and minimise risk;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug products from the market;

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- we may be required to recall such products and be sued and held liable for harm caused to patients, which could be costly and result in significant negative publicity; and
- our reputation may suffer.

Furthermore, regulatory authorities may require us to cross-report certain information about adverse medical events involving our drug candidates to relevant regulators in other jurisdictions within a specified time frame. If we fail to timely comply with such reporting obligations for any reason, we could be subject to disciplinary or other actions by such regulators, including criminal liability, civil penalties, product seizure and/or delays in approval or clearance of future drug candidates.

Any of the above negative developments could prevent us from achieving or maintaining regulatory approvals or market acceptance of the affected drug candidates, as well as substantially increase the costs of commercialising our drug candidates even if approved, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Adverse drug reactions and negative results from off-label use of our future approved drugs could materially harm our business reputation, product brand name and financial condition, and expose us to liability.

Off-label drug use refers to the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labelling. Even though the FDA, the NMPA or other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains a risk that our future approved drugs be subject to off-label drug use and prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities, which may render our future approved drugs less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name and financial condition. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and ultimately result in failure to obtain regulatory approvals for our drug candidates.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalise on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

As we have limited human and financial resources, we must limit our R&D programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalise on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more

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advantageous for us to retain sole development and commercialisation rights to such drug candidate. Such developments could have a material adverse effect on our business, financial condition and results of operations.

If the third parties we rely on to conduct certain aspects of our pre-clinical studies and clinical trials do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for or commercialise our drug candidates and our business could be substantially harmed.

In line with the industry norm, we have relied upon and plan to continue to rely upon third-party CROs, CDMOs and PIs to generate, monitor or manage data for our ongoing clinical and pre-clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs, CDMOs and PIs does not relieve us of our regulatory responsibilities. We and these third-party service providers are required to comply with GCPs for all of our drugs in clinical development. If we or any of these third-party service providers fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. If any of our relationships with these third-party service providers terminate, we may not be able to enter into arrangements with alternative service providers on commercially reasonable terms, or at all.

The CROs, CDMOs and PIs engaged by us have the right to terminate their agreements with us under terms and conditions stipulated in contracts which, among others, would have a material impact on their services. Except for remedies available to us under our agreements with such these third-party service providers, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If these third-party service providers do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for or successfully commercialise our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding third-party service providers involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. In addition, there is a natural transition period when a new service provider commences work and the new service provider may not provide the same type or level of services as the original provider. If any of our relationships with our third-party service providers are terminated, we may not be able to enter into arrangements with alternative service providers or to do so on commercially reasonable terms, and we may not be able to

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meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

In addition to third parties which support our clinical trials, our future revenue is dependent on our ability to work effectively with other collaborators to develop our drug candidates and obtain regulatory approvals as well. Our arrangements with these collaborators may be critical to successfully bringing products to market and commercialise them. We rely on these collaborators in various respects, such as to manage or assist with the regulatory filings and approval process and to assist with our commercialisation efforts.

We do not control our collaborators. Therefore, we cannot ensure that these third parties will adequately perform all of their obligations to us in a timely manner, or keep a business relationship with us. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialise the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

If we cannot maintain or develop clinical collaborations and relationships with PIs, physicians, KOLs, and other medical experts, our results of operation and prospects could be adversely affected.

Our relationships with PIs, physicians, KOLs, and other medical experts we cooperate with play an important role in our R&D and commercialisation activities. We have established extensive interaction channels with PIs, physicians, KOLs, and other medical experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with PIs, physicians, KOLs, and other medical experts, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our R&D process, may be inaccurate and lead us to develop products that do not have significant market potential. Moreover, we cannot assure you that our academic promotion and marketing strategy will be effective. Industry participants, including KOLs, may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

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RISKS RELATING TO THE COMMERCIALISATION OF OUR DRUG CANDIDATES

We currently do not have experience in launching and marketing drug candidates and the commercialisation of new products will require additional resources. There is no assurance that we will be able to successfully commercialise our drug candidates.

Our operations to date have been largely focused on raising capital and developing our drug candidates, including undertaking pre-clinical studies and conducting clinical trials. We currently do not have experience in building a sales and marketing team, conducting a comprehensive market analysis, obtaining licenses and approvals, or managing distributors and sales force for our drug candidates. Even if our drug candidates receive regulatory approvals for marketing in the United States or in PRC, we will still face significant commercialisation risks, including the risks described below and elsewhere in “– Risks Relating to the Commercialisation of Our Drug Candidates”.

The commercialisation of new products requires additional resources. The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified and professional sales and marketing personnel who have, among other things, sufficient experience in sales and marketing of drug products and extensive industry connections with distributors and hospitals, and are able to communicate effectively with medical professionals. Furthermore, since we expect to launch products, we expect to hire more employees with relevant experience and knowledge to strengthen our marketing and sales workforce in the long run. However, due to the intense competition for experienced personnel, we may be unable to attract, motivate and retain a sufficient number of qualified sales and marketing employees to support our business development and expansion, and our sales revenue and results of operations may be negatively affected. Our ability to successfully commercialise our drug products is also subject to other risks and uncertainties relating to, including, our ability to price the future products at an appropriate level, our ability to obtain adequate coverage and reimbursement for future products under reimbursement programmes by third-party payers and government authorities, our ability to achieve market penetration in light of competition from existing and potential new drugs or therapies indicated for ophthalmic diseases, and our ability to establish in-house manufacturing capacity or make arrangements with third-party contract manufacturers to produce sufficient quantities of supplies of our future products. As a result, there is no assurance that we will be able to successfully commercialise our drug candidates, which would delay our expected revenue generation and materially harm our business prospects.

We may not be able to successfully commercialise our Core Products or any of our drug candidates if we fail to obtain regulatory approvals or comply with ongoing regulatory obligations, which may involve factors that are out of our control.

In addition to our ability to successfully launch our future products, the successful commercialisation of our Core Products or any of our drug candidates depend on various factors involving governmental supervision that are beyond our control. In order to commercialise any of our drug candidates, we must first complete all requisite clinical trials and receive regulatory approvals to commence production and sale. We are not permitted to market any of our drug candidates in the United States, the PRC and other jurisdictions unless and until we receive the respective regulatory approvals. Securing regulatory

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approvals requires the submission of extensive clinical and pre-clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. It may also require the submission of information regarding the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. The regulations that govern regulatory approvals vary widely from country to country, and it may take years to obtain regulatory approvals in the United States, the PRC and other jurisdictions. If we fail to comply with regulatory requirements, possible risks include refusal by the FDA, the NMPA, or other comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of licence approvals, and fines, untitled or warning letters, or holds on clinical trials.

Even if our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information in the United States, PRC and any other jurisdictions where they receive NDA approvals. The FDA, the NMPA or other comparable regulatory authorities may withdraw approvals or impose restrictions on the marketing and manufacturing of our drug candidates if compliance with regulatory requirements and standards is not maintained.

Our ability to generate substantial revenue from our product or successfully commercialise any drug candidate also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities. For example, in China, each public medical institution has historically procured drugs through a provincial centralised drug purchase platform, and made substantially all of its purchases of pharmaceutical products through a centralised tender process. The centralised tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. Government authorities may attempt to control costs by limiting coverage and the amount of reimbursement for particular medications, requesting that the drug companies provide discounts from list prices or challenging them on such prices. Any such control on the pricing of our future products, and the delay or failure to obtain regulatory approvals and continue to be in compliance with ongoing regulatory obligations could impair our ability to generate revenue and materially harm our prospects.

Our future approved drugs may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Our future approved drugs may fail to gain sufficient market acceptance by physicians, patients, third-party players and others in the medical community. Doctors and patients may continue to prefer current treatments to the exclusion of our drugs for the same or similar indications. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drug candidates and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

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- the clinical indications for which our drug candidates are approved;
- the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- the cost effectiveness of our future approved drugs;
- the potential advantages of future approved drugs over other therapies;
- the timing of market introduction of our drug candidates as well as competitive therapies;
- the effectiveness of our marketing, sales and distribution strategies and operations;
- the views of physicians, hospitals and patients on the safety and efficacy of our drug candidates;
- our ability to manufacture commercial supplies of our future approved drugs, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with GMP regulations;
- the degree to which the approved labelling supports promotional initiatives for commercial success;
- a continued acceptable safety profile of our future approved drugs and the prevalence and severity of any side effects;
- results from additional clinical trials of our drug candidates or further analysis of clinical data from completed clinical trials of our future approved drugs by us or our competitors;
- the availability of adequate coverage and reimbursement under reimbursement programmes by third-party payers and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- our ability to enforce our intellectual property rights;
- our ability to avoid any third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

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If any approved drug candidates that we commercialise fail to achieve market acceptance in the medical professional community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favourably received than our drug candidates, are more cost-effective or render our drug candidates obsolete.

We have entered into a commercialisation licencing agreement with Grand Pharma and a license agreement with Santen in relation to the development, manufacture and commercialisation of one of our Core Products, CBT-001, in various regions, and may continue to seek strategic commercialisation partnerships or enter into additional licensing arrangements in the future, which is subject to risks.

We have entered into a commercialisation licencing arrangement (the “**License Agreement**”) with Grand Pharma, pursuant to which we granted Grand Pharma the exclusive, sublicensable and royalty-bearing license to manufacture and commercialise one of our Core Products, CBT-001, in Greater China. We will retain the rights for all development activities for CBT-001, and Grand Pharma will be responsible for using commercially reasonable efforts to promote, market, sell and distribute CBT-001 in the Greater China at its own costs pursuant to the License Agreement. In addition, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. For details, see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan”.

However, there is no assurance that we will be able to successfully commercialise CBT-001 through the commercialisation collaboration or that the royalty income to be generated from the future sales of CBT-001, if any, will be sufficient to cover our development costs. In addition, as CBT-001 is a potential first-in-class drug candidate using breakthrough technology to targeting pterygium, for which there is currently no approved drug therapy globally, its novelty could create additional uncertainty with respect to the execution of commercialisation strategies as part of the licensing arrangement between Grand Pharma and us.

Going forward, we intend to continue to explore potential strategic commercialisation partnerships with global pharmaceutical companies. Any of these relationships may require us to issue securities that dilute our existing shareholders, or disrupt our operations and business. In addition, we face significant competition in seeking appropriate strategic commercialisation partners and the negotiation process is time-consuming and complex.

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Commercialisation collaborations involving our drug candidates may be subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration and may fail to devote the necessary efforts and resources;
- collaborators could sell and market drugs that compete directly or indirectly with our drugs or drug candidates;
- we may be unable to identify appropriate collaborators for a particular drug candidate or negotiate satisfactory commercial arrangements, including with respect to cost sharing, licensing, royalty or other fees and geographic scope, on a timely basis or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardise or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the commercialisation of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need to pursue further commercialisation channels for the relevant drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs that results from our collaboration with them, and in such cases, we would not have the exclusive right to commercialise such intellectual property.

As a result, if we enter into commercialisation collaboration agreements or strategic partnerships or license our drugs, we may not be able to realise the benefit of such transactions if we are unable to successfully integrate them with our existing R&D, commercialisation plans and operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or licensing, we will achieve the income that justifies such transaction. We cannot assure you that our current or potential licensors or licensees will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our current or potential licensors or licensees might conclude that we have materially breached our license agreements. In particular, the License Agreement imposes, and we expect that our future licence agreements, if any, will impose, various development and other obligations on us. Pursuant to the Licence Agreement, Grand Pharma shall have the right to terminate this agreement upon written notice to us, if we fail to successfully complete the first patient dosing of CBT-001 in mainland China by 13 April 2022 (or within a mutually agreed extended timeline), or fail to obtain the regulatory approval for CBT-001 in mainland China by 13 April 2025 (or within a mutually agreed extended timeline). The first patient dosing in mainland China occurred on 6 March 2024 as its clinical trial progress was affected by

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COVID-19, which may give rise to Grand Pharma's right to terminate the License Agreement with us absent a mutually agreed extended timeline or an amendment or waiver of the relevant terms. Grand Pharma has continued to actively cooperate with us in the project administration of CBT-001 clinical trials in Mainland China. As of the Latest Practicable Date, we had not received any notice from Grand Pharma of its intention to terminate the License Agreement. There can also be no assurance that we will be able to obtain the regulatory approval for CBT-001 in mainland China by 13 April 2025, or will in the future strictly comply with all obligations under the License Agreement in a timely manner. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to delay the potential commercialisation of a particular drug candidate, reduce the scope of any sales or marketing activities, or increase our expenditures and undertake significant in-house sales and marketing and commercialisation activities at our own expense. If we elect to fund and undertake commercialisation activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into the necessary collaboration arrangements, it may adversely affect the commercial potential of any drugs for which may receive approvals in markets worldwide.

If competing drugs are more effective, have fewer side effects, are more effectively marketed and cost less than our drugs or drug candidates, or receive regulatory approval or reach the market earlier, our drug candidates may not be approved, and our drugs or drug candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete.

We face potential competition in the ophthalmology industry, from pharmaceutical and biopharmaceutical companies, academic institutions and public and private research institutions. Any drug candidates that we successfully develop and commercialise will compete with existing drugs and new drugs that may become available in the future.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialise drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than the drugs that we may develop or commercialise. Our competitors also may obtain approvals from the FDA, the NMPA or other comparable regulatory authorities for their drugs more rapidly than we are able to, which could result in their establishing a strong market position before we are able to enter. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercialising our drug candidates.

Our future pricing strategy and fluctuations, in particular, downward changes in pricing of our future products may have a material adverse effect on our business and results of operations.

The pricing of our future products depend on a variety of factors, including bargaining power and preferences of hospitals, prices of similar or comparable products offered by our future products' costs, prices of competing products, and our target patients' receptiveness to our products, some of which are beyond our control. For example, when setting the prices for our products, hospitals may have strong bargaining power depending on the availability of alternative products, demands of patients and the preferences of physicians. If hospitals

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seek to lower retail prices of our products, not only the profitability of our products that we sell directly to hospitals may be adversely affected, but also the profitability of our products will be decreased. Moreover, if relevant governmental authorities issue pricing guidance for our future products, the price at which we can sell the products may be affected. We may also face downward pricing pressure if our products are included in the medical insurance reimbursement list in the PRC or other comparable programs in the United States or other jurisdictions in which we have commercialisation plans, even if such inclusion is expected to increase the sales volume of our future products.

In addition, with the development of technologies and increasing competition in the ophthalmology industry, we may experience reduced pricing from our existing products, particularly along with the launch of new products that can replace or further improve the safety and efficacy profile of our products, while the manufacturing and material costs may remain constant or increase. If we are unable to successfully introduce more advanced and/or more profitable new products to the market, or if we fail to effectively control our operating and manufacturing costs, our business, financial condition and results of operations could be materially and adversely affected.

Even if we are able to commercialise any drug candidates, the drugs may become subject to national or other third-party insurance coverage, reimbursement practices, healthcare reform initiatives or unfavourable pricing regulations, which could make it difficult for us to sell our drug candidates profitably.

We intend to seek approvals to market our drug candidates in the United States, the PRC and other selected jurisdictions. The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approvals of the sale price of a drug before it can be marketed, and the pricing review period may not begin until after marketing or licensing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. For example, centralised procurement in China has strong bargaining power over pricing of biopharmaceutical products. As a result, even if we are able to commercialise any drug candidates, the drugs may become subject to reimbursement practices, healthcare reform initiatives or unfavourable price regulations that may delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates receive regulatory approvals.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as the federal health insurance program in the United States (namely, Medicare and Medicaid), and commercial payors are critical to new drug acceptance. Our ability to successfully commercialise our drug candidates, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities and third-party payors, such as private health insurers and health maintenance organisations. Government authorities and third-party payors decide which medications they will pay for and establish reimbursement levels. A primary trend in

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the global healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

We cannot be sure that reimbursement will be available for any drug that we commercialise and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approvals. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialise any drug candidate that we successfully develop or in-license.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effective data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our genetically modified drugs. Patients are unlikely to use our drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drug candidates. Additionally, there may be significant delays in obtaining reimbursement for approved drugs, and coverage may be more limited than the purposes for which the drug is approved by regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already

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reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States or the PRC. Third-party payors often rely upon national healthcare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for new drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialise drugs and our overall financial condition.

In China, pursuant to the Notice on Issuing the Opinions to Promote Drug Price Reform (《關於印發推進藥品價格改革意見的通知》) issued by seven PRC ministries, including the NDRC and the NMPA, government price controls on pharmaceutical products were lifted effective as of 1 June 2015, except for narcotic drugs and first-class psychotropic drugs. As a result, prices of pharmaceutical products are currently determined mainly by market competition through the centralised tender process at the provincial level, without being subject to price ceilings set by the NDRC. However, for a pharmaceutical product to be included on the NRDL, a ceiling of such product's reimbursable amount under the national medical insurance will be determined, based on negotiation with the government. Moreover, there is no assurance that such market-based pricing mechanism will result in higher product pricing compared to government-controlled pricing, as competition from other manufacturers, particularly those offering the same products at more competitive prices may force us to lower price of our drug candidates and may also impact the prices of our drug candidates once commercialised in the PRC. PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products. Pursuant to the Opinions to Promote the Normalisation and Institutionalisation of Centralised and Quantified Purchase of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》) issued on 22 January 2021, the General Office of the State Council further encouraged the collective procurement of public hospitals through the centralised purchase of drugs in large quantities. A centralised tender process will be initiated once the demand for certain drugs reach a certain quantity or amount, with the emphasis on high-priced drugs included on the NRDL and in great demand. This policy is intended to reduce the retail prices of pharmaceutical products by cutting the intermediaries between hospitals and manufacturers. Consolidated procurement and direct settlement between hospitals and manufacturers may increase the bargaining power of hospitals and increase the pricing pressure on our future drug candidates. In China, if we were to successfully launch commercial sales of our future products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patients' self-payment, which can make our products less competitive. Additionally, even if our application for the inclusion of our products in the NRDL is successful, our potential revenue from the sales of these products could decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL.

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National insurance coverage, reimbursement practices, healthcare reform initiatives or pricing regulations may limit the prices that hospitals, clinics and other medical practitioners can charge for our products, which in turn would limit the prices that we can charge them and adversely affect our profitability. We will need to monitor the pricing policies of hospitals and other affected market participants and adjust our own pricing policy where appropriate in order to balance the competitiveness of our products with our profitability. Any negative developments in respect of the above could have a material adverse effect on our business, financial condition and results of operations.

Our approved products will be subject to ongoing regulatory obligations and continued regulatory scrutiny, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with such regulatory requirements.

Our drug candidates, if and when approved by the FDA, the NMPA or any other comparable regulatory authorities, will be subject to ongoing regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information requirements of regulatory authorities in the United States, the PRC and comparable regulatory authorities in other countries. Certain changes to the drug, such as changes in manufacturing processes and additional labelling claims, may be subject to additional review and approvals by the FDA, the NMPA and comparable regulatory authorities, and the FDA, the NMPA or a comparable regulatory authority may withdraw approvals if compliance with their requirements and standards is not maintained.

Any regulatory approvals that we may receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidate. The FDA, the NMPA or any other comparable regulatory authorities may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the FDA, the NMPA and comparable regulatory authorities approve our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GMP and GCP for any clinical trials that we conduct post-approval.

The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products that are not currently approved and marketed in our targeted markets or from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drugs and, in turn, may adversely affect our sales and profitability in the United States, the PRC and other jurisdictions where we plan to commercialise our products. Unapproved foreign imports of prescription drugs are illegal under the laws of the United States, the PRC and many other jurisdictions. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower

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priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (which are known as “**parallel imports**”) into higher-priced markets could harm sales of our future approved drugs and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers’ ability to import lower priced versions of our future approved products or competing products from outside the United States, the PRC or other countries where we plan to commercialise our products. Any future legislation or regulations that increase consumer access to lower priced medicines from outside the United States, the PRC or other countries where we plan to commercialise our products could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabelled with respect to their content or manufacturers. These products are generally referred to as “counterfeit pharmaceutical products”. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products, and we are subject to these risks in connection with our substantial operations in a developing economy. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products could quickly erode the demand for our future approved drugs. Moreover, counterfeit drugs may or may not have the same chemical composition as our drugs do, which may make them less effective than our drugs, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigations such as product liability claims against us. In addition, counterfeit pharmaceutical products are not expected to meet our or our collaborators’ rigorous manufacturing, testing and inventory standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators’ brand names.

Guidelines, recommendations and studies published by various organisations could adversely affect our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organisations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our and our business partners’ ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

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RISKS RELATING TO OUR FINANCIAL PROSPECTS AND NEED FOR ADDITIONAL CAPITAL

We are a pre-revenue biotechnology company. We incurred net losses since our inception and throughout the Track Record Period, and we may continue to incur losses in the near future and may not achieve or maintain profitability. You may lose all or substantially all of your investment if our business fails.

We are a pre-revenue biotechnology company and face a significant risk of business failure. During the Track Record Period, we only generated revenue from a one-time upfront payment of US\$10.0 million made by Santen to us under the Santen Licensing Agreement (see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” for details). Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approvals or become commercially viable. Since our inception, we have devoted most of our financial resources to R&D, including pre-clinical studies and clinical trials for our drug candidates. We have incurred significant expenses related to the R&D of our drug candidates in the past. In the years ended 31 December 2022, 2023 and 2024, our R&D expenses amounted to US\$15.3 million, US\$27.5 million and US\$37.9 million, respectively. We also incurred administrative expenses during the Track Record Period. As a result, we recorded loss for the year of US\$66.8 million, US\$129.4 million and US\$99.1 million in the years ended 31 December 2022, 2023 and 2024, respectively.

You may lose substantially all of your investment in us given the high risks involved in our business and associated with the biotechnology industry. As of the Latest Practicable Date, none of our drug candidates had been approved for marketing and sale in any jurisdiction. We have not generated any revenue from the sale of pharmaceutical products, and we will continue to incur significant R&D and other expenses related to our ongoing operations. Our ability to generate revenue from our drug candidates will depend primarily on the success of the clinical trials, regulatory approvals, manufacturing and commercialisation of our drug candidates, which is subject to significant uncertainty. Even if we successfully complete clinical trials and obtain regulatory approvals to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

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We expect to continue to incur losses for the foreseeable future as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our commercialisation and sales workforce in anticipation of the future commercialisation of our drug candidates. In addition, we will continue to incur costs associated with operating as a public company going through a period of rapid growth. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercialising any future approved products, our ability to generate revenue and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approvals, or, if approved, fails to achieve market acceptance, we may never be able to generate revenue or become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would reduce the value of our Company, adversely affect the market price of our Shares, and impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations. As a result, you may lose substantially all of your investment in us if our business fails.

We had negative cash flow from operating activities throughout the Track Record Period and we will likely need substantial additional funding for our drug development programmes and commercialisation efforts, which may not be available on acceptable terms to us, or at all.

Our operations have consumed substantial amounts of cash since our inception. For the years ended 31 December 2022, 2023 and 2024, we recorded negative cash flow from operating activities of US\$20.1 million, US\$22.5 million and US\$26.5 million, respectively. While we believe that we have sufficient working capital to fund our current operations, we expect that we will continue to experience net cash outflow from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default in our payment obligations and may not be able to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

To date, due to our negative operating cash flow, we have needed external financing throughout our operating history, which we have obtained primarily through pre-IPO investments. We have raised approximately RMB10.0 million (equivalent to US\$1.4 million), US\$5.6 million, US\$11.5 million, and US\$127.0 million from Series A Financing, Series B-1 Financing, Series B-2 Financing and Series C Financing, respectively, under our Pre-IPO Investments.

We expect our expenses to increase significantly in connection with our ongoing activities, as we advance the clinical development of our various clinical stage drug candidates, continue R&D of our pre-clinical stage drug candidates, initiate additional clinical trials of, and seek regulatory approvals for, these and other future drug candidates and expand our manufacturing capacity. Our future capital requirements will depend on many factors, including:

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- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;
- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialisation activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approvals;
- any cash received from commercial sales of any drug candidates for which we receive regulatory approvals;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or license other drug candidates and technologies; and
- our headcount growth and associated costs.

Moreover, as we obtain regulatory approvals for our clinical stage drug candidates, we expect to incur significant commercialisation expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs required for the manufacture of any drug candidate that receives regulatory approvals may be substantial. However, financing may be unavailable in amounts or on terms acceptable to us. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our R&D programs or any future commercialisation efforts, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, the incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants restricting our operations or our ability to pay dividends, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We had net liabilities and net current liabilities during the Track Record Period, which expose us to liquidity risk, and such position may continue or recur after the Listing.

We recorded total liabilities during the Track Record Period, which amounted to US\$227.3 million, US\$327.6 million and US\$391.6 million as of 31 December 2022, 2023 and 2024, respectively. As of 31 December 2022, 2023 and 2024, we also had net current liabilities of US\$146.6 million, US\$265.9 million and US\$353.8 million, respectively. Our deficit position in the Track Record Period was primarily due to the issuance of convertible redeemable preferred shares at fair value through a series of Pre-IPO Investment, which were

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recorded as current liabilities in our consolidated statements of financial position. As of the Latest Practicable Date, we had not received any redemption notice from Series C Investors and a majority of Series C Investors have indicated to us that they have no intention to exercise the redemption rights for at least 12 months from 31 December 2024. See Note 2.1 to the Accountant's Report set out in Appendix I to this prospectus for further details. Our Preferred Shares will automatically convert into ordinary shares upon Listing, at which time we expect to reclassify them from liabilities to equity and, accordingly, turn into net assets position. However, there can be no assurance that we will not experience liquidity issues in the future. As of 31 December 2024, our cash and cash equivalents was US\$34.9 million. The redemption of the convertible redeemable preferred shares could have a materially adversely impact on our cash and liquidity position and financial condition.

Our deficit position exposes us to liquidity risk, and such position may continue or recur after the Listing. Our future liquidity, capital expenditure plans and the repayment of our outstanding debt obligations as and when they become due will primarily depend on our ability to maintain adequate cash and obtain adequate external financing, which may not be available on commercially reasonable terms, or at all. We may have net liabilities and net current liabilities in the future, which may limit our working capital for the purpose of operations or capital for our expansion plans. Additionally, there can be no assurance that we will be able to successfully take any of these actions in a timely manner, including prudently managing our working capital, or raising additional equity or debt financing on terms that are acceptable to us. This would in turn make us unable to continue our operations according to our plans and be forced to scale back our operations, and materially and adversely affect our business, financial condition and results of operations. For more details of our net liabilities and net current liabilities position, see "Financial Information – Discussion of Selected Balance Sheet Items".

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are an innovative ophthalmic biotechnology company with a relatively short operating history. Our operations to date have focused on organising and staffing our Company, business planning, raising capital, establishing our ophthalmic drug portfolio, conducting pre-clinical studies and clinical trials of our drug candidates, developing manufacturing capacity and building a sales network with our business partner.

As of the Latest Practicable Date, we had not generated any revenue from sale of pharmaceutical products. All of our portfolio drugs are still at various stages of development. We have not yet successfully obtained regulatory approvals to market any drug candidates from our development pipeline, and have not commercially manufactured or commercialised any such drug candidates. Our limited operating history, particularly in the rapidly evolving ophthalmology industry, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential investors to lose substantially all of their investment in our business.

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If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our strategies focus on identifying, developing and commercialising first-in-class and best-in-class ophthalmic therapies. See “Business – Our Strategies” for details. Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to identify and develop promising drug candidates in the highly competitive global ophthalmology market, effective coordination and integration of new facilities and new teams that we may develop, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realise our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

The discontinuation of any of the government grants or preferential tax treatment currently available to us could adversely affect our financial position, results of operations, cash flows and prospects.

Since our inception, we have benefited from certain government grants and preferential tax treatment. For the years ended 31 December 2022, 2023 and 2024, we recorded government grants under other income of US\$0.5 million, US\$0.9 million and US\$0.2 million, respectively. The government grants are subject to the discretion of relevant government authorities. In addition, Cloudbreak Suzhou and Cloudbreak Guangzhou were eligible for preferential tax treatment during the Track Record Period, under which certain R&D expenses could be deducted from our income tax expenditures if we had income tax obligations. We cannot guarantee that we will continue to be eligible for such deductions in the future and we may not be able to enjoy such deductions when we have income tax obligations. Consequently, our financial results in a particular period may vary relative to other periods depending on the potential changes in these government grants and preferential tax treatment addition to any business or operational factors that we may otherwise experience. The discontinuation of government grants or preferential tax treatment currently available to us could have an adverse effect on our financial condition, results of operations, cash flows and prospects.

Raising additional capital may cause dilution to our Shareholders and restrict our operations.

We may seek additional funding through equity offerings and debt financings. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, your ownership interest may be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. Our incurrence of additional indebtedness or issuance of certain equity securities could also require us to assume significantly increased fixed payment obligations and impose additional restrictive covenants on our business, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license

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drug development rights and other operating restrictions that could adversely impact our ability to pursue the development and commercialisation of our existing and future drug candidates.

Fair value change in our convertible redeemable preferred shares issued to Pre-IPO Investors and related valuation uncertainty have historically affected our financial condition and results of operations.

Historically, we designated the Preferred Shares as financial liabilities at fair value through profit or loss, as certain Pre-IPO Investors holding the convertible redeemable preferred shares were granted the right to require us to redeem the Preferred Shares they hold if the proposed Listing is not consummated within a certain period. Upon the completion of this Global Offering, all of such convertible redeemable preferred shares will be automatically converted into ordinary shares. Upon conversion, the convertible redeemable preferred shares will be recorded on a fair value basis based on market valuation. We use significant unobservable inputs in valuing certain of our assets and liabilities, including the convertible redeemable preferred shares and financial assets at fair value through profit or loss. The fair value change of convertible redeemable preferred share and financial assets at fair value through profit or loss may significantly affect our financial position and results of operations. Accordingly, such determination requires us to make significant estimates, which may be subject to material changes, and therefore inherently involves a certain degree of uncertainty. We recorded fair value changes in financial liabilities at fair value through profit or loss of US\$45.3 million, US\$95.8 million and US\$63.7 million for the years ended 31 December 2022, 2023 and 2024, respectively.

Factors beyond our control can significantly influence and cause adverse changes to the estimates we use and thereby affect the fair value of such assets and liabilities in the event we record any financial assets at fair value through profit or loss in the future. These factors include, but are not limited to, general economic condition, changes in market interest rates and stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results, which could materially and adversely affect our results of operation and financial condition.

We incurred indebtedness in the past, and may incur additional indebtedness in the future, which may adversely affect our financial condition and results of operations.

We did not have any outstanding bank borrowings as of 31 December 2022, 2023 and 2024. Such borrowings had been fully settled on 31 December 2024. As of 30 April 2025 and the Latest Practicable Date, we had unutilised banking facilities of US\$45.0 million and US\$45.0 million, respectively, and none of which were restricted. See “Financial Information – Indebtedness – Bank Borrowings” in this prospectus for details. We may incur additional indebtedness in the future and may not be able to generate sufficient cash to satisfy our future debt obligations.

Our future indebtedness could have an adverse effect on us by, among others, increasing our vulnerability to adverse developments in general economic or industry conditions, such as significant increases in interest rates. Our future borrowings may subject us to certain restrictive covenants which may restrict or otherwise adversely affect our

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operations, such as the covenants that may restrict our ability to incur additional debt, repay or transfer certain indebtedness, or reduce registered capital. In addition, some of the loans may have restrictive covenants linked to our financial performance, such as maintaining a prescribed maximum debt-to-asset ratio or minimum profitability levels during the term of the loans.

Moreover, if any of our future indebtedness is required to be secured by our assets by the terms of the loan agreements we may enter into, in the event that we default on payment obligations of the secured indebtedness or are unable to comply with the restrictions and covenants imposed by the loan agreements in our future debt obligations, banks could terminate their commitments to us, accelerate the payments and declare all amounts borrowed due and payable, enforce the security or terminate the loan agreements. If any of the foregoing events occurs, there can be no assurance that our assets and cash flow will be sufficient to repay all of our debts as they become due, or that we will be able to obtain alternative financing on commercially reasonable terms. In such event, if the banks enforce any security over our assets, our business, financial condition, results of operations and prospects would be adversely affected.

We have granted, and may continue to grant, equity incentives, which may result in increased share-based compensation expenses and diluted effect to our Shareholders.

We approved and adopted the Series B Equity Incentive Arrangement, the Series C Equity Incentive Arrangement and the 2023 Equity Incentive Scheme to incentivise and recognise the contribution of certain employees, adviser and officers of our Company. Under the Equity Incentive Arrangements, as of the Latest Practicable Date, an aggregate of 25,159,685 Class A Ordinary Shares had been issued as incentive awards granted, representing approximately 3.24% of the total issued share capital of our Company. Immediately before the Global Offering, an aggregate of 2,225,000 Shares will be further issued pursuant to RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements, representing approximately 0.27% of the total enlarged issued share capital of our Company upon Listing. For the years ended 31 December 2022, 2023 and 2024, our share-based payment expenses were US\$1.3 million, US\$13.6 million and US\$11.3 million, respectively.

We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to them in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations and financial conditions. In addition, our granting of share-based awards could dilute your interest in our Company.

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RISKS RELATING TO OBTAINING REGULATORY APPROVALS, COMMERCIALISATION OF OUR DRUG CANDIDATES, AND DOING BUSINESS OUTSIDE OF CHINA

We will face challenges and expenses in obtaining regulatory approvals of our drug candidates from the FDA or comparable foreign regulatory authorities elsewhere, which could prevent or delay our ability to market our drug candidates outside of China.

We are concurrently conducting clinical trials in the United States and the PRC, and we have also commenced phase 3 MRCTs for our Core Product CBT-001 in New Zealand, Australia and India. Obtaining regulatory approvals for drug candidates in one country does not mean that regulatory approvals will be obtained in any other countries. Approval processes vary among countries and can involve additional clinical trials and validation and additional administrative review periods. Conducting clinical trials outside of China could prove particularly challenging and expensive and could lead to significant delay.

In addition, any safety or efficacy issues, product recalls or other incidents related to products approved and marketed in the United States and other jurisdictions may impact approvals of those products by the FDA or other comparable foreign regulatory authorities. For example, the FDA may require us to enter a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance, or the FDA may suspend, withdraw, or modify marketing approvals if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drug candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labelling or promotional materials to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, provision of corrective information to healthcare practitioners, or the FDA's imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drugs, withdrawal of the product from the market, or voluntary product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or withdrawal of approvals;
- the FDA's suspension or modification of any ongoing clinical trials;
- the FDA's suspension or imposition of restrictions on operations, including costly new manufacturing requirements;

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- product seizure or detention, or refusal to permit the import or export of our drug candidates, or the requirement for us to initiate a product recall; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labelling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved labels. The FDA and other regulatory authorities actively enforce laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

Accordingly, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approvals that we may have obtained and we may not achieve or sustain profitability.

If the FDA does not conclude that our drug candidates satisfy the requirements for the Section 505(b)(2) NDA regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for some of our drug candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to seek approval of our clinical-stage drug candidates under the 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (“**FDCA**”). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for the NDA approval comes from studies that were not conducted by or for the applicant, and for which the applicant does not have a right of reference. If the FDA in the future does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approvals. If this were to occur, the time and financial resources required to obtain FDA approvals for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot guarantee that we will receive the requisite or timely approvals for commercialisation of such product candidate. While operating under accelerated approvals, we will be subject to certain restrictions that we would not be subject to upon receiving regular approvals. The FDA may require us to conduct a confirmatory study to verify the predicted clinical benefit and

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additional safety studies, if we are to obtain approvals under the 505(b)(2) regulatory pathway from the FDA. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn.

Notwithstanding the approvals of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA adopts an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if such 505(b)(2) application does not rely on the previously approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, approvals may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approvals of our product candidates would significantly limit our ability to generate sufficient revenues, and any failure to obtain such approvals for all of the indications and labelling claims we deem desirable could reduce our potential revenues.

We are subject to the risks of doing business globally. Specifically, we may explore the licensing of commercialisation rights or seek collaborations worldwide, which will expose us to risks of conducting business in the international markets.

Because we operate in the United States and the PRC and conduct our clinical trials in these and other jurisdictions and may in the future operate in other jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: changes in a specific jurisdiction's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain jurisdictions; enforcement of anti-corruption and anti-bribery laws, such as the United States Foreign Corrupt Practices Act of 1977, or FCPA; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

Global market expansion is an important component of our growth strategy. We intend to focus on opportunities in the United States and the PRC in particular. If we fail to obtain or grant licenses or enter into collaboration arrangements with third parties in other markets, or if an existing or future third-party collaboration is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

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- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- unexpected changes in laws and regulatory requirements and difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection such as third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labour laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labour unrest;
- failure of our employees and contracted third parties to comply with anti-corruption and anti-bribery laws, such as United States Department of the Treasury's Office of Foreign Assets Control rules and regulations and the FCPA as amended; and
- business interruptions resulting from geopolitical actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics (including, for example, the COVID-19 pandemic).

These and other risks may materially adversely affect our ability to procure equipment and raw material and to attain or sustain any future revenue from international markets.

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We face challenges associated with operating in the United States and China and on a geographically dispersed basis, making it difficult to evaluate our current business and predict our future performance.

The first operating subsidiary within our Group was founded in September 2015 based in Irvine, California, the United States. As of the Latest Practicable Date, we had built an R&D centre in Guangzhou, Guangdong, the PRC and an R&D centre in Irvine, California, the United States, a pilot production facility in Suzhou, Jiangsu, the PRC, and a finance and legal team in Hong Kong. We have also established a subsidiary in Australia and a subsidiary in Germany to support our clinical trials and our intellectual property rights protection. Our operations to date have focused on building our management team and R&D capabilities, establishing our drug candidate pipeline and related intellectual property portfolio and conducting pre-clinical studies and clinical trials of our drug candidates. We have a limited operating history and we had no products approved for commercial sale as of the Latest Practicable Date. Operating on a geographically dispersed basis with operations in the United States, the PRC, Australia and Germany presents unique coordination, geographic, political and other challenges.

Our limited operating history, particularly in light of the rapidly evolving and highly competitive ophthalmology industry, may make it difficult to evaluate our current business and reliably predict our future performance. Consequently, any statements about our future success or viability are not based on any substantial operating history or commercialised products. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential investors to lose all or substantially all of their investment in our business.

The trade relations between China and the United States or other jurisdictions may affect our business operations and any changes in the United States and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The United States government has made statements and taken certain actions that may lead to potential changes to United States and international trade policies towards China. In January 2020, the “**Phase One**” agreement was signed between the United States and China on trade matters and went into effect on 14 February 2020, under which China agreed to expand purchases of certain United States goods and services by a combined US\$200 billion over 2020 and 2021 from 2017 levels. It remains unclear what additional actions, if any, will be taken by the United States or other governments with respect to other future international trade agreements, the imposition of tariffs on goods imported into the United States, tax policies related to international commerce, or other trade matters. It is unknown whether new tariffs or new laws or regulations will be adopted, or the effect that any such actions would have on us or the ophthalmology industry.

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Although we have not started commercialisation of drug candidates, any unfavourable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and directly disrupt our drug development and the manufacture of our drug candidates. Such unfavourable policies may also negatively impact the hiring of scientists and other R&D personnel, the demand for our drug products or the competitive position of our drug products, or prevent us from selling our drug products in the United States or other countries. If any new tariffs, policies, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the United States government takes retaliatory trade actions due to recent United States-China trade tensions, such changes could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the United States and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approvals. If we obtain approvals from the FDA or the NMPA for any of our drug candidates and if we then begin to market those drugs in the United States or in the PRC, our operations may be subject to various laws and regulations in the United States and the PRC, including (i) federal and state fraud and abuse laws in the United States, such as the Federal Anti-Kickback Statute and the United States Federal False Claims Act, (ii) physician payment transparency laws and regulations in the United States, such as the United States Federal Physician Payments Sunshine Act (Sunshine Act), and (iii) relevant laws in the PRC, such as the PRC Anti-Unfair Competition Law (《反不正當競爭法》), the PRC Drug Administration Law (《藥品管理法》) and its implementing regulations, and the PRC Criminal Law (《刑法》). Our current and future operations also may be subject to regulation by United States federal, state and local authorities including, among others, the Centres for Medicare and Medicaid Services, and other divisions within the United States Department of Health and Human Services such as the Office of the Inspector General and the Office for Civil Rights. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirements, we could be subject to applicable penalties.

Furthermore, efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, imprisonment, contractual damages, reputational damage,

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diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material adverse effect on our business and results of operations.

If any of the physicians or other providers or entities with whom we expect to do business, or we, are found to be not in compliance with applicable laws, such persons could be exposed to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, which may adversely affect our business.

RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS

The United States Court of Appeals for the Federal Circuit (the “Federal Circuit”) has solidified our win before the United States Patent Trial and Appeal Board (“PTAB”) in an *Inter Partes* Review (“IPR”) proceeding regarding the validity of a patent owned by us relating to one of our Core Products, CBT-001. Such patent validity claims (if any) and any adverse results arising therefrom may result in reputational harms to our Company and our brand name.

On 7 August 2020, Allgenesis Biotherapeutics Inc. (“**Allgenesis**”) requested an IPR of U.S. Patent No. 10,149,820 (the “**’820 Patent**”) owned by Cloudbreak Therapeutics, LLC (“**Cloudbreak USA**”). The ’820 Patent is one of the four granted U.S. patents for CBT-001 in one of our Group’s CBT-001 patent families. On 15 February 2022, Cloudbreak USA received a favourable final written decision in the IPR, issued by the PTAB, which was then appealed by Allgenesis on 31 August 2022 to the Federal Circuit. A three-judge panel of the Federal Circuit published an opinion dismissing Allgenesis’ appeal on 7 November 2023. On 14 December 2023, the Federal Circuit entered its mandate finalising the panel’s decision to dismiss the appeal, and signifying the formal final resolution of the appeal before the Federal Circuit. The Federal Circuit’s decision has become final as Allgenesis’ deadlines for seeking reconsideration or review of the panel’s decision have passed. See “Business – Intellectual Property – *Inter Partes* Review of ’820 Patent for CBT-001” for details.

There are inherent uncertainties associated with legal proceedings. In particular, patent validity assessments involve an analysis of complex legal and factual issues, the determination of which is often difficult to foresee. Future patent validity claims like the IPR proceeding (if any) and any adverse results arising therefrom may result in reputational harms to our Company and our brand name.

We may be subject to intellectual property infringement or misappropriation claims or other legal challenges in court or before the USPTO or comparable foreign authority which could result in costly litigation, significant expenses or substantial damages, limit our R&D activities, and delay or prevent us from selling our products.

Our commercial success depends, in part, upon our technologies, drug candidates and operations not infringing, misappropriating or violating intellectual property rights owned by others and being able to resolve claims of intellectual property infringement and/or misappropriation expeditiously without major financial expenditures or adverse consequences. Many pharmaceutical companies have developed worldwide patent portfolios of varying sizes and breadth. Many patents may cover a marketed product, including but not

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limited to, the composition of the product, methods of use, formulations and production processes. Not all such patents have expired globally, including potentially in the jurisdictions where we are developing and intend to commercialise our drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents related to aspects of our business are likely to be issued.

As the ophthalmology industry expands and more patents are issued, and as we expand our portfolio accordingly, we may be exposed to greater risk of claims of infringement of patent rights. Given the nature of the ophthalmology industry, we may, in the ordinary course of business, be subject to intellectual property infringement or misappropriation claims in various jurisdictions where we operate and where our drugs are ultimately sold. Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our drug candidates, technologies or methods. We may also be subject to allegations by third parties of unfair competition, defamation or violation of their other rights. We could also be subject to intellectual property claims related to alleged infringements by our third-party partners, such as suppliers.

Patent and trademark infringement, trade secret misappropriation and other intellectual property claims and proceedings brought against us, whether successful or not, can be complex and time-consuming and could result in substantial costs, negative publicity and harm to our reputation and market position. Such claims and proceedings can also distract and divert our management and key personnel from other tasks important to the success of our business. Moreover, the legal threshold for initiating such claims and proceedings is low, so that even claims with a low probability of success could be initiated and require significant resources and attention to defend. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favour on questions of infringement, validity, enforceability, or priority and it could materially and adversely affect our ability to develop and commercialise any of our drug candidates and any other drug candidates covered by the asserted third party patents. In order to successfully challenge the validity of any such patent in federal court in the United States, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such patent claim in the United States, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If third parties bring successful claims against us for infringement, misappropriation, or other violations of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercialising one or more of our drug candidates. Defence of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement, misappropriation, or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages, which we may not be able to be

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indemnified by our future licensing-in partners, if any. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialisation of our drug candidates. Any such license might not be available on reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialise one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent and other intellectual property infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favour, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigations or proceedings could substantially increase our operating losses and reduce the resources available for R&D activities or any future sales, marketing or distribution activities.

Accordingly, intellectual property litigation or disputes could force us to do one or more of the following:

- cease developing, manufacturing or selling products that incorporate the challenged intellectual property;
- cease the use and registration of certain names, domain names, brands or trademarks in connection with some or all of our products and business activities in some or all jurisdictions throughout the world;
- obtain and pay for licenses from the holder of the infringed intellectual property right, which licenses may not be available on reasonable terms, or at all;
- redesign or reengineer products;
- change our business processes; and
- pay substantial damages, court costs and attorneys' fees, including potentially increased damages for any infringement or violation found to be wilful.

The exact scope of patent claims if and when issued may differ from its scope in the application stage, and as a result, we cannot ensure that our drug candidates will not infringe patents that are issued in the future. Based on the freedom to operate (“FTO”) analysis conducted on the active ingredient and the formulation of our clinical-stage products in the United States and the PRC, we are not aware of any issued patents that may affect our rights to conduct R&D or commercialise Core Product in the United States and the PRC at the contemplated timeframe. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to identify whether any existing patents

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that cover a company's products, and to assess whether making, using, offering to sell, or selling the products would infringe any existing patents. The potential scope of an FTO investigation can be immense and all patent databases used in such investigations have limitations. Patent applications in the United States, the PRC and the WIPO ("**World Intellectual Property Organization**") are typically not published until 18 months after the original filing, or in some cases, may not be published until patent issuance. Because patent applications can take many years to issue and the exact scope of patent claims if and when issued may differ from its scope in the application state, third parties may have currently pending patent applications which may later result in issued patents that any of our drug candidates may infringe, or which such third parties claim to be infringed by our technologies. Therefore, we cannot guarantee that our FTO searches and analysis have exhaustively reviewed all the existing and future patents that potentially cover our products.

As a result of the foregoing, any intellectual property-related disputes or litigation, regardless of outcome or merit, could result in substantial costs and expenses, adverse publicity or diversion of management resources, any of which could have a material adverse effect on our business, financial condition and results of operations.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages, and patents, trademarks, trade secrets and other forms of intellectual property protections may not be adequate which may harm our competitive position.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- our competitors may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or have licensed;
- we, our future in-licensed partners (if any) or the ultimate owner, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future license, which could result in the patent applications not issuing or being invalidated after issuing;
- we, our future in-licensed partners (if any) or the ultimate owner, might not have been the first to file patent applications covering certain of our inventions that we own, or license in the future, which could result in the patent applications not issuing or being invalidated after issuing;
- our competitors may independently develop similar or alternative technologies or duplicate any of the technologies that we own or license without infringing our, or our future licensing-in partners' (if any), or the ultimate owners' intellectual property rights, and even if we defend or assert our patents by filing lawsuits

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alleging patent infringement and engage in complex, lengthy and costly litigation or other proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed;

- our future licensing-in partners (if any) or the ultimate owners' pending patent applications may not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain future products many years before we obtain marketing approvals for products containing such future products, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of such patents may be limited;
- our competitors might conduct R&D activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may not be able to protect our intellectual property rights that we own or license across the world or prevent unfair competitions from third parties;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate or commercialise our future products; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our drug candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates or development pipelines throughout the world, which depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies.

Our commercial success will depend, where relevant, on our ability to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and development pipelines. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of the patents and patent applications that we own or license have been, are being or may be challenged at a future point in time in opposition, derivation, re-examination, *inter partes* review, post-grant review or interference proceedings. The patent position of ophthalmic pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. We cannot be certain

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whether patents will be issued or granted with respect to our own patent applications that are currently pending, the claim scopes of our own patent applications will be limited before patent is issued or granted, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates and development pipeline, or otherwise provide us with any competitive advantage. In particular, on 13 March 2024, the European Patent Office had received an opposition filed by a third party with respect to one of our patents relating to CBT-001 which we consider an ancillary and immaterial patent for CBT-001. As of the Latest Practicable Date, the European Patent Office had issued a written notification with respect to this opposition action. Please see “Business – Intellectual Property – Overview” for details.

Publication of discoveries often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as competing applications and may not be approved in the end.

As such, we do not know the degree of future protection that we will have on our drugs and technology, if any. If the patent applications we had applied are not granted in the end, or the scope of intellectual property rights we obtained is not adequate, third parties could develop or commercialise drugs similar to ours and compete against us. As a result, a failure to obtain adequate intellectual property protection with respect to our drug candidates or development pipeline could have a material adverse impact on our business.

The patent application and approval process may be complex, expensive, and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications in a timely manner or at a reasonable cost in each and every key jurisdiction, even for our clinical-stage drug candidates. For example, the patent applications for our clinical-stage drug candidates are filed or obtained in a limited number of jurisdictions but not the others. See “Business – Intellectual Property – Overview” in this prospectus for details of our patent and patent applications. Numerous governmental fees such as filing fees, periodic maintenance fees, renewal fees, annual fees and various other fees on patents and patent applications are due to be paid to the USPTO, the China National Intellectual Property Administration (the “CNIPA”) and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The USPTO, the CNIPA and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We rely on our outside counsel or agent to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property (if any). Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of rights, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalise and submit formal

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documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not have the right to control the preparation, filing, prosecution, maintenance, extension, enforcement, and defence of patents and patent applications covering the drug candidates that we license from third parties (if any), which could have a material adverse effect on us.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defence of patents and patent applications covering the drug candidates that we may license from third parties in the future. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If we enter into licensing-in agreements in the future, and such future licensing partners fail to prosecute, maintain, enforce or defend the patents we license in, or lose rights to those patents or patent applications, the rights we will have licensed may be reduced or eliminated, and our right to develop and commercialise any of our drugs that are subject of such potential licensed rights could be adversely affected.

In spite of our best efforts, our future licensing partners from which we license patents may conclude that we materially breach the in licensing agreements and might therefore terminate such agreements, thereby removing our ability to develop and commercialise drug products covered by these licensing-in agreements. If such licenses are terminated, we may be required to seek alternative licensing-in arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. In addition, we may seek to obtain additional licenses from third parties and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favourable to these third parties, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. If such alternative or additional licensing-in arrangements are not available, we may need to modify or cease the development, our manufacture, or commercialisation of one or more of our drug candidates and competitors would have the freedom to seek regulatory approvals of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our future licensing partners may not be the sole and exclusive owners of the intellectual property rights we in-license in some cases. The third parties we license patents from may have obtained the rights to such patents through license agreements with the entities that own or control such patents and have in turn sublicensed such rights to us. We are not a party to the license agreements under which these third parties obtain their rights and therefore cannot ensure that they will comply with their obligations under such agreements. If any of our future licensing partners breach or otherwise violate any such agreements, their rights thereunder may be terminated and our licensing partners may no longer be able to sublicense such rights to us. In addition, our future licensing partners may not control prosecution and enforcement of such patents, and if they lose their rights to any patents or other intellectual property rights upon which we depend or we lose our sublicense

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rights to such patents and other intellectual property, we may be required to cease the development and commercialisation of our products and it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to receive approval, our business will be adversely affected.

Our business relies on, and will continue to rely on, various intellectual property rights, including patents, trademarks, trade secrets, copyright and designs to protect our product and research findings, brand name, reputation, product appearance and technology. We have sought to protect our proprietary position by filing patent applications in the United States, the PRC, Europe, Australia, Hong Kong, Canada, Japan, Brazil, Mexico, Taiwan, South Korea, India and other jurisdictions related to our drug candidates that we consider are important to our business. As of the Latest Practicable Date, we had 60 granted patents and 168 pending patent applications worldwide. See “Business – Intellectual Property” in this prospectus for details. However, the patent and other intellectual property position of pharmaceutical companies is generally highly uncertain, involves complex legal and factual considerations, and is subject to frequent litigation. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications are typically not published until at least several months after filing, or in some cases not at all. Industry players cannot be certain that they were the first to make the inventions claimed in their patents or pending patent applications, or that they were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of any intellectual property rights is highly uncertain. Moreover, changes in either the patent laws or interpretation of the patent laws in various countries where our applications or patents are filed may diminish the value of our patents or narrow the scope of our patent protection.

Effective intellectual property protection is expensive to develop and maintain, and the costs of defending and maintaining our rights may also be significant. To the extent that we become involved in patent disputes, any adverse determination against us could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialise our technology or drug candidates and compete directly with us. As we intend to commercialise our drug candidates in various jurisdictions including United States and the PRC, we may be dependent on the laws of a wide range of jurisdictions to protect, maintain and enforce our intellectual property rights throughout the world. We have not yet sought intellectual property protection in all jurisdictions where we ultimately intend to sell our products, and as a result of commercial pressures or otherwise, we may significantly expand our business into such jurisdictions without the benefit of clear, enforceable intellectual property protections. The laws of these jurisdictions may also be insufficient to protect our intellectual property rights to the same extent or in the same manner as the laws of the jurisdictions in which we currently have sought intellectual property protections or of the jurisdictions where investors may be located.

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Many companies have encountered significant problems in protecting, obtaining and defending intellectual property rights in certain jurisdictions. In particular, the legal systems of certain developing countries do not favour or consistently enforce patents, trade secrets, trademarks and other forms of intellectual property protection, which could make it difficult and time-consuming to stop the infringement, misappropriation or other violation of our intellectual property rights. Competitors may be able to use our proprietary technology and other intellectual property rights in jurisdictions where intellectual property protection may not be prioritised by the relevant legal systems. Furthermore, we cannot assure you as to the degree and scope of protection which our existing or future patents may afford us over our drug candidate portfolio. For example, there is no assurance that any of our pending patent applications will finally lead to issued patents. Likewise, we cannot assure you that:

- competitors will not develop similar or superior products outside the protection of our patents;
- competitors will not infringe on our patents;
- we will have adequate resources to enforce our patents; or
- we will obtain sufficient remedies in the case of infringement, misappropriation, or other violations of our patents.

We cannot assure you that we will be able to file, prosecute, transfer and maintain all necessary or desirable intellectual property applications at a reasonable cost or in a timely manner, or that we will always be able to identify patentable aspects of our R&D output before it is too late to obtain patent protection, nor can we provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future. If we are unable to obtain and maintain patent in respect of any of our current and future patent applications and other intellectual property protection for our products, drug candidates and other technologies, our competitors could develop and commercialise technology and drugs similar or identical to ours, and our ability to successfully commercialise our technology and drugs may be adversely affected, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisers have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisers do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary

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damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while in the standard confidentiality agreements and non-compete clauses in agreements with our key personnel, we typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Confidentiality agreements with employees and third parties may not prevent unauthorised disclosure of trade secrets and other proprietary information.

We rely on employee and third-party confidentiality agreements to safeguard our intellectual property, such as trade secrets, know-how and other proprietary information. Nevertheless, there can be no guarantee that an employee or a third party will not make an unauthorised disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorised disclosures. In addition, to the extent that our employees, consultants, contractors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and other third parties might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable.

We sometimes engage third parties to conduct research relevant to our drug candidates. The ability of these individuals or research institutions to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardised, which could adversely affect our business.

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Changes in patent law in the jurisdictions we conduct business could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other ophthalmic pharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the ophthalmology industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in any jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we, or our licensors in the future (if any), are currently pursuing, and may pursue in the future, (i) will issue or be granted, (ii) the jurisdiction(s) in which they will issue, or be granted or (iii) whether the claims of any future issued patents will provide sufficient protection from competitors.

Recently enacted United States laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, in addition to the “first-to-file” system summarised above, the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. These changes include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review and *inter partes* review. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of patents that may issue from our pending patent applications, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Recent United States Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

In addition, we cannot be certain that issued or granted patents will not later be found to be invalid or unenforceable or that the coverage claimed will not be significantly reduced before the patent is issued and/or reinterpreted after issuance. For example, we, or our future licensors (if any), may be subject to a third-party pre issuance submission of prior art to the USPTO, or the CNIPA, or become involved in opposition, derivation, revocation, re-examination, invalidation, post-grant review, *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. For example, a patent owned by us was challenged following an *inter partes* review proceeding. See “ – The United States Court of Appeals for the Federal

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Circuit (the “**Federal Circuit**”) has solidified our win before the United States Patent Trial and Appeal Board (“**PTAB**”) in an IPR proceeding regarding the validity of a patent owned by us relating to one of our Core Products, CBT-001. Patent validity claims like this in the future (if any) and any adverse results arising therefrom may result in reputational harms to our Company and our brand name.” above and “Business – Intellectual Property – *Inter Partes Review* of ’820 Patent for CBT-001” in this prospectus for details.

An adverse determination regarding the scope or validity of our patent rights in any of these proceedings could adversely affect our ability to prevent others from utilising the invention claimed under our patent rights, and may also result in reputational harms to our Company and our brand name. If we are unable to enforce our patent rights against others, third parties may commercialise drug candidates and compete directly with us without payment to us.

The uncertainty in patent linkage, patent term extension and data and market exclusivity for pharmaceutical products in China and in the United States, as applicable, could increase the risk of early generic competition with our products in China.

In many jurisdictions, various policies on patent linkage, patent term adjustments and extensions, and data and market exclusivity may be available. For example, in the United States, the Federal Food, Drug and Cosmetic Act, as amended by the law generally referred to as “Hatch-Waxman”, provides for patent-term restoration, patent linkage and statutory exclusivities that can prevent submissions or approvals of certain follow-on marketing applications. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

If we seek patent protection of our drug candidates or technology in the United States in the future, depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our United States patents, if issued, may be eligible for limited patent term extension under Hatch-Waxman. Hatch-Waxman permits a patent extension term of up to five years as compensation for patent term lost during the product’s testing phase, which is the time between IND and NDA submission, and during the approval phase, which is the time between NDA submission and FDA approval. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent applicable to an approved product may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, the applicable time period or the scope of patent protection afforded could be less than we request.

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In China, the Fourth Amendments to the PRC Patent Law (《中華人民共和國專利法修正案》) was adopted on 17 October 2020 and took effect on 1 June 2021, providing a patent term extension. According to the Fourth Amendments to the PRC Patent Law, patent term extension of up to five years is available to invention patents claiming new drugs, to compensate for the time spent during regulatory process. However, the implementing rules for the patent term extension have not yet been adopted and therefore the implementation, interpretation and enforcement of laws and regulations regarding the patent term extension are still subject to changes. Even if we apply for patent term extension, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be shorter than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than we request, the period during which we can enforce our patent rights for that product will not be extended in the same manner as we expect and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our exclusive right during any patent term extension period may be limited or may not cover a competitor's product or product use. The Fourth Amendments to the PRC Patent Law also provides a patent linkage system, pursuant to which the patent holder or a party of interest can file a lawsuit against certain follow-on applicant for drug patent disputes, in particular, for judgment of whether the drug candidate in the follow-on application would fall into the scope of the drug patent. However, there have been few precedents for patent linkage in China.

In view of the potential changes and development in the implementation rules in patent term extension and patent linkage in China, a lower-cost generic drug can emerge onto the market much more quickly. These factors could result in weaker protection for us against generic competition in China than could be available to us in some other applicable jurisdictions. Our competitors may obtain approvals of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be affected.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or future approved drugs in a non-infringing manner.

Our competitors may seek approval to market their own drugs that are the same as, similar to or otherwise competitive with our future approved drugs or drug candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our R&D before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

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We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We strive to protect our intellectual property rights, such as trademarks and trade names. As of the Latest Practicable Date, we had registered four and 12 trademarks in Hong Kong and the PRC, respectively. The registered or unregistered trademarks or trade names that we own or license may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition.

Although we take prudent measures to ensure the originality of our creation to avoid claims arising from copying, sometimes independent creations may still constitute infringement of certain trademark rights. Therefore, as much as we would endeavour to avoid any infringement dispute, we cannot assure you that third parties will not assert trademark claims against our Group during the course of our operation, and an adverse infringement decision could subject our Group to significant liability to third parties, or otherwise subject our Group to injunctions which prohibit the further use of the design in dispute. During the Track Record Period, the Chinese characters “撥雲” in the name of one of our subsidiaries, Guangzhou Cloudbreak, was alleged to have infringed certain trademarks of a third party in the PRC, and we subsequently changed the Chinese name for Guangzhou Cloudbreak to avoid alleged infringements. In addition, third parties have filed, and may in the future file, registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our products.

RISKS RELATING TO OUR OPERATIONS

We may not realise the benefits of collaborations which we have entered into or may enter into in the future. If we fail to comply with our obligations in the license agreements or otherwise experience disruptions to our business relationships with our licensing partners, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into a commercialisation licensing arrangement with Grand Pharma. In the future, we may also seek and form collaborations or entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialisation efforts with respect to our drug candidates and any future drug candidates that we may develop. We will carefully select our partners and products in order to collaborate and align interests and leverage each other's capabilities and infrastructure to develop significant products and bring novel therapies to patients in an efficient and cost-effective manner. However, if we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialisation activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

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At this time, we cannot predict what form such strategic collaborations might take in the future. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates, because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with additional third parties for development and commercialisation of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to such third parties. Further, collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaboration partners with marketing and distribution rights to one or more products fail to effectively implement commercialisation plans and strategies, or may not commit sufficient resources to their marketing and distribution;
- collaboration partners have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaboration partners may not pursue manufacturing and commercialisation of our drug candidates or may fail to effectively implement manufacturing and commercialisation plans and strategies, or may not to continue or renew manufacture or commercialisation programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardise or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialisation of our drug candidates, or that result in costly litigations or arbitrations that divert management attention and resources;
- our collaborators may breach the collaborations, and any termination of collaborations may result in our inability to generate revenue in the foreseeable future and a need for additional capital to pursue further development or commercialisation of the applicable drug candidates; and/or
- collaboration partners may own or co-own intellectual property covering our drug candidates that results from our collaboration with them, and in such cases, we would not have the exclusive right to commercialise such intellectual property.

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In addition, we may not achieve the revenue and cost synergies expected from our existing or future licensing or collaboration arrangement. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Even if we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration.

We also face significant competition in seeking appropriate partners to collaborate with, and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a collaboration or licensing arrangements for our drug candidates in the future, because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development, manufacturing and commercialisation of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

The commercialisation licensing arrangement we entered into with Grand Pharma and the license agreement we entered into with Santen both required us to establish a joint development committee with Grand Pharma or Santen respectively. Similar joint development committees may also be required under the licensing agreements we may enter into in the future. Such joint development committee is usually responsible for facilitating the communications between us and the licensing partner, reviewing and approving the development plans, and setting strategies for obtaining regulatory approvals. As the joint development committee monitors the development progress and make key decisions on development strategies, the development of CBT-001, in the case of our commercialisation licensing arrangement with Grand Pharma and our license agreement with Santen, and other drug candidates, in the case of our future licensing arrangements with our future collaborators, may be materially and adversely affected if such joint development committee do not perform properly. In addition, the joint development committee usually consists of equal members from us and the respective licensing partner. If a joint development committee cannot reach a decision in any matter properly before it due to deadlock, such matter may need to be resolved by the senior management of us and Grand Pharma or the future licensing partner through negotiations, which may lead to delays in drug development and may damage the relationship between us and Grand Pharma or the future licensing partner if further disputes arise from such negotiations.

As a result, we may not be able to realise the benefit of or choose to exercise any options under current or future collaborations or strategic partnerships, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay our R&D program(s), delay its potential commercialisation or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialisation activities at our own expense. If we elect to

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fund and undertake development or commercialisation activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialisation activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We operate in a competitive industry and may fail to compete effectively.

The ophthalmology industry is highly competitive. We face potential competition from many different market players, including large multinational pharmaceutical companies, established pharmaceutical companies, specialty pharmaceutical companies in the ophthalmology industry, academic institutions and public and private research institutions. These entities are or may be seeking to develop drugs, therapies and approaches to treat our targeted ophthalmic diseases or their underlying causes.

The companies we are competing against or against which we may compete in the future may have significantly greater financial resources and expertise in drug R&D, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Mergers and acquisitions in the ophthalmology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development pipelines.

Failure to retain the services of our senior management and key scientific personnel could severely disrupt our business and growth.

Our success significantly depends upon the continued service of our senior management and key scientific personnel. If we lose any of our senior management and key scientific personnel, we may not be able to identify, hire and train suitable qualified replacements and may incur additional expenses and time to recruit and train new personnel, which could severely disrupt our business and growth.

In addition, although each member of our senior management and key scientific personnel has signed an agreement with non-compete clauses with us, we may not always be able to successfully enforce these provisions should any of them leave us. Any of the above developments could severely disrupt our business and growth.

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Our success depends on our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel.

Our success depends on our team of scientists and other technical personnel and their ability to keep pace with cutting-edge technologies and developments in the ophthalmology industry. In particular, scientists with education, training and experience at renowned research universities and pharmaceutical or biotechnology companies are in particularly high demand in the United States, the PRC and other parts of the world. As a result, such scientists are well-sought after by our competitors and we may face challenges in attracting and retaining skilled scientists and other technical personnel. We compete vigorously with ophthalmic pharmaceutical companies and may not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with changes in customer needs and technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to manufacture and supply certain of our drug candidates or key materials for manufacturing our future approved drugs, and if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed.

Although we have developed our own pilot production facility in Suzhou, Jiangsu, the PRC and produced certain drug products by ourselves for clinical trial purposes, we still from time to time engage CDMOs and rely on certain third parties to supply certain of our drug candidates or key materials. For the commercial manufacturing of our future approved drugs such as CBT-001, we may also rely on third parties. For example, we have entered into a commercialisation licensing arrangement with Grand Pharma, under which we granted license to manufacture and commercialise CBT-001 in Greater China to Grand Pharma.

Reliance on third-party suppliers may expose us to the following risks, any of which could limit supply of our drug candidates or key materials for manufacturing our drug candidates used in clinical trials or for the commercial sale, result in higher costs, or impair our ability to continue our drug R&D or deprive us of potential product revenues:

- the third parties we rely on may encounter difficulties in achieving the volume of production needed to satisfy commercial demand or clinical trial demand in a timely manner, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of future products, may experience shortages of qualified personnel to adequately staff production operations and may be subject to natural or man-made disasters, epidemics, hostilities, social unrest, and other factors out of their control;

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- the third parties we rely on, in particular in relation to difficult-to-make drugs or key materials, may increase the prices of drugs or key materials supplied to us, and, if we are unable to increase our prices in response to cost increases, our profit margin in the future will decrease and our results of operations will suffer;
- the third parties we rely on could default on their agreements with us to meet our requirements for commercial supply of our future approved drugs or key materials or supply of drug candidates or key materials for manufacturing our drug candidates used in clinical trials;
- the third parties we rely on may not perform as agreed to successfully produce, store, sell and distribute our future approved drugs or key materials and we may incur additional cost;
- the third parties we rely on are subject to ongoing periodic unannounced inspection by the regulatory authorities and we do not have control over their compliance with these regulations and requirements;
- if the third parties we rely on were to terminate our arrangements, we may be forced to delay the commercialisation of our future approved product. Our ability to continue our research and development may be impaired, and we may be unable to identify third-party manufacturers on acceptable terms or at all because the FDA, the NMPA or other comparable regulatory authorities may carry out the extended examination activities for the manufactures to verify the authenticity and consistency of the application materials;
- the third parties we rely on may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardise or invalidate our intellectual property or proprietary information or expose us to potential liability; and
- the third parties we rely on, may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties.

Our reliance on third parties reduces our control over our development and commercialisation activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, regulatory authorities may require that our drug candidates and any products that we may eventually commercialise be manufactured according to GMP. Any failure by our third-party manufacturers to comply with GMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of drug candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approvals of any of our drug candidates, or result in inability to meet our commercial or clinical trial demand. In addition, such failure could be the basis for the regulatory authorities to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of

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ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of products, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

We rely on third-party CROs to conduct, supervise, and monitor our clinical trials, and if they perform in an unsatisfactory manner, it may harm our business.

In line with industry practice, we conduct some of the clinical trials by engaging CROs who meet our requirements. While we have agreements governing their activities and our designated team works closely with and supervises their activities, we ultimately may have limited control over many aspects of the activities they undertake with respect to our drug development programs. We remain responsible for ensuring that our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GCP requirements for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. If we or our CROs fail to comply with the applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA, the NMPA or comparable regulatory regulators may determine that our clinical trials did not comply with GCPs, whether or not the shortcomings are due to us or our CROs. In addition, if we or our CROs fail to recruit a sufficient number of patients, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would increase our R&D costs and delay the regulatory approvals and commercialisation process.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical trials. These CROs may also have relationships with other parties, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. In addition, our CROs could terminate their relationship with us. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, we may not be able to obtain regulatory approvals for, or successfully commercialise our drug candidates. We may also be required to withdraw from clinical trials due to changing standards of care or the failure of our PIs to comply with clinical protocols. As a result, our ability to generate revenues could be delayed, our costs could increase and our business and future prospects could be materially harmed.

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We, our research partners or our further customers may become subject to the U.S. Biosecure Act (the “Biosecure Act”). If the Biosecure Act is enacted in the proposed form, and if we, our research partners or our further customers were to be listed as or designated as “biotechnology companies of concern,” our ability and our future customers’ ability to engage in business with the U.S. government or with companies that engage in business with the U.S. government may be limited, which could disrupt or diminish our business activities.

We, our research partners or our further customers may become subject to the Biosecure Act, which, if enacted in its proposed form, would prohibit U.S. government agencies from procuring or using any biotechnology equipment or service that is from a so-called “biotechnology company of concern”, as well as prohibit U.S. government agencies from contracting with any entities that do so in performance of the contract. The most recent version of the Biosecure Act that passed the U.S. House of Representatives on 9 September 2024 names five specific Chinese biotechnology companies as “biotechnology companies of concern”, and gives the U.S. government the authority to identify other entities for inclusion as “biotechnology companies of concern”. Specifically, the U.S. government may identify an entity as a “biotechnology company of concern” if it is subject to the control or operates on behalf of the government of a “foreign adversary” (defined by law to be China, Iran, North Korea, and Russia); is involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service; and poses a risk to the national security of the U.S., based on: (i) engaging in joint research with, being supported by, or being affiliated with a foreign adversary’s military, internal security forces, or intelligence agencies; (ii) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or (iii) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent.

The most recent House version of the legislation would delay the application of the Biosecure Act’s provisions (i) until 1 January 2032, with respect to biotechnology equipment or services provided or produced by one of the named biotechnology companies of concern under a contract or agreement entered before the effective date of the legislation; and (ii) for a period of five years after the issuance of the regulation identifying new biotechnology companies of concern, with respect to biotechnology equipment and services provided or produced by an entity that the government identifies in the future as a biotechnology company of concern. As at the Latest Practicable Date, the Biosecure Act had not yet been enacted into law.

In the long run, if the Biosecure Act is enacted in the proposed form, and if we, our research partners or our future customers or were to be listed as or designated as “biotechnology companies of concern,” our ability and our future customers’ ability to engage in business with the U.S. government or with companies that engage in business with the U.S. government may be limited, which could disrupt or diminish our business activities.

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We may not be able to develop our manufacturing capacity of our pilot production facility in Suzhou, Jiangsu, the PRC and other potential manufacturing facilities as planned, or obtain approval from regulators for our manufacturing facilities, or avoid damage or interruption to our manufacturing facilities. The manufacture of pharmaceutical drugs is a highly exacting and complex process. If we encounter problems in manufacturing our drug candidates, our business could suffer.

We plan to develop our own manufacturing capacity, by improving the pilot production facility in Suzhou, Jiangsu, the PRC, and building a sizeable commercial production facility in Suzhou in the future that meets various quality standards set by relevant regulatory authorities globally. If the improvement or the construction of the manufacturing facility is significantly delayed by epidemics such as the COVID-19 pandemic or similar events, the development of our manufacturing capacity will be adversely impacted. If regulatory or other problems (including breach of contract) require the construction of the Suzhou facility to be suspended or even abandoned, we will not be able to develop the manufacturing capacity as planned, which would materially and adversely impact our business. Once completed and in operation, if the facility or the equipment in our manufacturing facilities is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our facility. In the event of a temporary or protracted loss of either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with necessary regulatory requirements.

In addition, our manufacturing facilities are expected to be required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA or other comparable regulatory authorities to ensure compliance with GMP regulations. Accordingly, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so.

If our current or planned Suzhou manufacturing facilities are not approved by regulators or damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capacity. Once our planned commercial manufacturing facility is built, we may also face geographical concentration risks as our two manufacturing facilities in China by then will be located in the same city of Suzhou, and we cannot foresee any geopolitical actions, cultural climate, economic condition or natural conditions in Suzhou, which may affect the operation and manufacturing capacity of our manufacturing facilities. In such event, we would be forced to identify and rely partially or entirely on third-party manufacturers for an indefinite period of time. Any new facility needed to replace an existing production facility would need to comply with the necessary regulatory requirements and be tailored to our production requirements and processes. We also would need regulatory approvals before using any products or drugs manufactured at a new facility in clinical trials or selling any products or drugs that are ultimately approved.

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Any disruptions or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialise our products or drug candidates, which would adversely affect our business and results of operations.

We may not be able to maintain effective quality control over our products.

The quality of our products depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardise any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

We are exposed to product liability and other liability claims or lawsuits, which may cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical trials of our drug candidates, and we will face an even greater risk if we produce, market, promote and commercialise any drug candidates. Any such product liability claims may include allegations of defects in manufacturing, quality assurance, storage, transportation and distribution, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialisation of our drug candidates, and even successful defence would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;

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- loss of revenue;
- the inability to commercialise our drug candidates; and
- a decline in our Share price.

If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

We maintain insurance policies that are required under applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. We also maintain product liability insurance covering our clinical trials. In the future, our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialisation of products we develop. Even if we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We depend on a stable and adequate supply of quality materials, including raw materials and consumables and R&D and manufacturing equipment, from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require raw materials, such as raw materials of excipients and active pharmaceutical ingredients, consumables and other materials needed for R&D purposes. In the event of significant price increases for such materials for reasons such as decreasing supply, interruption of transportation or otherwise, we cannot assure you that we will be able to raise the prices of our products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability.

In addition, any significant disruption in our supplier relationships could harm our business. For example, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs would increase significantly once we enter commercial production of drugs once they receive marketing approvals. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approvals of our drug candidates or our ability to timely meet market demand for our commercialised products, as applicable. Our suppliers may not be able to keep up with our growth needs or may reduce

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or cease their supply of materials to us at any time. In addition, we cannot assure you that our suppliers have obtained and will be able to renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operation, which in turn may result in shortage of materials supplied to us. Any interruption in our supply of materials due to any of the above or for any other reason would force us to procure supplies from replacement suppliers, which may not be available to us on commercially favourable terms or at all. This in turn could have a material adverse effect on our business, financial condition and results of operations.

If our products and supplies are not stored and shipped properly, the products and supplies could be damaged, which could negatively affect us.

Our supplies may become unusable or unsafe for use when exposed to unfavourable environmental conditions or when stored or shipped improperly. If we or any applicable third party fails to provide and maintain proper storage and shipping for our R&D supplies and ingredients, our products or drug candidates, such products could become unsuited for further use and require replacement orders, which could be costly and delay our operating activities and in turn, have a material adverse effect on our business, financial condition and results of operations.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended 31 December 2022, 2023 and 2024, our R&D expenses amounted to US\$15.3 million, US\$27.5 million and US\$37.9 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our services. We intend to continue to enhance our technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may render our technologies obsolete, which could significantly reduce demand for our services and harm our business and prospects.

Increased labour costs could slow our growth and affect our profitability.

Our operations require a sufficient number of qualified employees. In recent years, the average labour cost in the pharmaceutical market has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further increase in labour cost. If there is a significant increase in our labour cost, our operations and profitability may be adversely affected.

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Any failure to comply with existing laws, regulations and industry standards such as quality standards set out by applicable laws, regulations or industry standards, or any adverse actions by the drug approval authorities against us could negatively impact us.

In many jurisdictions where we intend to commercialise our products, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop and manufacture such drug. For example, we may need to obtain clearance from the FDA, the NMPA or other relevant regulatory authorities in the event that pre-clinical studies are filed as part of an IND application to seek authorisation to begin clinical trials, or clinical trials are filed as part of an NDA, license application or other filing to seek marketing approvals. These regulatory authorities may conduct scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. We cannot assure you that we will be able to pass all inspections and obtain or maintain all necessary clearance in relation to drug discovery, development and manufacturing from the regulatory authorities.

In addition, the ophthalmology industry in China as well as other jurisdictions we intend to expand into in the future are highly regulated and constantly evolving, with laws, regulations and policies that are subject to change. If we fail to comply or keep abreast with laws and regulations, industry standards and policies, we could be subject to fines or other punitive actions against us. In addition, our ongoing development projects could be terminated and any data we submitted to regulatory authorities could be disqualified, each of which could have a material adverse impact on our reputation, business, financial condition and results of operations and prospects. Moreover, any action against us for violation of the relevant regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Changes in government regulations or practices relating to the pharmaceutical and ophthalmology industries may have a material adverse impact on us.

The pharmaceutical and ophthalmology markets are heavily regulated in the United States and the PRC, and the regulation may encompass the approval, registration, manufacturing, packaging, licensing and marketing process. Changes in government regulations or in practices relating to the pharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may cause difficulty for us to satisfy such requirements or increase our compliance costs, may have a material adverse impact on our business, financial condition, results of operations and prospects.

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Our failure to obtain or renew certain approvals, licences, permits and certificates required for our business may materially and adversely affect us.

We are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including the relevant regulatory authorities ordering us to cease operations, implement potentially costly corrective measures or any other action which could materially disrupt our business operations.

In addition, some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. We cannot assure you that we will be able to successfully procure such renewals and/or reassessment when due, and any failure to do so could severely disrupt our business. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain them, which in turn could restrict our scope of permitted business activities and constrain our drug development and revenue generation capability. Any of the above developments could have a material adverse effect on our business, financial condition and results of operations.

We may be involved in litigations, legal disputes, claims or administrative proceedings which could be costly and time-consuming to resolve.

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. Any litigation or proceeding to which we become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as changes in the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Our insurance might not cover claims brought against us, provide sufficient payments to financially cover all of the costs to resolve such claims or continue to be available on terms acceptable to us.

If we are found to have violated laws protecting the confidentiality of patients and other covered information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business.

We may be subject to patient privacy regulation by governments in the jurisdictions in which we conduct our business or clinical trials. There are numerous laws in the jurisdictions in which we operate that protect the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. Local and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities and potentially result in regulatory penalties and significant legal liability, if our information security efforts fail.

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These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance.

For example, there are numerous United States federal and state laws and regulations related to the privacy and security of personal information. In particular, the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (“**HIPAA**”) establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “**protected health information**”) and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates” – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, and subject to other civil and /or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws.

Additionally, the Gramm-Leach-Bliley Act of 1999, along with its implementing regulations (“**GLBA**”) restricts certain collection, processing, storage, use and disclosure by covered companies of certain personal information, requires notice to individuals of privacy practices and provides individuals with certain rights to prevent the use and disclosure of certain non-public or otherwise legally protected information. The GLBA also imposes requirements regarding the safeguarding and proper destruction of personal information through the issuance of data security standards or guidelines. In addition, many states in the United States have laws that protect the privacy and security of sensitive and personal information. Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Consumer Privacy Act of 2018 (the “**CCPA**”), as amended by the California Privacy Rights Act (the “**CPRA**”), contains disclosure obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information. Failure to comply with the CCPA and the CPRA may result in significant civil penalties, injunctive relief, or statutory or actual damages as determined by the California Privacy Protection Agency (“**CPPA**”) and the California Attorney General through its investigative authority. Other states, including Virginia, Colorado, Utah, Connecticut, Indiana, Iowa, Tennessee, Texas, Montana, and others have enacted privacy laws similar to the CCPA /CPRA that impose new obligations or limitations in areas affecting our business and we continue to assess the impact of these state legislation, on our business as additional information and guidance becomes available. Compliance with these new privacy regulations may result in additional costs and expense of

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resources to maintain compliance. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we may be subject, if enacted.

Regulatory authorities in China also have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》), which became effective in June 2017, created China's first national-level data protection for "network operators" referring to the owners or administrators of a network as well as network service providers. The Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect in September 2021, provides for a security review procedure for the data activities that may affect national security. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the "**Personal Information Protection Law**"), which became effective from November 2021, provides the circumstances under which a personal information processor could process personal information and the requirements for such circumstances. The Personal Information Protection Law clarifies the scope of application, the definition of personal information and sensitive personal information, the legal basis of personal information processing and the basic requirements of notice and consent. The Measures for Cybersecurity Review (《網絡安全審查辦法》), which became effective since February 2022, requires that any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. The Provisions on Facilitating and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》) effective from 22 March 2024 further clarifies the implementation and connection of the existing data cross-border transfer security assessment, personal information cross-border standard contract and personal information protection certification regarding data outbound. The Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》), which became effective since July 2019, classifies information, such as data, generated by human genetic resource materials, as human genetic resource information and specifies requirements on collection and utilisation of such information.

Determining whether protected information has been handled in compliance with applicable privacy and other standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Any mishandling, access, breach or loss of information could result in legal claims or proceedings, reputational harm and liability under the laws that protect information, which could have a material adverse effect on our business, financial condition and results of operations.

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Our employees, collaborators, service providers, independent contractors, PIs, consultants, vendors, CROs and CDMOs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, service providers, independent contractors, PIs, consultants, vendors, CROs and CDMOs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorised activity that violates the FDA's, the NMPA's or comparable regulatory authorities' regulations, manufacturing standards, laws that require the true, complete and accurate reporting of financial information or data and other applicable rules and regulations.

We may not be able to identify and deter employee from misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from non-compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from the NRDL or comparable lists, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

Fluctuations in exchange rates may expose us to exchange rate volatility.

Our reporting currency is US Dollars, and the exchange rates between our functional currencies, particularly, US Dollars, Renminbi and Hong Kong Dollars, may have an impact on our reported results of operations. In addition, following the Global Offering, we may also maintain a significant portion of the proceeds from the offering in Hong Kong dollars before they are used in our business operations, which may take place in the United States, the PRC and other jurisdictions, as we expect to conduct clinical trials and commercialise our future products in those jurisdictions. The value of the Renminbi against the US dollar, Hong Kong dollar and other currencies may be affected by changes in international economic and political developments and relevant foreign exchange policies. Consequently, the exchange rate of Renminbi against our reporting currency and our other functional currencies may be volatile. For the years ended 31 December 2022, 2023 and 2024, we had net foreign exchange gains of US\$0.6 million, US\$0.7 million and US\$0.6 million, respectively.

Under the current policy, the Renminbi is pegged against a basket of currencies, determined by the PBOC, against which it can rise or fall within stipulated ranges against different currencies each day. We cannot predict when and how exchange rates in the currencies we may use may change going forward. Fluctuations in exchange rates may affect the value, translated or converted into US dollars or Hong Kong dollars, of our assets, any future earnings or any declared dividends. During the Track Record Period, we did not enter into any agreements to hedge our exchange rate exposure. In any event, to the extent such hedges are available, their effectiveness may be limited and we may be unable to hedge our exposure successfully, or at all.

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Our business and operations could be adversely affected by the effects of natural disasters, health pandemics or epidemics and other outbreaks or other unforeseen catastrophic events, including the outbreak of COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic. Countries across the world, including both the United States and the PRC, have imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. In addition, our employees could be subject to quarantine policies implemented by local authorities to combat pandemics or epidemics such as the COVID-19 pandemic. These policies and restrictions may disrupt our business and delay our clinical programs and timelines, which may negatively impact our business, operating results and financial condition.

For example, our clinical trials could be affected by the COVID-19 pandemic or other outbreaks. We commenced phase 3 MRCT in the United States for CBT-001 in June 2022, more than three years after its phase 2 clinical trial was completed in April 2018, which was affected by COVID-19 pandemic. Site initiation and patient enrolment may be delayed due to prioritisation of hospital resources toward an outbreak and some patients may not be able to comply with clinical trial protocols if quarantines or other restrictions impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients as well as PIs and site staff who, as healthcare providers, may have heightened exposure to disease, could be delayed or disrupted, which would adversely impact our clinical trial operations. The CROs and CDMOs we engaged to support our clinical trials in the United States, China and Australia experienced complete or partial shutdown because of the COVID-19 pandemic, and the regulatory approval process in the United States, Australia and China were also adversely affected by the COVID-19 pandemic. The economic fallout of the COVID-19 outbreak, or other outbreaks that cause a broad impact globally, may materially affect us economically. Such disruption, if sustained or recurrent, could make it difficult for us to access capital, which could negatively affect our liquidity in the future. In addition, a recession or market correction resulting from an outbreak, including the spread of COVID-19, could materially affect our business and the value of our Shares.

We are vulnerable to natural disasters, health epidemics such as Ebola virus disease, Zika virus disease, H1N1 flu, H7N9 flu, avian flu, SARS in addition to the COVID-19 pandemic, acts of war or terrorism and other calamities. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, environmental accidents, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems and other similar events, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations, including ongoing clinical trials and manufacturing activities. We are also susceptible to potential wars or terrorist attacks, which may injure our employees, cause loss of lives, disrupt our business and destroy our markets. The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations and prospects.

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Our risk management and internal control systems, as well as the risk management tools available to us, may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of relevant organisational frameworks, policies, procedures and risk management methods in order to manage our risk exposure, primarily including market risk, credit risk, liquidity risk, operational risk, compliance risk and legal risk, and we expect to continue to improve such risk management and internal control systems from time to time. See “Business – Risk Management and Internal Controls” for further details. However, our risk management and internal control systems may not be fully effective in mitigating our risk exposure in all market environments or against all types of risks, including risks that are unidentified or unanticipated.

During the Track Record Period, we issued share certificates to an investor from Series C Financing after the signing of investment agreement, but without receiving the payment of committed capital from the investor. The investor subsequently defaulted on its payment obligations and surrendered the Shares issued by us. See “History – Pre-IPO Investments – Series C Financing” for details. Such incident could have been prevented with more stringent risk management and internal control measures. In addition, we will become a public company upon completion of this offering, and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. In addition, in preparation for the Global Offering, we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

Our risk management capabilities are limited by the information, tools or technologies available to us. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Effective implementation of our risk management and internal controls policies and procedures also depends on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events,

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our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

Our internal information technology system, or those used by our partners or CROs or CDMOs or other contractors or consultants may fail or suffer security breaches or other disruptions, which could adversely affect our business and reputation.

Despite the implementation of security measures, our information technology systems and those of our current or future CROs, CDMOs, consultants and other service providers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorised access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our R&D programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data.

To the extent that any disruption or security breach may result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. A security breach may result in the loss of, damage to, or public disclosure of personally identifiable information or health information of the patients enrolled in our clinical trials, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data or systems. From 20 February 2019 to 4 March 2019, our Executive Director and chief operating officer, Mr. Dinh, received multiple emails impersonating Dr. Ni, whose email account was hacked due to a cyber-attack. In these emails, Mr. Dinh was asked to wire funds from Cloudbreak USA's bank account to the bank accounts of two Hong Kong companies designated by the hacker. Dr. Ni was travelling outside of the United States during that period, and the major communication channel between Dr. Ni and Mr. Dinh was via email. There was no indication that such emails were sent from a hacker, hence Mr. Dinh acted based on such emails. Mr. Dinh requested invoices to support the fund transfer, fabricated copies of which were provided in the emails impersonating Dr. Ni. On 9 March 2019 after the funds had been remitted, Dr. Ni noticed the wire transfer related emails in the deleted folder of his email box. He then realised that his email account had been hacked and used to commit a financial crime. Dr. Ni immediately contacted Mr. Dinh and crime reports were subsequently submitted to both Irvine, U.S. and Hong Kong police departments. To our knowledge, no arrest has been made. A US\$1.065 million loss was caused by this cyber-attack incident. We received an insurance compensation in the amount of US\$410,000 in connection with the incident, which covered a portion of such loss.

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The cyber-attack incident took place when Cloudbreak USA was at early-stage operation and had not yet established a robust internal control system. Subsequent to the incident, we have taken additional security measures and implemented enhanced internal control protocols to prevent future cyber-attacks and protect our email system. In addition, we have strengthened our financial control functions and have appointed a chief financial officer and designated a financial controller who are responsible for our treasury management and cash flow maintenance. We have also adopted authorisation procedures under which the approval from both financial controller and the chief financial officer are required for transaction with payment amount greater than US\$50,000. See “Business – Risk Management and Internal Controls – Internal Control” in this prospectus for details. Up to the Latest Practicable Date, we had not encountered any additional cyber-attacks. However, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased, and we may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognised until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organised crime affiliates, terrorist organisations or hostile foreign governments or agencies.

We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our vendors’ computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

Failure to comply with existing or future laws and regulations related to privacy or data security or cybersecurity could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity, and could negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

The Measures for Cybersecurity Review (網絡安全審查辦法) (the “MCR”) became effective on 15 February 2022, which stipulates that the operators carrying out data processing activities that affect or may affect national security, shall conduct cyber security review. According to the MCR, an operator who controls more than one million users’ personal information must report to the cyber security review office for a cyber security review if it intends to be listed abroad. However, the MCR does not provide any further explanation or interpretation for “listed abroad” or “affects or may affect national security.” We cannot guarantee whether we will be subject to the cyber security review for our capital raising activities or if new rules or regulations promulgated in the future will impose additional compliance requirements on us.

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The Cyber Data Security Regulation (《網絡數據安全管理條例》) promulgated by the State Council on 30 August 2024, which has been effective on 1 January 2025, serves as a comprehensive implementing regulation for the compliance requirements set out by the Cybersecurity Law, Data Security Law, and Personal Information Protection Law. The Network Data Security Regulation introduces several key obligations, including requiring network data processors to specify the purpose and method of personal information processing, as well as the types of personal information involved, before any personal information is processed. It also clarifies definitions for important data, outlines the obligations of those handling important data, establishes broader contractual requirements for data sharing between data processors, and introduces a new exemption for regulatory obligations regarding cross-border data transfers. It remains to be seen how this regulation will be interpreted and implemented, and to what extent it will affect our operations.

Compliance with these and any other applicable laws, regulations, standards and obligations relating to data privacy, security and transfers is a rigorous and time-intensive process and may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, fines, penalties, judgments, negative publicity and reputational damage, and may otherwise materially and adversely affect our business, financial condition and results of operations. We may not be able to respond quickly or effectively to regulatory, legislative and other developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Failure to comply with anti-corruption laws could subject us to investigations, sanctions or fines, which may harm our reputation and materially and adversely affect us.

We have adopted policies and procedures designed to ensure that we and our researchers, marketing and sales personnel and other staff comply with anti-bribery and anti-corruption laws in the course of sales and marketing and drug R&D. See “Business – Risk Management and Internal Controls” for further details. However, our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses.

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We may be subject to anti-corruption laws in various jurisdictions. In the United States, we are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. As our business continues to expand, the applicability of the FCPA and other anti-bribery laws to our operations will continue to increase. We are also subject to anti-bribery and anti-corruption laws in China, and the PRC government has implemented various anti-bribery and anti-corruption regulations, including requiring market participants to adopt internal controls and risk management measures addressing bribery and corruption risks and undergo periodic inspections from relevant regulatory authorities as to their anti-bribery and corruption status, and prohibiting market participants and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. Several major pharmaceutical companies have been investigated in connection with anti-bribery enforcement in the PRC.

We cannot assure you that our researchers, marketing and sales personnel and other staff, as well as third parties that we collaborate with, such as business partners, CROs, CDMOs, PIs, hospitals and medical professionals, will fully comply with anti-bribery and anti-corruption regulations at all times, or that we or they will be able to detect and identify all instances of improper practices in respect of our clinical trials and other parts of our business. In the event of any bribery or corruption incidents involving our employees or parties otherwise associated with us, we may be subject to investigations, sanctions or fines, and our reputation could be significantly harmed by any negative publicity stemming from such incidents, which may materially and adversely affect our business, financial condition, results of operations and prospects.

We are subject to environmental protection, health and safety laws and regulations, and may be exposed to potential costs for compliance and liabilities, including consequences of accidental contamination, biological hazards or personal injuries.

Our business operations are subject to national and local laws and regulations pertaining to environmental protection and health and safety, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in our drug discovery, development and manufacturing process. Due to the nature of drug development and manufacturing activities, we cannot fully eliminate the risk of accidental contamination or exposure to biological hazards in the course of our operations. In the event of any such accidents, we could be held liable for damages, clean-up costs, and administrative actions against us, in addition to suffering potentially significant disruptions to our manufacturing capacity. In addition, both our existing and planned manufacturing facilities in Suzhou have undergone or need to undergo trial operation stage (which normally lasts for six to 12 months) and passed or need to pass the environment impact assessment by the relevant administrative authorities in charge of environmental protection and health and safety, before they were to be or can be put into official operation. We incurred a *de minimis* amount of costs in relation to environmental law compliance during the Track Record Period.

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As the requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may have difficulties complying with, or accurately predicting the potentially substantial cost of complying with, these laws and regulations, which may subject us to rectification orders, substantial fines, monetary damages and suspension or cessation of research activities and other business operations. Any of the above negative developments could have a material and adverse impact on our business, financial condition and results of operations and prospects.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. We also maintain product liability insurance covering our clinical trials. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Our reputation is key to our business success. Negative news or publicity about us, our Single Largest Shareholders or any of them, Directors or our management may adversely affect our reputation, business and growth prospects.

Any negative news or publicity concerning us, our Single Largest Shareholders, Directors, management, affiliates or any entity that shares the Cloudbreak brand name, even if proven untrue, could adversely affect our reputation, business and growth prospects. We cannot assure you that negative publicity about us or any of our affiliates or any entity that shares such names would not damage our brand image. Given our specialised industry and market, negative publicity and word of mouth could travel quickly and negatively impact our relationships with third parties, which could have a material adverse effect on our business, financial condition and results of operations.

Some of our leased properties have title defects and did not complete registration procedures at relevant authorities. We may be required to cease occupation and use of such leased properties if there is a valid claim for them, or subject to penalties arising from the non-registration of lease agreements.

As of the Latest Practicable Date, the lessors of three out of our ten leased properties in the PRC had not provided valid title certificates or other ownership documents or relevant documents evidencing their rights to lease the properties. We use these three leased properties as corporate housing for several employees and office use. Any dispute or claim in relation to these properties, including lessors' alleged unauthorised lease of these properties, could force us to relocate such corporate housing. If any of our leases are terminated or becomes unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. If we fail to find suitable replacement properties on terms acceptable to us for the affected operations, our business, financial condition and results of operations may be adversely affected. For details, see "Business – Land and Properties" in this prospectus.

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In addition, as of the Latest Practicable Date, three of our lease agreements for our leased properties had not yet been registered with the relevant authorities. Pursuant to the applicable PRC laws and regulations, the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfil the registration requirements, which may increase our expenses, in the future.

RISKS RELATING TO DOING BUSINESS IN CHINA

Failure to respond to economic and social developments as well as the laws, rules, regulations and licensing requirements in the PRC, could have a material effect on us.

Since a portion of our business, assets and operations is located in or derived from our activities in the PRC, we are subject to economic, social as well as legal and regulatory developments in the PRC. Generally, the PRC government regulates the economy and related industries by imposing industrial policies and regulating the PRC's macro-economy through fiscal and monetary policies. Over the past few decades, the PRC government has implemented various measures in relation to economic development and the allocation of resources. These measures may be beneficial to the overall PRC economy, but may influence how we conduct our business operations, and therefore have impacts on our business, financial condition, results of operations and prospects. It may be difficult for us to predict all the risks that we could face as a result of the current economic, social and legal development and many of these risks are beyond our control. Failure to respond to such development and risks could materially affect our business operations and financial performance.

Our performance will continue to be affected by the PRC economy, which in turn is influenced by the global economy. Any prolonged slowdown in the PRC economy may affect our business and results of operations. Moreover, trade tensions or any escalation therein among major economies may affect the availability and cost of various imported goods, including potentially equipment and materials which rely on in our operations. These trade tensions may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive for us to procure from overseas suppliers or even becoming illegal to export. In addition, trade tension among the countries may also lead to changes in laws and policy, which could make it more costly, difficult or time-consuming for us to obtain regulatory approvals for our drug candidates in the United States and other overseas jurisdictions. Similarly, our patent applications that are currently pending in the United States could also be negatively impacted by escalations in the trade tensions.

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Failure to respond to changes and development with respect to PRC laws, rules and regulations could have an impact on us.

A portion of our business operations are conducted in China through our PRC subsidiaries, and governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes where, unlike common law systems, decided legal cases may be cited for reference but have limited value as precedent. Since 1979, the PRC government has been promulgating a comprehensive system of laws and regulations governing economic matters in general. In particular, since the pharmaceutical industry in the PRC is experiencing ongoing development and reform, the laws and regulations relating to this industry are evolving and developing. Any failure to respond to development in the regulatory environment in the PRC could materially affect our business and impede our ability to continue our operations.

Moreover, PRC laws and regulations relating to the pharmaceutical industry could further intensify and add to the requirements on interpretation and compliance for companies operating in the changing environment. A claimant may elect to submit a dispute to an arbitration organisation in Hong Kong or the PRC. Awards that are made by PRC arbitral authorities recognised under the Arbitration Ordinance of Hong Kong can be enforced in Hong Kong. Hong Kong arbitration awards may be recognised and enforced by PRC courts, subject to the satisfaction of certain PRC legal requirements. Evolving laws and regulations and enforcement requirements thereof in China could impact us in a number of ways, including in maintaining adequate licenses and permits to conduct business and contractual enforcement.

Filing with the CSRC is required in connection with the Global Offering, and we cannot predict whether we will be able to complete such filing.

On 17 February 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (境內企業境外發行證券和上市管理試行辦法) (the “**Overseas Listing Trial Measures**”) and five supporting guidelines, which came into effect on 31 March 2023. The Overseas Listing Trial Measures will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime. Pursuant to the Overseas Listing Trial Measures, where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also requires subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and listings.

On the same day, the CSRC also held a press conference for the release of the Overseas Listing Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (關於境內企業境外發行上市備案管理安排的通知), which, among others, clarifies that companies that satisfy all of the following conditions shall be deemed as “Existing Applicants” and are not required to complete the overseas listing filing immediately, but shall complete filings as required if they conduct refinancing or are involved in other circumstances that require filing with the CSRC (i) the

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application for overseas offering or listing shall have been approved by the relevant overseas regulatory authority or stock exchange (such as passing the hearing for the listing application of its shares on the Stock Exchange) prior to 31 March 2023; (ii) the company is not required to re-apply for offering and listing procedures to the overseas regulatory authority or securities exchanges (such as a new hearing for the listing application of its shares on the Stock Exchange) after 31 March 2023; and (iii) such overseas securities offering or listing shall be completed on or prior to 30 September 2023.

Based on the foregoing, we are required to complete the filing procedures with the CSRC in connection with the Global Offering. We cannot assure you that we could meet such requirements, obtain such permit from the relevant government authorities, or complete such filing in a timely manner or at all. Any failure may restrict our ability to complete the Global Offering or any future capital raising activities, which would have a material adverse effect on our business and financial positions. However, as the Overseas Listing Trial Measures was recently promulgated, there remains substantial uncertainties as to its interpretation and implementation and how it may impact our ability to raise or utilise fund and business operation.

We may be subject to restrictions on how we operate our business in connection with the requirements as stipulated in legislations or regulations on privacy and data protection, such as the Measures for Cybersecurity Review or the Cyber Data Security Regulation.

On 28 December 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective from 15 February 2022. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad (國外上市). The Cyber Data Security Regulation (《網絡數據安全管理條例》) promulgated by the State Council on 30 August 2024, which has been effective on 1 January 2025, serves as a comprehensive implementing regulation for the compliance requirements set out by the Cybersecurity Law, Data Security Law, and Personal Information Protection Law. It remains to be seen how this regulation will be interpreted and implemented, and to what extent it will affect our operations.

Our PRC Legal Advisers conducted a telephonic consultation (the “**Consultation**”) on 25 September 2023 with the China Cybersecurity Review Technology and Certification Center (the “**Center**”). The Center is authorised by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. See “Regulatory Overview – Regulations relating to the PRC – Regulations relating to Personal Information and Data Protection – Cybersecurity” and “Business – Legal and Regulatory Matters – Data Security and Data Privacy” for details. Based on the Consultation, and as advised by our PRC Legal Advisers, our Directors believe that as long as there is no

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material change to our current business and no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

Furthermore, based on the facts that (i) the MCR came into effect recently, and its implementation and interpretation is subject to uncertainties, and (ii) we have not been involved in any investigations on cybersecurity review initiated by the CAC on such basis and nor have we received any inquiry, notice, warning, or sanctions in such respect, we believe such regulations would not have a material adverse impact on our business operations or our Global Offering. Considering that (i) we have not been involved in any cybersecurity review or investigation by the CAC or other authorities with respect to the MCR; (ii) we have not been informed that we are recognised as a crucial information infrastructure operator by any relevant authority; (iii) the data processed by us has not been included in the effective core data and important data catalogs by any authority; and (iv) we have taken reasonable and adequate technical and management measures to ensure data security, we are of the view that the likelihood that our business operation or the Global Offering might give rise to national security risks is remote. However, the MCR was released within a recent year, and certain provisions of which are still unclear and are subject to the finalisation or clarifications by relevant authorities. As such, the PRC regulatory authorities may have broad discretion in the interpretation of “affect or may affect national security”. If we were deemed as a data processor that “affects or may affect national security” by the PRC regulatory authorities under their broad discretion, we may be subject to cybersecurity review. If we fail to pass such cybersecurity review, our Global Offering may be impeded, our business operations may be adversely affected, and/or we may be subject to other severe penalties and/or action by the competent government authorities.

On 7 July 2022, the CAC promulgated the Measures for the Security Assessment of Data Cross-border Transfer (《數據出境安全評估辦法》), which took effect on 1 September 2022. The Measures for the Security Assessment of Data Cross-border Transfer requires the data processor providing data overseas and falling under any of the circumstances prescribed by the CAC apply for the security assessment of cross-border data transfer by the national cybersecurity authority through its local counterpart. See “Regulatory Overview – Regulations relating to the PRC – Regulations relating to Personal Information and Data Protection – Cybersecurity” and “Business – Legal and Regulatory Matters – Data Security and Data Privacy” for details.

On 22 February 2023, the CAC issued the Measures for the Standard Contract for Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》), (the “**Standard Contract Measures**”), along with the formal version of the standard contractual clauses for cross-border transfer of personal information stipulated under the Personal Information Protection Law. The Standard Contract Measures came into effect on 1 June 2023, and a six-month grace period is provided. Any violation of the Standard Contract Measures shall be punished in accordance with the Personal Information Protection Law and other laws and regulations.

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On 22 March 2024, the CAC issued the Provisions on Facilitating and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》) (the “**Cross-Border Data Flows Provisions**”), which provides certain circumstances under which data processors shall, through the local cyberspace administration at the provincial level, apply to the national cyberspace administration for security assessment of cross-border data transfer. See “Business – Legal and Regulatory Matters – Data Security and Data Privacy” for details. The Cross-Border Data Flows Provisions also provides that, where the data processors other than critical information infrastructure operators provide personal information (excluding sensitive personal information) overseas of not less than 100,000 but not more than one million individuals, or the sensitive personal information of not more than 10,000 individuals, cumulatively as of 1 January of the current year, it shall conclude a standard contract with overseas recipients or pass the authentication on personal information protection. Articles 3 to 6 of the Cross-Border Data Flows Provisions mainly provide the exemptions from applying for the security assessment or authentication, and filing the standard contracts. Exemptions include but are not limited to international trade, cross-border transportation, academic cooperation, transactional manufacturing, marketing and other activities that do not involve personal information or important data, among others. Any failure to comply with such requirements may subject us to, among others, suspension of services, fines, revoking relevant business permits or business licenses and penalties.

Some of the clinical trial data, collected by certain PRC research institutions (such as hospitals and medical institutions) that collaborate with us in connection with our clinical trials in the PRC, contains the participants’ individual information in connection with the clinical trials which has been referred to in the patient consent letter. Such information, excluding personal identification information that can be used to directly identify the participant such as names, name initials, addresses, or phone numbers, would be sorted and sent to us, and then stored on our server located in the United States by directly logging onto the server system using an access-controlled account. Other than the aforementioned information which only relates to clinical trials, no other individual information will be transmitted overseas. The server is operated in secured systems, which have implemented measures such as access control, firewall settings, encrypted transmission, regular backups, and other safeguards to ensure data security. For details, see the internal controls measures on personal data and clinical results protection as disclosed under “Business – Risk Management and Internal Controls – Internal Control” in this prospectus.

In response to the evolving cybersecurity regulatory requirements and in order to maintain prudent compliance with the abovementioned cybersecurity laws and regulations, on 14 June 2024, Cloudbreak Guangzhou has proactively submitted a filing application for the standard contract for the outbound transfer of personal information (the “**Standard Contract Filing**”, where personal information includes patient clinical data) to the Guangdong Cyberspace Affairs Office through the Outbound Data Transfer Filing System (數據出境申報系統) website for the outbound transfer of personal information transmitted in our clinical trials in the PRC. The Guangdong Cyberspace Affairs Office responded to our filing application on the Outbound Data Transfer Filing System dated 22 January 2025, confirming that the responsibility for the Standard Contract Filing in connection with our clinical trials in the PRC rests with the PRC research institutions we collaborate with, such

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as hospitals and medical institutions, which collect and transmit the clinical trial data. It also confirmed that, under the current regulations, we are not required to proceed with the Standard Contract Filing for our current clinical trials in the PRC.

Notwithstanding the foregoing, we cannot guarantee that future regulatory developments will not impose stricter requirements that may result in new obligations on our part. Additionally, we cannot guarantee that our PRC research institution collaborators will fully comply with their obligations under applicable laws and regulations. Should these collaborators fail to complete the required filings or otherwise fall short of compliance, there is a risk that the PRC regulatory authorities may raise concerns regarding the compliance of our data collection and transmission practices in our clinical trials in the PRC. Such concerns could result in disruptions to our clinical trial operations and could ultimately have a material adverse effect on our ability to process clinical trial data, which may, in turn, negatively impact our business, operating results and financial condition.

You may experience difficulties in effecting service of legal process upon us or our management that reside in China or enforcing judgements obtained from foreign courts against us or our management.

Some of our Directors and officers reside within the PRC, and a portion of our assets and their respective assets are located within the PRC. As a result, it may be difficult to effect service of process within the United States or elsewhere outside the PRC upon us or most of our Directors and officers, including with respect to matters arising under the United States federal securities laws or applicable state securities laws. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC of judgments obtained from foreign courts against us or our management may be difficult or impossible.

On 14 July 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute.

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On 18 January 2019, the Supreme People's Court and the Hong Kong SAR Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the Mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court and the completion of the relevant legislative procedures in Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. Under the New Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. However, we cannot assure you that all final judgments that are compliant with the Arrangement will be recognised and effectively enforced by the relevant PRC court.

We may be subject to additional social insurance fund, housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees. Such social insurance plans consist of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. The amount we are required to contribute for each of our employees under such plan and with regard to the housing provident fund should be calculated based on the actual income of our employees, together with the minimum and maximum level as from time to time prescribed by national laws and regulations and local authorities. Any failure to make timely and adequate social welfare contribution for its employees may trigger an order of correction from competent authority requiring the employer to make up the full amount of such overdue social welfare contribution within a specified period of time, and the competent authority may further impose fines or penalties.

During the Track Record Period, we did not pay social insurance and housing provident fund in full for our employees based in the PRC. As advised by our PRC Legal Advisers, we may be required to make up the deficiencies and be subject to late fees and fines for our insufficient contributions to the social insurance and housing provident fund. Pursuant to relevant PRC laws and regulations, the relevant PRC authorities may demand us to pay the outstanding social insurance contributions within a stipulated deadline and we may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay. If we fail to make such payments within the deadline set by the relevant PRC authorities, we may be liable to a fine of one to three times the amount of the outstanding contributions. With respect to a failure to pay the full amount of housing funds as required, the housing funds

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management centre in China may require payment of the outstanding amount within a prescribed period. If the payment is not made within such time limit, an application may be made to the PRC courts for compulsory enforcement. See “Business – Legal and Regulatory Matters – Legal Proceedings and Compliance” for details.

As of the Latest Practicable Date, no competent government authorities imposed administrative action, fine or penalty to us with respect to the payment of social insurance or housing provident fund or required us to settle the outstanding amount of social insurance payments or housing provident fund contributions. Our Directors believe that such non-compliance would not have a material adverse effect on our business or results of operations, considering that: (i) we had not been subject to any administrative actions, fines or penalties during the Track Record Period and up to the Latest Practicable Date due to such non-compliance; (ii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing funds; (iii) we were neither aware of any employee complaints filed against us nor involved in any labour disputes with our employees with respect to social insurance and housing funds during the Track Record Period and up to the Latest Practicable Date; (iv) we would make full payment within the stipulated deadline as required by relevant PRC authorities once we receive the notifications from the relevant PRC authorities requiring us to pay the shortfalls; and (v) as advised by our PRC Legal Advisers, based on the above and provided that the relevant regulations and policies issued by PRC governments are still in effect, as long as we could make full payment within the stipulated deadline if required by relevant authorities in the future, the likelihood that the relevant social insurance authorities would collectively take initiative to recover the historically unpaid social insurance from us and/or impose the administrative penalties on us due to our failure to make full payment of the social insurance is remote, and the likelihood that the relevant housing provident fund authorities would impose any other administrative penalties on us due to our failure to make full payment of the housing provident funds is remote. We made provisions of approximately US\$321,000 as of 31 December 2024 in connection with the shortfall amount of the social insurance and housing provident fund contribution. We have been paying for social insurance premium and housing provident funds for all our employees based in the PRC in compliance with applicable laws and regulations since August 2023.

We cannot guarantee you that the competent government authorities will not require us to settle the outstanding amount within the specified time limit or impose late payment penalties on us. In addition, as the laws and policies related to social insurance and housing provident fund may continue to evolve, we cannot assure you that our employment policies and practices will always be regarded as fully complying with the relevant laws and regulations in China, and we may face labour disputes or government investigations. Compliance with relevant laws and regulations may increase our operating expenses, especially our staff costs, and may have a material and adverse impact on our financial position and results of operations.

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We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

On 17 March 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek government approvals before any scientific data involving a “state secret” may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term “state secret” is not clearly defined, if and to the extent our R&D of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

The regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on 28 May 2019, effective from 1 July 2019, and last amended on 10 March 2024, stipulates that in order to obtain marketing authorisation for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources, or HGR, at clinical institutions without export of HGR materials. However, the two parties shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. These regulations are important to our business because all transfers of patient starting material from hospitals to labs must be reported to the relevant administrative departments under these provisions. While we currently are in full compliance with these provisions, it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws are often uncertain and in flux. Many statutory requirements include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. Compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

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Failure to take timely and appropriate measures to cope with the regulatory compliance requirements under the PRC Foreign Investment Law may lead to rectification obligations, penalties or other regulatory sanctions on us.

The PRC Foreign Investment Law (《中華人民共和國外商投資法》), or the FIL, was enacted by the NPC on 15 March 2019 and became effective on 1 January 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law (《中外合資經營企業法》), the Sino-foreign Cooperative Joint Venture Enterprise Law (《中外合作經營企業法》) and the Wholly Foreign-Invested Enterprise Law (《外資企業法》), together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL facilitates foreign investment regulatory regime to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law (《外商投資法實施條例》) were promulgated by the State Council on 26 December 2019 and became effective on 1 January 2020. The FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. Moreover, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

Over the recent years, People's Bank of China, or PBOC, and the SAFE promulgated a series of measures, including strict vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. Existing or further limitations on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

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Dividends we receive from our subsidiaries located in the PRC may be subject to PRC withholding tax, which could materially and adversely affect the amount of dividends, if any, we may pay our Shareholders.

We are a holding company incorporated under the laws of Cayman Islands and as such rely on dividends and other distributions on equity from our PRC subsidiaries to satisfy part of our liquidity requirements. Pursuant to the EIT Law, a withholding tax rate of 10% currently applies to dividends paid by a PRC “resident enterprise” to a foreign enterprise, unless the jurisdiction of the foreign investor’s tax residence has a tax treaty with China that provides for preferential tax treatment.

Pursuant to the Arrangement between the Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “**Double Tax Avoidance Arrangement**”) and relevant PRC tax laws on the interpretation of the Arrangement, a preferential withholding tax rate of 5% may apply if the PRC enterprise is at least 25% held by the Hong Kong enterprise for at least 12 consecutive months prior to distribution of the dividends and certain other conditions, for example, the beneficial ownership requirement, are met. On 3 February 2018, the STA issued the Announcement on Certain Issues Concerning the “Beneficial Owners” in the Tax Treaties (《關於稅收協定中「受益所有人」有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner.

If our Hong Kong subsidiary holds any equity interest in our PRC subsidiary and does not engage in any substantive business activity in the future, based on the abovementioned principles, PRC tax authorities would not consider our Hong Kong subsidiary as the “beneficial owner” of any dividends paid from our PRC subsidiary and would deny the claim for the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary is not considered as a “beneficial owner,” dividends from our PRC subsidiary to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and it would impact our ability to pay dividends in the future.

Restrictions on foreign currency conversion may limit our foreign exchange transactions, including dividend payments on our Shares, which may adversely affect the value of your investment.

The convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of foreign currency out of the PRC are required to comply with applicable PRC regulations. A portion of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends, or otherwise satisfy foreign currency denomination obligations.

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Under existing PRC foreign exchange regulations, payments of current account items, including the payment of dividends, interest payments and expenditures from the transaction, can be made in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. However, approvals from appropriate governmental authorities are required where Renminbi is to be converted into foreign currency and remitted out of the PRC to pay capital expenses such as the repayment of bank loans denominated in foreign currencies. Since a portion of our future revenue is expected to be denominated in Renminbi, any existing and future restrictions on currency exchange may limit our ability to utilise revenue generated in Renminbi to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Any failure by the Shareholders or beneficial owners of our Shares to comply with certain PRC foreign exchange regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or SAFE Circular 37, and the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《國家外匯管理局關於發佈〈境內機構境外直接投資外匯管理規定〉的通知》), or SAFE Circular 30. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle”. SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. According to the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) released in February 2015 by SAFE, as amended in December 2019, local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, under SAFE Circular 37 from June 2015.

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Failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

In addition, we may not always be fully aware or informed of the identities of our beneficial owners who are PRC nationals or entities, and may not be able to compel them to comply with relevant SAFE rules and other regulations. We cannot assure you that all of our Shareholders or beneficial owners will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by SAFE rules or other regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

PRC regulations on loans to, and direct investment in PRC entities by offshore holding companies may limit our ability to use the proceeds of the Global Offering to make loans or additional capital contributions to our PRC subsidiaries, which could restrict our ability to utilise the proceeds from the Global Offering effectively and affect our ability to fund and expand our business.

Under China's existing foreign exchange regulations, foreign exchange transactions under capital accounts continue to be subject to foreign-exchange regulations and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts and the SAMR through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) and the SAFE.

On 30 March 2015, SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or SAFE Circular 19, which came into force from 1 June 2015. On 9 June 2016, SAFE further promulgated the Circular on the Reform and Standardisation of the Management Policy of the Settlement of Capital Projects (《關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign

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exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. For example, under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign currency registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to its non-affiliated company. On 23 October 2019, SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), or SAFE Circular 28, according to which non-investment foreign-invested enterprises are permitted to make domestic equity investments with their capital funds provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. On 10 April 2020, SAFE promulgated the Circular on Optimising Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》), or SAFE Circular 8, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing evidentiary materials concerning authenticity of each expenditure, provided that their capital use shall be authentic and in line with provisions, and conform to the prevailing administrative regulations on the use of income under capital accounts.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalise on or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

We may be treated as a PRC tax resident enterprise under the EIT Law, which may subject us to PRC income taxes on our worldwide income. Gains on the sales of Shares and dividends on the Shares may be subject to PRC income taxes.

We are a holding company incorporated under the laws of Cayman Islands. Under the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) (the “EIT Law”), which came into effect on 1 January 2008, and its implementation rules, enterprises organised under the laws of jurisdictions outside the PRC with their “de facto management bodies” located within the PRC may be considered “PRC tax resident enterprises” and subject to a uniform 25% PRC income tax on their worldwide income. The implementation rules to the EIT Law define the term “de facto management body” as “body that exercises full and substantial control over and overall management of the business, productions, personnel, accounts and properties of an enterprise”. The Notice on Identifying Chinese-Controlled Offshore Enterprises as Chinese Resident Enterprises in accordance with Criteria for Determining Place of Effective Management (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) and the Administrative Measures on the Corporate Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資

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控股居民企業所得稅管理辦法(試行)》) issued in April 2009 and July 2011 set out certain criteria for specifying what constitutes a “de facto management body” in respect of enterprises that are established offshore by PRC enterprises. However, no such criteria are provided in these or other publications by the PRC State Administration of Taxation in respect of enterprises established offshore by private individuals or foreign enterprises like us. As a result, it is unclear whether we will be deemed to be a “PRC tax resident enterprise” for the purpose of the EIT Law even though substantially all of the operational management of our Company is currently based in the PRC. There can be no assurances that we will not be treated as a PRC resident enterprise under the EIT Law and not be subject to the enterprise income tax rate of 25% if our global income in the future. If we were treated as “PRC tax resident enterprise”, or if there is any change or discontinuation or non-renewal of such favourable tax treatments, we would be subject to PRC income taxes on our worldwide income, which may adversely affect our distributable profit to our Shareholders.

Under the EIT Law and its implementation regulations, a non-PRC resident enterprise is generally subject to enterprise income tax at a rate of 10% with respect to its PRC-sourced income, including dividends received from a PRC company and gains derived from the disposition of equity interests in a PRC company, subject to reductions under any special arrangement or applicable treaty between the PRC and the jurisdiction in which the non-PRC resident enterprise resides. Pursuant to a Notice promulgated by the SAT on 6 November 2008, we intend to withhold tax at 10% from dividends payable to non-PRC resident enterprise holders of Shares (including HKSCC Nominees Limited). Non-PRC enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ approvals. We cannot assure you whether and how enterprise income tax on gains derived upon sale or other disposition of Shares will be collected from non-PRC resident enterprise holders of Shares. If such tax is collected in the future, the value of such non-PRC enterprise holders’ investments in Shares may be materially and adversely affected.

In addition, under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and its implementation regulations, non-PRC resident individual holders of Shares are subject to individual income tax at a rate of 20% on gains realised upon sale or other disposition of Shares. However, pursuant to the Circular Declaring That Individual Income Tax Continues to Be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the MOF and the SAT on 30 March 1998, gains of individuals derived from the transfer of listed shares in enterprises may be exempt from individual income tax. If individual income tax on such gains is collected by PRC tax authorities in the future, the value of such individual holders’ investments in Shares may be materially and adversely affected.

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Any failure to comply with the PRC regulations regarding our employee equity incentive plans may subject us to fines and other legal or administrative sanctions.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》). Accordingly, PRC residents who participate in any stock incentive plan of a company listed on an overseas stock market are required to register with the SAFE or its local counterparts through the domestic company to which the said company is affiliated, collectively entrust a domestic agency (may be the Chinese affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration. We and our employees who are PRC residents and individual beneficial owners who may be granted equity-based incentive awards under the employee equity incentive plans will be subject to these rules due to our listing on the Stock Exchange. We will assist our employees who are PRC residents to register their Shares underlying the equity-based incentive awards. However, any failure of our PRC individual beneficial owners and holders of equity-based incentive awards to comply with the SAFE registration requirements in the future may subject them to fines and sanctions. In addition, SAFE Circular 37 stipulates that PRC residents who participate in a share incentive plan of an overseas non-publicly-listed special purpose company may register with SAFE or its local branches before restricted share units or restricted shares are vested. We and our PRC employees who may be granted restricted share units or restricted shares are subject to these regulations. Failure of the PRC grantees to complete their SAFE registrations may subject these PRC residents to fines up to RMB300,000 for entities and up to RMB50,000 for individuals, and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, or otherwise materially adversely affect our business.

In addition, the State Taxation Administration of the PRC has issued circulars concerning restricted share units or restricted shares. Under these circulars, employees working in the PRC with restricted share units or restricted shares vested, will be subject to PRC individual income tax (“IIT”). The PRC subsidiaries of an overseas listed company have obligations to file documents related to restricted share units or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their restricted share units or restricted shares. If our employees fail to pay or our PRC subsidiaries fail to report and withhold IIT according to relevant laws, rules and regulations in the future, both may face sanctions imposed by the tax authorities or other PRC government authorities.

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The M&A Rules and certain other PRC regulations establish procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements. The M&A Rules require that the MOFCOM shall be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honoured brand. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

Moreover, the Anti-Monopoly Law (《中華人民共和國反壟斷法》) promulgated by the Standing Committee of the National People's Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with MOFCOM.

In addition, the Rules on Implementation of Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors promulgated by MOFCOM (《商務部實施外國投資者併購境內企業安全審查制度的規定》), effective in September 2011 and Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》) that came into effect in January 2021, requires acquisitions by foreign investors of PRC companies engaged in certain industries crucial to national security be subject to security review before consummation of any such acquisition.

In the future, we may grow our business by acquiring complementary businesses. Compliance with the requirements of the above-mentioned rules and regulations and any required approval processes, including obtaining approval from competent government authorities may delay or inhibit our ability to complete such transactions.

RISKS RELATING TO THE GLOBAL OFFERING

There has been no prior public market for our Shares.

No prior public market currently exists for our Shares. The initial issue price for our Shares was the result of negotiations between our Company and the Overall Coordinators (for themselves and on behalf of the Underwriters), and the Offer Price may differ significantly from the market price of the Shares following the Global Offering. We have applied to the Stock Exchange for the listing of, and permission to deal in, the Shares. A listing on the Stock Exchange, however, does not guarantee that an active trading market for our Shares will develop, or if it does develop, will be sustained following the Global Offering or that the market price of our Shares will not decline following the Global Offering.

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The trading volume and market price of our Shares may be volatile, which may result in substantial losses for investors subscribing for or purchasing our Shares pursuant to the Global Offering.

The trading volume and market price of the Shares may be subject to significant volatility in responses to various factors. Some of these factors are beyond our control, including:

- variations in our drug development programmes and operating results;
- our announcement of changes to our expectations or targets for timing of milestones associated with our drug development milestones;
- our announcement of the outcome of clinical trials for our drug candidates;
- other announcements made by us or our competitors or other biotech companies;
- changes in financial estimates by securities analysts;
- regulatory developments in the United States, China or other jurisdictions in which we may conduct clinical trials or have commercialisation plans affecting us;
- our competitors;
- investors' perception of us and of the investment environment in Asia, including Hong Kong and China;
- developments in the global ophthalmology market;
- changes in pricing made by us or our competitors;
- acquisitions by us or our competitors;
- the depth and liquidity of the market for our Shares;
- additions to or departures of, our executive officers and other members of our senior management;
- sales or anticipated sales of additional Shares; and
- the general economy and other factors.

Biotech companies listed under Chapter 18A of the Listing Rules are generally viewed as being early stage and significantly riskier than those companies traditionally listed on the Stock Exchange. The trading market for Biotech Companies (including the depth and liquidity for that market) may take time to develop and could be subject to significant and adverse changes. Our Shares and the shares of other biotech companies could be subject to

RISK FACTORS

significant volatility unrelated to company-specific performance or corporate developments. For example, adverse announcements by another unrelated biotech company could adversely impact the trading price for our Shares. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

Future sales or perceived sales or conversion of substantial amounts of our Shares in the public market could have a material adverse effect on the prevailing market price of our Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholding.

Prior to the Global Offering, there has not been a public market for our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the Global Offering due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, the market price of our Shares could decline as a result of future sales or issuances of a substantial number of our Shares or other securities relating to our Shares in the public market, or the perception that such sales or issuances may occur. Moreover, such future sales or perceived sales may also adversely affect the prevailing market price of our Shares and our ability to raise capital in the future at a favourable time and price. The Shares held by the Single Largest Shareholders are subject to certain lock-up undertakings. See “Underwriting” for details. We cannot assure you that the Single Largest Shareholders will not dispose of such Shares they may own now or in the future.

Furthermore, if additional funds are raised through our issuance of new equity, including primary offering of Shares, convertible securities or equity-linked securities including through the vesting of the Shares which have been granted under the Equity Incentive Arrangements, other than on a pro-rata basis to existing Shareholders, the percentage ownership for such Shareholders may be reduced. Such new securities may also confer rights and privileges that take priority over those conferred by the Shares.

You will incur immediate and significant dilution and may face further dilution if we issue additional Shares or other equity securities in the future.

The Offer Price of the Offer Shares is higher than the net tangible asset value per Share immediately prior to the Global Offering. Therefore, purchasers of the Offer Shares in the Global Offering will experience an immediate dilution in pro forma consolidated net tangible asset book value of US\$1.16 per Share based on the Offer Price of HK\$10.10 per Share and our Shareholders prior to the Global Offering will experience an increase in the pro forma consolidated net tangible assets book value per Share of their Shares. Moreover, in order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the Offer Shares may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

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We cannot assure you that the Shares will remain listed on the Stock Exchange.

Although it is currently intended that the Shares will remain listed on the Stock Exchange, there is no guarantee of the continued listing of the Shares. Among other factors, our Company may not continue to satisfy the listing requirements of the Stock Exchange. Holders of Shares would not be able to sell their Shares through trading on the Stock Exchange if the Shares were no longer listed on the Stock Exchange.

Our Company was incorporated under the laws of the Cayman Islands and these could provide different protections to minority shareholders than the laws of other jurisdictions.

Our corporate affairs are governed by our Memorandum and Articles of Association, and by the Cayman Companies Act and the common law of the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders could differ from those established under statutes or judicial precedent in Hong Kong or other jurisdictions with which minority Shareholders may be more familiar. Such differences could mean that minority Shareholders could have different protections than they would have under the laws of Hong Kong or other jurisdictions with which minority Shareholders are more familiar. See “Summary of the Constitution of the Company and the Cayman Companies Act” set out in Appendix III to this prospectus for details.

Our Single Largest Shareholders have substantial control over the Company and their interests may not be aligned with the interests of other Shareholders.

Immediately following the Global Offering, our Single Largest Shareholders will hold approximately 20.52% of our Shares, assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements. Our Single Largest Shareholders will, through their voting power at the Shareholders’ meetings and his delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of any dividend payments, as well as our management. Our Single Largest Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Single Largest Shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

RISK FACTORS

Because we do not expect to pay dividends in the foreseeable future after the Global Offering, you must rely on price appreciation of our Shares for a return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after the Global Offering to fund the R&D of our drug candidates and the continued growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Directors have significant discretion as to whether to distribute dividends. Even if our Directors decide to declare and pay dividends, the amount of dividends actually distributed to our Shareholders, and the timing, amount and form of future dividends, if any, will depend on, among others, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Directors. Any declaration and payment as well as the amount of dividends will also be subject to our constitutional documents and the relevant laws.

Therefore, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares, and there is no guarantee that our Shares will appreciate in value after the Global Offering or even maintain the price at which you purchased the Shares. You should not rely on an investment in our Shares as a source for any future dividend income. You may not realise a return on your investment in our Shares and you may even lose your entire investment in our Shares.

You should read the entire prospectus and only rely on the information included in this prospectus to make your investment decision, and we strongly caution you not to rely on any information contained in press articles or other media coverage relating to us, our Shares or the Global Offering.

There has been, prior to the publication of this prospectus, and there may be, subsequent to the date of this prospectus but prior to the completion of the Global Offering, press and media coverage regarding us and the Global Offering. Such press and media coverage may include, among other things, certain financial information, projections, valuations and other forward-looking information about us and the Global Offering that does not appear in this prospectus. We have not authorised the disclosure of any such information and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this prospectus, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their decisions on the basis of the information contained in this prospectus only and should not rely on any other information.

WAIVERS AND EXEMPTIONS

In preparation for the Listing, our Company has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules.

MANAGEMENT PRESENCE IN HONG KONG

According to Rule 8.12 of the Listing Rules, our Company must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. We do not have a sufficient management presence in Hong Kong for the purpose of satisfying the requirement under Rule 8.12 of the Listing Rules. As our principal business operations are primarily located in the United States and the PRC, our management is best able to attend to its function by being primarily based outside of Hong Kong. As such, the Joint Sponsors have applied, on behalf of our Company, to the Stock Exchange for, and the Stock Exchange has granted us a waiver from strict compliance with Rule 8.12 of the Listing Rules subject to, among others, the following conditions:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed two authorised representatives, who will act as our principal channel of communication with the Stock Exchange. The two authorised representatives appointed are Dr. Ni, our chairman of the Board, Executive Director and chief executive officer, and Ms. Fung Nga Fong, one of our joint company secretaries. Ms. Fung Nga Fong is situated and based in Hong Kong and will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange. Both of our authorised representatives will be readily contactable by telephone and email to deal promptly with enquiries from the Stock Exchange;
- (b) pursuant to Rule 3.20 of the Listing Rules, each Director has provided their contact information to the Stock Exchange and to the authorised representatives. This will ensure that the Stock Exchange and the authorised representatives should have means for contacting all Directors promptly at all times as and when required. In the event that a Director expects to travel or is otherwise out of office, he/she will endeavor to provide his/her phone number of the place of his/her accommodation to the authorised representatives or maintain an open line of communication via his/her mobile phone;
- (c) each Director who is not ordinarily resident in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period;
- (d) pursuant to Rule 3A.19 of the Listing Rules, we have appointed Fosun International Capital Limited as our Compliance Adviser, which will have access at all times to our authorised representatives, Directors, senior management and other officers of our Company, and will act as an additional channel of communication between the Stock Exchange and us;

WAIVERS AND EXEMPTIONS

- (e) meetings between the Stock Exchange and our Directors could be arranged through our authorised representatives or the Compliance Adviser, or directly with our Directors within a reasonable time frame. Our Company will promptly inform the Stock Exchange of any changes of our authorised representatives and/or the Compliance Adviser;
- (f) we will appoint other professional advisers (including legal advisers in Hong Kong) after the Listing to assist us in dealing with any questions which may be raised by the Stock Exchange and to ensure that there will be prompt and effective communication with the Stock Exchange; and
- (g) our Company has designated staff members as the communication officer at our headquarters in Hong Kong after the Listing who will be responsible for maintaining day-to-day communication with Ms. Fung Nga Fong, one of our joint company secretaries, and our Company's professional advisers in Hong Kong, including our legal advisers in Hong Kong and the Compliance Adviser, to keep abreast of any correspondences and/or enquiries from the Stock Exchange and report to our executive Directors to further facilitate communication between the Stock Exchange and our Company.

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DIRECTORS' RESPONSIBILITY FOR THE CONTENTS OF THIS PROSPECTUS

This prospectus, for which our Directors (including any proposed director named as such in this prospectus) collectively and individually accept full responsibility, includes particulars given in compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the Securities and Futures (Stock Market Listing) Rules (Chapter 571V of the Laws of Hong Kong) and the Listing Rules for the purpose of giving information to the public with regard to our Group. Our Directors, having made all reasonable enquiries, confirm that to the best of their knowledge and belief the information contained in this prospectus is accurate and complete in all material aspects and not misleading or deceptive, and there are no other matters the omission of which would make any statement in this prospectus misleading.

CSRC FILING

On 10 December 2024, the CSRC issued the Notice of Filing for the Global Offering and for the listing of the Shares on the Stock Exchange, confirming the filing information of our Company's overseas listing and indicating that we have completed the relevant filing procedures prior to the listing, provided that no further requirements were raised by the CSRC regarding our filing.

THE HONG KONG PUBLIC OFFERING, UNDERWRITING AND THIS PROSPECTUS

This prospectus is published solely in connection with the Hong Kong Public Offering, which forms part of the Global Offering. For applicants under the Hong Kong Public Offering, this prospectus set out the terms and conditions of the Hong Kong Public Offering.

The Offer Shares are offered solely on the basis of the information contained and representations made in this prospectus and on the terms and subject to the conditions set out herein. No person is authorised to give any information in connection with the Global Offering or to make any representation not contained in this prospectus, and any information or representation not contained herein and therein must not be relied upon as having been authorised by the Company, the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Underwriters, any of their respective directors, agents, employees or advisers or any other party involved in the Global Offering.

Neither the publication of this prospectus nor any offering, sale or delivery made in connection with the Offer Shares should, under any circumstances, constitute a representation that there has been no change or development reasonably likely to involve a change in our affairs since the date of this prospectus or imply that the information contained in this prospectus is correct as of any date subsequent to the date of this prospectus.

Further information regarding the structure of the Global Offering, including its conditions, is set out in "Structure of the Global Offering" of this prospectus and the procedures for applying for our Hong Kong Offer Shares are set out in "How to apply for Hong Kong Offer Shares."

INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING

PROCEDURES FOR APPLICATION FOR HONG KONG OFFER SHARES

The procedures for applying for Hong Kong Offer Shares are set out in “How to Apply for Hong Kong Offer Shares” in this prospectus.

STRUCTURE OF THE GLOBAL OFFERING

Details of the structure of the Global Offering, including its conditions, are set out in “Structure of the Global Offering” in this prospectus.

RESTRICTIONS ON OFFER OF THE OFFER SHARES

Each person acquiring the Hong Kong Offer Shares under the Hong Kong Public Offering will be required to, or be deemed by his/her/its acquisition of Offer Shares to, confirm that he/she/it is aware of the restrictions on offers of the Offer Shares described in this prospectus.

No action has been taken to permit a public offering of the Offer Shares in any jurisdiction other than in Hong Kong, or the publication of this prospectus in any jurisdiction other than Hong Kong. Accordingly, this prospectus may not be used for the purpose of, and does not constitute, an offer or invitation in any jurisdiction or in any circumstances in which such an offer or invitation is not authorised or to any person to whom it is unlawful to make such an offer or invitation. The publication of this prospectus and the offering of the Offer Shares in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions pursuant to registration with or authorisation by the relevant securities regulatory authorities or an exemption therefrom.

APPLICATION FOR LISTING ON THE STOCK EXCHANGE

We have applied to the Listing Committee for the granting of the listing of, and permission to deal in, the Shares, including (i) any Shares which may be issued by us pursuant to the Global Offering; (ii) any Shares to be issued pursuant to the Equity Incentive Arrangements, including pursuant to the exercise of share options, the vesting of outstanding RSUs, or other awards that have been or may be granted from time to time; and (iii) any Shares which may be issued upon exercise of all options, RSUs and share awards which may be granted pursuant to the Post-IPO Equity Incentive Scheme.

Save as aforesaid, no part of our Shares or loan capital is listed on or dealt in on the Stock Exchange or any other stock exchange and no such listing or permission to list is being or proposed to be sought in the near future.

INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING

COMMENCEMENT OF DEALINGS IN THE SHARES

Dealings in the Shares on the Stock Exchange are expected to commence on Thursday, 3 July 2025. The Shares will be traded in board lots of 500 Shares each. The stock code of the Shares will be 2592.

ADMISSION OF THE SHARES INTO CCASS

If the Stock Exchange grants the listing of, and permission to deal in, the Shares and we comply with the stock admission requirements of HKSCC, the Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the Listing Date or any other date as determined by HKSCC. Settlement of transactions between participants of the Stock Exchange is required to take place in CCASS on the second Business day after any trading day. All activities under CCASS are subject to the HKSCC Rules and HKSCC Operational Procedures in effect from time to time. Investors should seek the advice of their stockbroker or other professional adviser for details of the settlement arrangement as such arrangements may affect their rights and interests. All necessary arrangements have been made enabling the Shares to be admitted into CCASS.

REGISTER OF MEMBERS AND STAMP DUTY

Our Company's principal register of members will be maintained by our principal share registrar, Harneys Fiduciary (Cayman) Limited, in the Cayman Islands and the Company's register of members in Hong Kong will be maintained by the Hong Kong Share Registrar, Tricor Investor Services Limited, in Hong Kong. Unless the Directors otherwise agree, all transfer and other documents of title of the Shares must be lodged for registration with and registered by the Hong Kong Share Registrar and may not be lodged in the Cayman Islands.

All Offer Shares will be registered on the register of members of our Company in Hong Kong. Dealings in the Shares registered on our register of members in Hong Kong will be subject to Hong Kong stamp duty. The stamp duty is charged to each of the seller and purchaser at the ad valorem rate of 0.1% of the consideration for, or (if greater) the value of, the Shares transferred. In other words, a total of 0.2% is currently payable on a typical sale and purchase transaction of the Shares. In addition, a fixed duty of HK\$5 is charged on each instrument of transfer (if required).

CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary based on present law of certain U.S. federal income tax considerations relevant to the acquisition, ownership and disposition of Offer Shares. This summary addresses only Shareholders that purchase Offer Shares in the Global Offering and will hold Offer Shares as capital assets (generally, property held for investment). The discussion is a general summary only; it is not a substitute for tax advice. This summary does not purport to be a comprehensive description of all U.S. federal income tax considerations that may be relevant to particular investors in light of their particular circumstances. This summary does not address the tax treatment of Shareholders subject to special treatment under U.S. federal income tax laws, including banks and certain other financial institutions, insurance companies, controlled foreign corporations or passive foreign

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investment companies, regulated investment companies, real estate investment trusts, dealers in securities, securities traders that elect to mark-to-market, certain U.S. expatriates, tax-exempt organisations, partnerships, S corporations or other pass-through entities, investors subject to the alternative minimum tax, or investors that will hold Offer Shares as part of a straddle, hedging, conversion or other integrated financial transaction or investors that own (directly, indirectly or constructively) 5% or more by vote or value of our Company's equity interests.

As used herein, the term **"U.S. Holder"** means a beneficial owner of Offer Shares that, for U.S. federal income tax purposes, is (i) a citizen or individual resident of the United States, (ii) a corporation, or other business entity treated as a corporation, created or organised under the laws of the United States or its political subdivisions, (iii) an estate the income of which is subject to U.S. federal income tax without regard to its source, (iv) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all substantial decisions of the trust or (v) a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes). A **"Non-U.S. Holder"** is any Shareholders that is not a U.S. Holder.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) acquires, holds or disposes of Offer Shares, the U.S. federal income tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Prospective purchasers that are partnerships should consult their own tax advisers concerning the U.S. federal income tax consequences to them and their partners of the acquisition, ownership and disposition of Offer Shares.

Treatment of our Company as a Domestic U.S. Corporation for U.S. Federal Income Tax Purposes

Even though our Company is incorporated in the Cayman Islands, our Company has filed U.S. corporation income tax returns and has otherwise taken the position that, pursuant to Section 7874 of the U.S. Internal Revenue Code of 1986, as amended (the **"Code"**), our Company is treated as a U.S. corporation for U.S. federal income tax purposes. Our Company's treatment as a U.S. corporation for U.S. federal income tax purposes may have adverse tax implications for Shareholders. The remaining discussion contained in this section "Certain U.S. Federal Income Tax Considerations" assumes that our Company will be treated as a U.S. corporation for U.S. federal income tax purposes. Because our Company will be treated as a U.S. corporation for U.S. federal income tax purposes, various U.S. withholding regimes would apply to our Company under applicable law. However, our Company currently believes that no mechanism is available through the trading, settlement, and security transferring facilities in Hong Kong for holders to provide to our Company or an applicable withholding agent the certifications required by applicable U.S. Treasury regulations to prove any particular holder's U.S. tax status. Additionally, our Company cannot provide any assurances as to how the trading, settlement, and security transferring facilities in Hong Kong or an applicable withholding agent will apply the relevant U.S. withholding laws. EACH PROSPECTIVE INVESTOR IN OFFER SHARES IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF

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ACQUIRING, HOLDING AND DISPOSING OF SHARES IN LIGHT OF OUR TREATMENT AS A U.S. CORPORATION AND SUCH PROSPECTIVE INVESTOR'S OWN CIRCUMSTANCES.

Tax Considerations Applicable to U.S. Holders

Distributions

The gross amount of distributions, if any, on the Offer Shares will constitute dividends to the extent paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Dividends received by a corporate U.S. Holder may be eligible for a dividends received deduction, subject to applicable limitations. Dividends received by certain non-corporate U.S. Holders, including individuals, are generally taxed at the lower applicable capital gains rate provided certain holding period and other requirements are satisfied. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital and first be applied against and reduce a U.S. Holder's adjusted tax basis in its Offer Shares, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our Offer Shares.

Sale or Other Taxable Disposition of the Offer Shares

Upon the sale, exchange or other taxable disposition of the Offer Shares, a U.S. Holder generally will recognize capital gain or loss equal to the difference between (i) the amount of cash and the fair market value of any property received upon the sale, exchange or other taxable disposition and (ii) such U.S. Holder's adjusted tax basis in the Offer Shares. Such capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period in such Offer Shares is more than one year at the time of the sale, exchange or other taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to certain limitations.

Information Reporting and Backup Withholding

A U.S. Holder may be subject to information reporting and backup withholding at a rate of 24% when such holder receives payments on the Offer Shares (including constructive dividends) or receives proceeds from the sale or other taxable disposition of Offer Shares. Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the U.S. International Revenue Service ("IRS") that the holder previously failed to properly report payments of interest or dividends; or

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- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption. However, as described above, at the present time, our Company believes that no mechanism is available through the trading, settlement, and security transferring facilities in Hong Kong for holders to provide to our Company or an applicable withholding agent the certifications required by applicable U.S. Treasury regulations to prove exemption from backup withholding. U.S. Holders may request from their brokers or custodians documentation showing any backup withholding tax applied in order to substantiate their own tax refund or credit, although there is no guarantee that such documentation will be provided or that such refund or credit claim will be successful.

Tax Considerations Applicable to Non-U.S. Holders

Dividends

The gross amount of distributions, if any, on the Offer Shares (other than certain pro rata distributions of Offer Shares to all Company shareholders) will be treated as U.S. source dividends to the extent paid from our Company's current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent the amount of a distribution exceeds our Company's current and accumulated earnings and profits, the excess will be treated first as a non-taxable return of capital up to such holder's tax basis in the Offer Shares and thereafter as capital gain from the sale of such Offer Shares, subject to the tax treatment described below in "– Gain on Disposition of the Offer Shares" in this section. Because our Company does not expect to maintain calculations of our Company's current or accumulated earnings and profits, as determined under U.S. federal income tax principles, it is expected that distributions generally will be reported to Non-U.S. Holders as U.S. source dividends.

Subject to the discussions below describing dividends that are effectively connected with a Non-U.S. Holder's conduct of a trade or business within the United States and in "– Information Reporting and Backup Withholding" and "– Additional Withholding Requirements" in this section, dividends paid to a Non-U.S. Holder will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. A Non-U.S. Holder that claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to certify its entitlement to benefits under such treaty, generally on a properly completed IRS Form W-8BEN or W-8BEN-E (as applicable). However, it should be noted that, at the present time, our Company believes that no mechanism is available through the trading, settlement, and security transferring facilities in Hong Kong for holders to provide to our Company or the applicable withholding agent the certifications required by applicable U.S.

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Treasury regulations to receive the benefit of any lower applicable treaty withholding tax rate. Accordingly, our Company expects that U.S. federal income tax withholding at a 30% rate will be made from all dividends. In addition, our Company also expects that there may not be a mechanism available for Non-U.S. Holders to obtain the documentation required to make a claim with the IRS for a refund or credit of U.S. federal income tax withheld from such dividends.

Dividends that are treated as effectively connected with a Non-U.S. Holder's conduct of a trade or business within the United States (and, if an applicable income tax treaty so requires, that are attributable to a permanent establishment or a fixed base of the Non-U.S. Holder within the United States), are generally exempt from the 30% withholding tax described in the preceding paragraph if the Non-U.S. Holder complies with applicable certification and disclosure requirements, generally by providing a properly completed IRS Form W-8ECI, in which event, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates generally applicable to United States persons. However, as described above, at the present time, our Company believes that no mechanism is available through the trading, settlement, and security transferring facilities in Hong Kong for holders to provide to our Company or the applicable withholding agent the certifications required by applicable U.S. Treasury regulations to avoid U.S. federal income tax withholding on dividends that are effectively connected income of a Non-U.S. Holder. Accordingly, U.S. federal income tax withholding at a 30% rate may be made from such dividends. Our Company also expects that there may not be a mechanism available for Non-U.S. Holders to obtain the documentation required to make a claim with the IRS for a refund or credit of U.S. federal income tax withheld from such dividends. Any U.S. effectively connected income received by a Non-U.S. Holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Gain on Disposition of the Offer Shares

Subject to the discussions below in "– Information Reporting and Backup Withholding" and "– Additional Withholding Requirements" in this section, a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax on any gain recognised on a disposition of Offer Shares unless:

- such gain is effectively connected with the conduct of a trade or business in the United States by such Non-U.S. Holder, in which event such Non-U.S. Holder generally will be subject to U.S. federal income tax on such gain in substantially the same manner as a U.S. person (except as provided by an applicable tax treaty) and, if it is treated as a corporation for U.S. federal income tax purposes, may also be subject to a branch profits tax at a rate of 30% (or a lower rate if provided by an applicable tax treaty), subject to certain adjustments;

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- such Non-U.S. Holder is an individual who is present in the United States for 183 days or more during the taxable year of such sale, exchange or other disposition and certain other conditions are met, in which event such gain (net of certain U.S. source losses) generally will be subject to U.S. federal income tax at a rate of 30% (except as provided by an applicable tax treaty); or
- our Company is or has been a “United States real property holding corporation” for U.S. federal income tax purposes at any time during the shorter of (x) the five year period ending on the date of such sale, exchange or other disposition and (y) such Non-U.S. Holder’s holding period with respect to such Shares, and certain other conditions are met.

Generally, a corporation is a “United States real property holding corporation” if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business (all as determined for U.S. federal income tax purposes). Our Company believes that it is not, and does not presently anticipate that it will become, a United States real property holding corporation. However, because this determination is made from time to time and is dependent upon a number of factors, some of which are beyond our control, including the value of our assets, there can be no assurance that our Company will not become a United States real property holding corporation. If our Company were a United States real property holding corporation during the period described in the third bullet point above, gain recognised by a Non-U.S. Holder on sale or other disposition of the Offer Shares generally would be treated as income effectively connected with the conduct of a trade or business in the United States by such Non-U.S. Holder, with the consequences described in the first bullet point above (except that the branch profits tax would not apply), unless such Non-U.S. Holder owned (directly and constructively) five percent or less of our ordinary shares during such period and our ordinary shares are treated as “regularly traded on an established securities market” at any time during the calendar year of such sale, exchange or other disposition.

Information Reporting and Backup Withholding

Generally, our Company, or U.S. related financial intermediaries through which payments are made, must report annually to the IRS and to Non-U.S. Holders the amount of distributions made to Non-U.S. Holders and the amount of any tax withheld with respect to those payments. Copies of the information returns reporting such distributions and withholding may also be made available to the tax authorities in the country in which a Non-U.S. Holder resides under the provisions of an applicable income tax treaty or tax information exchange agreement.

A Non-U.S. Holder will generally not be subject to backup withholding with respect to payments of dividends, provided our Company receives a properly completed statement to the effect that the Non-U.S. Holder is not a U.S. person and our Company does not have actual knowledge or reason to know that the holder is a U.S. person. The requirements for the statement will be met if the Non-U.S. Holder provides its name and address and certifies, under penalties of perjury, that it is not a U.S. person (which certification may generally be made on IRS Form W-8BEN or W-8BEN-E, as applicable) or if a financial

INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING

institution holding Offer Shares on behalf of the Non-U.S. Holder certifies, under penalties of perjury, that such statement has been received by it and furnishes our Company or its paying agent with a copy of the statement. However, as described above, at the present time, our Company believes that no mechanism is available through the trading, settlement, and security transferring facilities in Hong Kong for holders to provide to our Company or the applicable withholding agent the certifications required by applicable U.S. Treasury regulations to prove exemption from backup withholding. Therefore, it is possible backup withholding may be applied at a 24% rate, but in such case, no withholding as described in “– Dividends” in this section should be applied. In addition, our Company also expects that there may not be a mechanism available for Non-U.S. Holders to obtain the documentation required to make a claim with the IRS for a refund or credit of such backup withholding. Non-U.S. Holders may request from their brokers or custodians documentation showing the amount of dividends received and the amounts of U.S. withholding tax applied with respect to those dividends in order to substantiate their own tax refund or credit, although there is no guarantee that such documentation will be provided or that such refund or credit claim will be successful.

Except as described below under “– Additional Withholding Requirements” in this section, the payment of proceeds from a disposition of Offer Shares to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States. In the case of a payment of proceeds from the disposition of Offer Shares to or through a non-U.S. office of a broker that is either a U.S. person or a U.S. related person, information reporting (but not backup withholding) on the payment is required unless the broker has documentary evidence in its files that the Non-U.S. Holder is not a U.S. person and the broker has no knowledge to the contrary.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a Non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS. However, our Company expects that there may not be a mechanism available for Non-U.S. Holders to obtain the documentation required to make a claim with the IRS for a refund or credit of any backup withholding.

Additional Withholding Requirements

Under sections 1471 to 1474 of the Code (such Sections commonly referred to as “**FATCA**”), a withholding tax of 30% will be imposed in certain circumstances on payments of dividends on Offer Shares. In the case of payments made to a “foreign financial institution” (such as a bank, a broker, an investment fund or, in certain cases, a holding company), as a beneficial owner or as an intermediary, this tax generally will be imposed, subject to certain exceptions, unless such institution (i) has agreed to (and does) comply with the requirements of an agreement with the United States, or an “**FFI Agreement**”, or (ii) is required by (and does comply with) applicable foreign law enacted in connection with an intergovernmental agreement between the United States and a foreign jurisdiction (“**IGA**”), in either case to, among other things, collect and provide to the U.S. tax authorities or other relevant tax authorities certain information regarding U.S. account holders of such institution and, in either case, such institution provides the withholding agent with a certification as to

INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING

its FATCA status. In the case of payments made to a foreign entity that is not a financial institution (as a beneficial owner), the tax generally will be imposed, subject to certain exceptions, unless such entity provides the withholding agent with a certification as to its FATCA status and, in certain cases, identifies any “substantial” U.S. owner (generally, any specified U.S. person that directly or indirectly owns more than a specified percentage of such entity). If Offer Shares are held through a foreign financial institution that has agreed to comply with the requirements of an FFI Agreement or is subject to similar requirements under applicable foreign law enacted in connection with an IGA, such foreign financial institution (or, in certain cases, a person paying amounts to such foreign financial institution) generally will be required, subject to certain exceptions, to withhold tax on payments made to (i) a person (including an individual) that fails to provide any required information or documentation or (ii) a foreign financial institution that has not agreed to comply with the requirements of an FFI Agreement and is not subject to similar requirements under applicable foreign law enacted in connection with an IGA. Each U.S. Holder should consult its own tax advisor regarding the application of FATCA to the ownership and disposition of Offer Shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. EACH PROSPECTIVE INVESTOR IN OFFER SHARES IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF ACQUIRING, HOLDING AND DISPOSING OF SHARES IN LIGHT OF SUCH PROSPECTIVE INVESTOR’S OWN CIRCUMSTANCES.

PROFESSIONAL TAX ADVICE RECOMMENDED

Potential investors in the Global Offering are recommended to consult their professional advisers if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposal of, and dealing in the Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Underwriters, any of their respective directors or any other person or party involved in the Global Offering accepts responsibility for any tax effects on, or liabilities of, any person resulting from the subscription, purchase, holding or disposal of, dealing in, or the exercise of any rights in relation to, the Shares.

EXCHANGE RATE CONVERSION

Solely for your convenience, this prospectus contains translations of certain figures in Hong Kong dollars into U.S. dollars, and vice versa, at specified rates.

Unless we indicate otherwise, all translations of financial data in Renminbi and Hong Kong dollars into U.S. dollars and from U.S. dollars into Renminbi in this prospectus were made at a rate of RMB7.1761 to US\$1.00 and HK\$7.8499 to US\$1.00, the respective exchange rate on the Latest Practicable Date quoted by the People’s Bank of China.

No representation is made that any amounts in Hong Kong dollars or U.S. dollars can be or could have been at the relevant dates converted at the above rates or any other rates or at all.

INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING

LANGUAGE

If there is any inconsistency between this prospectus and the Chinese translation of this prospectus, this prospectus shall prevail. Translated English names of Chinese laws and regulations, governmental authorities, departments, entities (including certain of our subsidiaries), institutions, natural persons, facilities, certificates, titles and the like included in this prospectus and for which no official English translation exists are unofficial translations for identification purposes only. In the event of any inconsistency, the Chinese name prevails.

ROUNDING

Unless otherwise stated, all the numerical figures are rounded to one or two decimal places. Any discrepancies in any table or chart between totals and sums of amounts listed therein are due to rounding.

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

DIRECTORS

Name	Address	Nationality
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Executive Directors

Dr. NI Jinsong	6142 Wycliffe Cir Reno, NV 89519-7346 USA	American
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Mr. Van Son DINH	32 Cassidy Irvine, CA 92620 USA	American
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Dr. YANG Rong	23732 Via Potes Mission Viejo, CA 92691-3501 USA	American
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Non-executive Directors

Dr. LI Jun Zhi	25461 Rapid Falls Rd Laguna Hills, CA 92653 USA	American
----------------	---	----------

Mr. CAO Xu (曹旭)	Room 1, 9/F, Unit 1, Block 4 Baicuiyuan Beihai Road, First Main Street Tianjin Economic-Technological Development Area Tianjin City PRC	Chinese
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Mr. XIA Zhidong (夏志東)	Room 1001, Building 1 China Merchants Jiangwan International Jiefang Avenue, Qiaokou District Wuhan City Hubei Province PRC	Chinese
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DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Name	Address	Nationality
------	---------	-------------

Independent Non-executive Directors

Mr. LAI Hin Wing Henry Stephen (賴顯榮)	20/F, Block 35 550 Victoria Road Baguio Villa Pok Fu Lam, Hong Kong	Chinese (Hong Kong)
Mr. LIU Chung Mun (廖仲敏)	Unit C, 30th Floor, Block 1 Island Crest No. 8 First Street Sai Ying Pun, Hong Kong	Australian
Ms. NIE Sijiang (聶四江)	Room 101, Block 51 No. 18 Hujing Road Chancheng District Foshan City Guangdong Province PRC	Chinese

For further information regarding our Directors, see “Directors and Senior Management” in this prospectus.

PARTIES INVOLVED IN THE GLOBAL OFFERING

Joint Sponsors *(in alphabetical order)*

CCB International Capital Limited
12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center
99 Queen’s Road Central
Hong Kong

Overall Coordinators *(in alphabetical order)*

CCB International Capital Limited
12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center
99 Queen’s Road Central
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Joint Global Coordinators
*(in alphabetical order with
respective to (i) the Joint
Sponsors, and (ii) the other
Joint Global Coordinators,
respectively)*

CCB International Capital Limited
12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center
99 Queen's Road Central
Hong Kong

CMB International Capital Limited
45/F, Champion Tower
3 Garden Road
Central, Hong Kong

Quam Securities Limited
5/F and 24/F (Rooms 2401 and 2412)
Wing On Centre, 111 Connaught Road Central
Hong Kong

Joint Bookrunners
*(in alphabetical order with
respective to (i) the Joint
Sponsors, and (ii) the other
Joint Bookrunners,
respectively)*

CCB International Capital Limited
12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center
99 Queen's Road Central
Hong Kong

BOCI Asia Limited
26/F, Bank of China Tower
1 Garden Road
Central, Hong Kong

BOCOM International Securities Limited
9/F, Man Yee Building
68 Des Voeux Road Central
Hong Kong

**China Galaxy International Securities (Hong Kong)
Co., Limited**
20/F, Wing On Centre
111 Connaught Road Central
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

China Industrial Securities International Capital Limited

32/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

CMBC Securities Company Limited

45/F, One Exchange Square
8 Connaught Place
Central, Hong Kong

CMB International Capital Limited

45/F, Champion Tower
3 Garden Road
Central, Hong Kong

First Shanghai Securities Limited

19/F, Wing On House
71 Des Voeux Road Central
Hong Kong

Fosun International Securities Limited

Suite 2101-2105, 21/F, Champion Tower
3 Garden Road
Central, Hong Kong

Huafu International Securities Limited

Unit 2603-2604, 26/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

ICBC International Securities Limited

37/F ICBC Tower
3 Garden Road
Hong Kong

Livermore Holdings Limited

Unit 1214A, 12/F, Tower II
Cheung Sha Wan Plaza
833 Cheung Sha Wan Road
Kowloon, Hong Kong

Patrons Securities Limited

Unit 3214, 32/F, Cosco Tower
183 Queen's Road Central
Sheung Wan, Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Quam Securities Limited

5/F and 24/F (Rooms 2401 and 2412)
Wing On Centre, 111 Connaught Road Central
Hong Kong

Ruibang Securities Limited

9/F, Sang Woo Building
227-228 Gloucester Road
Wan Chai, Hong Kong

Soliton Securities Limited

Rooms 803-805, Peter Building
58-62 Queen's Road Central
Central, Hong Kong

SPDB International Capital Limited

33/F, SPD Bank Tower, One Hennessy
1 Hennessy Road
Hong Kong

uSMART Securities Limited

Room 2406, 24/F, FWD Financial Centre
308 Des Voeux Road Central
Sheung Wan, Hong Kong

Joint Lead Managers

*(in alphabetical order with
respect to (i) the Joint
Sponsors, and (ii) the other
Joint Lead Managers,
respectively)*

CCB International Capital Limited

12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited

62/F, The Center
99 Queen's Road Central
Hong Kong

BOCI Asia Limited

26/F, Bank of China Tower
1 Garden Road
Central, Hong Kong

BOCOM International Securities Limited

9/F, Man Yee Building
68 Des Voeux Road Central
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

China Galaxy International Securities (Hong Kong) Co., Limited

20/F, Wing On Centre
111 Connaught Road Central
Hong Kong

China Industrial Securities International Capital Limited

32/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

CMBC Securities Company Limited

45/F, One Exchange Square
8 Connaught Place
Central, Hong Kong

CMB International Capital Limited

45/F, Champion Tower
3 Garden Road
Central, Hong Kong

First Shanghai Securities Limited

19/F, Wing On House
71 Des Voeux Road Central
Hong Kong

Fosun International Securities Limited

Suite 2101-2105, 21/F, Champion Tower
3 Garden Road
Central, Hong Kong

Huafu International Securities Limited

Unit 2603-2604, 26/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

ICBC International Securities Limited

37/F ICBC Tower
3 Garden Road
Hong Kong

Livermore Holdings Limited

Unit 1214A, 12/F, Tower II
Cheung Sha Wan Plaza
833 Cheung Sha Wan Road
Kowloon, Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Patrons Securities Limited

Unit 3214, 32/F, Cosco Tower
183 Queen's Road Central
Sheung Wan, Hong Kong

Quam Securities Limited

5/F and 24/F (Rooms 2401 and 2412)
Wing On Centre,
111 Connaught Road Central
Hong Kong

Ruibang Securities Limited

9/F, Sang Woo Building
227-228 Gloucester Road
Wan Chai, Hong Kong

Soliton Securities Limited

Rooms 803-805, Peter Building
58-62 Queen's Road Central
Central, Hong Kong

SPDB International Capital Limited

33/F, SPD Bank Tower, One Hennessy
1 Hennessy Road
Hong Kong

uSMART Securities Limited

Room 2406, 24/F, FWD Financial Centre
308 Des Voeux Road Central
Sheung Wan, Hong Kong

Capital Market Intermediaries
*(in alphabetical order with
respective to (i) the Joint
Sponsors, and (ii) the other
Capital Market Intermediaries,
respectively)*

CCB International Capital Limited

12/F, CCB Tower
3 Connaught Road Central
Central, Hong Kong

Huatai Financial Holdings (Hong Kong) Limited

62/F, The Center
99 Queen's Road Central
Hong Kong

BOCI Asia Limited

26/F, Bank of China Tower
1 Garden Road
Central, Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

BOCOM International Securities Limited

9/F, Man Yee Building
68 Des Voeux Road Central
Hong Kong

China Galaxy International Securities (Hong Kong) Co., Limited

20/F, Wing On Centre
111 Connaught Road Central
Hong Kong

China Industrial Securities International Capital Limited

32/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

CMBC Securities Company Limited

45/F, One Exchange Square
8 Connaught Place
Central, Hong Kong

CMB International Capital Limited

45/F, Champion Tower
3 Garden Road
Central, Hong Kong

First Shanghai Securities Limited

19/F, Wing On House
71 Des Voeux Road Central
Hong Kong

Fosun International Securities Limited

Suite 2101-2105, 21/F, Champion Tower
3 Garden Road
Central, Hong Kong

Huafu International Securities Limited

Unit 2603-2604, 26/F, Infinitus Plaza
199 Des Voeux Road Central
Sheung Wan, Hong Kong

ICBC International Securities Limited

37/F ICBC Tower
3 Garden Road
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Livermore Holdings Limited

Unit 1214A, 12/F, Tower II
Cheung Sha Wan Plaza
833 Cheung Sha Wan Road
Kowloon, Hong Kong

Patrons Securities Limited

Unit 3214, 32/F, Cosco Tower
183 Queen's Road Central
Sheung Wan, Hong Kong

Quam Securities Limited

5/F and 24/F (Rooms 2401 and 2412)
Wing On Centre, 111 Connaught Road Central
Hong Kong

Ruibang Securities Limited

9/F, Sang Woo Building
227-228 Gloucester Road
Wan Chai, Hong Kong

Soliton Securities Limited

Rooms 803-805, Peter Building
58-62 Queen's Road Central
Central, Hong Kong

SPDB International Capital Limited

33/F, SPD Bank Tower, One Hennessy
1 Hennessy Road
Hong Kong

uSMART Securities Limited

Room 2406, 24/F, FWD Financial Centre
308 Des Voeux Road Central
Sheung Wan, Hong Kong

Legal Advisers to Our Company

As to Hong Kong laws and U.S. laws:

Hogan Lovells

11/F, One Pacific Place
88 Queensway
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

As to PRC laws:

Haiwen & Partners

20/F, Fortune Financial Center
5 Dong San Huan Central Road
Chaoyang District
Beijing 100020
China

As to Cayman Islands laws:

Harney Westwood & Riegels

3501 The Center
99 Queen's Road Central
Hong Kong

As to PRC intellectual property laws:

JunHe LLP Shanghai Office

26/F, HKRI Centre One
HKRI Taikoo Hui
288 Shimen Road (No. 1)
Shanghai
PRC

As to U.S. intellectual property laws:

Jun He Law Offices P.C.

20380 Town Center Lane, Suite 128
Cupertino, CA 95014
UNITED STATES

**Legal Advisers to the Joint
Sponsors and the Underwriters**

As to Hong Kong and U.S. laws:

Ashurst Hong Kong

43/F Jardine House
1 Connaught Place
Central, Hong Kong

As to PRC laws:

Jingtian & Gongcheng

34/F, Tower 3, China Central Place
77 Jianguo Road
Beijing 100025
China

**Auditor and Reporting
Accountant**

PricewaterhouseCoopers

*Certified Public Accountants and
Registered Public Interest Entity Auditor*
22/F, Prince's Building
Central
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING

Industry Consultant

Frost & Sullivan

Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.
Room 2504, Wheelock Square
1717 West Nanjing Road
Jing'an District, Shanghai
China

Receiving Bank

**China Construction Bank (Asia)
Corporation Limited**

26th Floor, China Construction Bank Tower
3 Connaught Road Central
Central, Hong Kong

CORPORATE INFORMATION

Registered Office	Harneys Fiduciary (Cayman) Limited 4th Floor, Harbour Place 103 South Church Street P.O. Box 10240 Grand Cayman KY1-1002 Cayman Islands
Principal place of business and head office in the U.S.	8921 Research Drive Irvine, CA 92618 United States
Principal place of business in Hong Kong	Unit 2308, 23/F Lippo Centre Tower 1 89 Queensway Hong Kong
Company's Website	<u>www.cloudbreakpharma.com</u> <i>(information on this website does not form part of this prospectus)</i>
Joint Company Secretaries	AU Thomas Tsz Ngai (歐子毅) (HKICPA) Unit 2308, 23/F Lippo Centre Tower 1 89 Queensway Hong Kong FUNG Nga Fong (馮雅芳) (HKICPA) Unit 2308, 23/F Lippo Centre Tower 1 89 Queensway Hong Kong
Authorised Representatives	NI Jinsong Unit 2308, 23/F Lippo Centre Tower 1 89 Queensway Hong Kong FUNG Nga Fong (馮雅芳) Unit 2308, 23/F Lippo Centre Tower 1 89 Queensway Hong Kong
Audit Committee	LIU Chung Mun (廖仲敏) (Chairman) NIE Sijiang (聶四江) LAI Hin Wing Henry Stephen (賴顯榮)

CORPORATE INFORMATION

Remuneration Committee	NIE Sijiang (聶四江) (<i>Chairlady</i>) LAI Hin Wing Henry Stephen (賴顯榮) LIU Chung Mun (廖仲敏)
Nomination Committee	LAI Hin Wing Henry Stephen (賴顯榮) (<i>Chairman</i>) NIE Sijiang (聶四江) LIU Chung Mun (廖仲敏)
Principal share registrar and transfer office in the Cayman Islands	Harneys Fiduciary (Cayman) Limited 4th Floor, Harbour Place 103 South Church Street, P.O. Box 10240 Grand Cayman KY1-1002 Cayman Islands
Hong Kong Share Registrar	Tricor Investor Services Limited 17/F, Far East Finance Centre 16 Harcourt Road Hong Kong
Compliance Adviser	Fosun International Capital Limited 2101-2105, 21/F, Champion Tower 3 Garden Road, Central Hong Kong
Principal Banks	China Construction Bank Corporation Suzhou Hi-Tech Industrial Development Zone sub-branch No. 95 Shishan Road Suzhou New District, Suzhou City Jiangsu Province China China Construction Bank (Asia) Corporation Limited CCB Centre 18 Wang Chiu Road Kowloon Bay Hong Kong China CITIC Bank International Limited iSQUARE, 63 Nathan Road Tsim Sha Tsui, Kowloon Hong Kong

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this prospectus were extracted from different official government publications, available sources from public market research and academic research. In addition, we commissioned Frost & Sullivan, an independent industry consultant, to prepare the F&S Report, upon which this section is based. We believe that the source of this information is an appropriate source for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information from official government sources has not been independently verified by us, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Joint Sponsors, any of the Underwriters, any of their respective directors and advisers, or any other persons or parties involved in the Global Offering, and no representation is given as to its accuracy. Our Directors confirm that, after taking reasonable care, there is no adverse change in the market information since the date of the F&S Report which may qualify, contradict or have an impact on the information disclosed in this section in any material respect.

OVERVIEW OF OPHTHALMIC DRUG MARKET

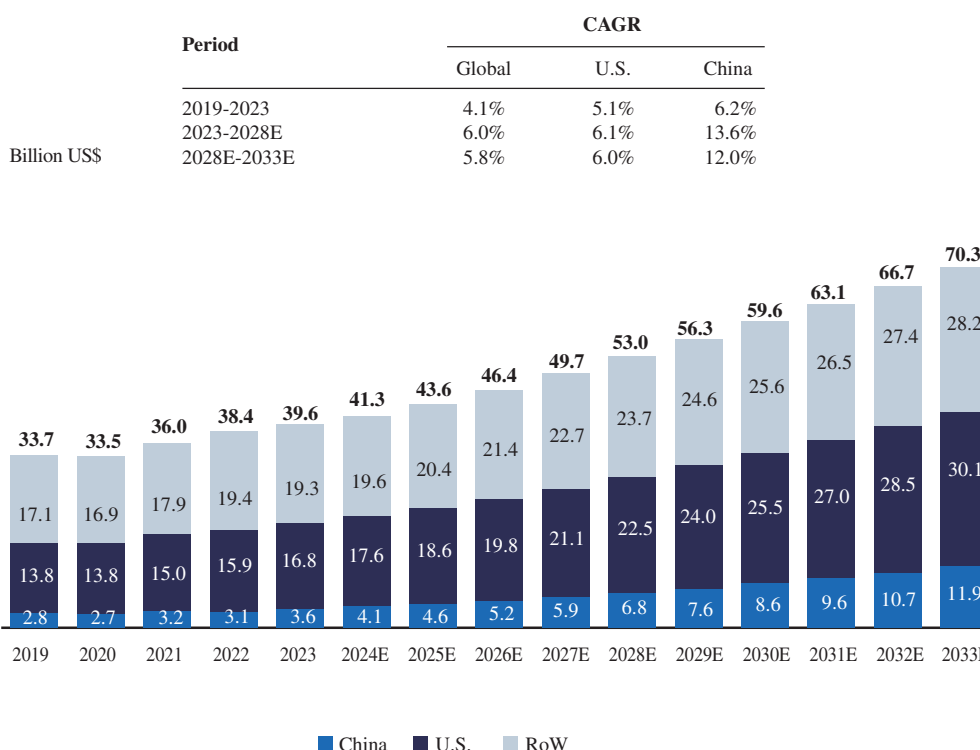
Global Ophthalmic Drug Market

Ophthalmic diseases are the disease conditions that affect any of the eye components such as cornea, optic nerve, lens, retina, choroid, cornea or ocular surface. There are more than one hundred recognised ophthalmic diseases. Ophthalmic diseases can be categorised into two categories, namely, non-vision threatening ophthalmic diseases including dry eye diseases (“**DED**”), pinguecula and conjunctivitis (inflammation of the conjunctiva), and vision threatening ophthalmic diseases including pterygium, retinal diseases (diseases that are major causes of visual impairment and blindness), glaucoma and juvenile myopia and presbyopia. Non-vision threatening ophthalmic diseases can also lead to a variety of severe complications in the absence of timely treatment.

The number of people with major ophthalmic diseases continues to increase across the globe. The global ophthalmic drug market has grown rapidly in recent years. The following chart sets out the ophthalmic drug market size from 2019 to 2033 in the United States, China and the rest of the world (“**RoW**”), respectively:

INDUSTRY OVERVIEW

Global Ophthalmic Drug Therapies Market Size and Forecast, 2019-2033E



Source: literature review, expert interview, annual reports published by market players, F&S analysis

Key Growth Drivers of the Global Ophthalmic Drug Market

Enlarging Patient Pool. Poor eye health and impaired vision have a negative effect on the quality of life and restrict equitable access to and achievement in both educational institutions and workplace. The number of people with major ophthalmic diseases continues to increase across the globe. Due to the widespread use of digital devices, juvenile myopia and DED affected over 550 million and 900 million patients globally in 2023, respectively. Additionally, the overall growth of the aging population and the increasing prevalence of diabetes and hypertension have also boosted the prevalence of pterygium, pinguecula, and age-related ophthalmic diseases such as glaucoma. With the soaring prevalence of ophthalmic diseases and the related increase in disability-adjusted life years (i.e. years lost due to ill-health, disability or early death), the demand for proper treatment is expected to increase in the coming years. This will in turn facilitate the growth of the ophthalmology market.

Unmet medical needs. As the living standards continue to rise and the public awareness of ophthalmic disease improves, demand for better healthcare in ophthalmic disease will keep growing in the future. However, currently, the R&D by multinational ophthalmic players is mainly focused on retinal diseases and glaucoma. There are also much clinical need of ophthalmic patients that have not being addressed, such as pterygium, pinguecula, juvenile myopia and MGD, for which there is no effective and safe treatment option. The development of new drugs for these diseases is worth looking forward to.

INDUSTRY OVERVIEW

Innovative ophthalmic therapies. With strengthened knowledge and advancing research efforts, the field of ophthalmology has progressed steadily. For example, anti-VEGFs have now expanded beyond the original indication (i.e. wet age-related macular degeneration, “wAMD”) and are approved for a slew of retinal diseases including DME. Moreover, the ophthalmic diseases treatment options in the next decade will bring advancements in aspects such as technology platforms, formulation or dosage form, and will lay the foundation for the overall market growth. For instance, the majority of MKIs are used for oncology treatment, and as further clinical studies reveal proven safety and efficacy in the treatment of ocular diseases, MKIs will offer more possibilities for the treatment of ocular diseases.

Favourable policy environment. Many countries have made significant development in enhancing eye health in the past few decades. The seventy-fourth World Health Assembly decided to endorse the global targets for effective coverage of refractive errors and effective coverage of cataract surgery to be achieved by 2030. Further, in 2022, China issued the 14th Five-Year Plan (2021-2025) for National Eye Health (《“十四五”全國眼健康規劃(2021-2025)》), proposing to reduce the burden of costs led by major vision-threatening diseases such as juvenile myopia. In addition, the Chinese government has promulgated a series of policies to shorten the review and approval period for innovative drugs, which will accelerate market entry process for drugs with potential to address urgent and unmet clinical needs in the ophthalmic field.

Market Trends for the Global Ophthalmic Drug Market

Broader therapeutic indications. Anti-allergic, anti-inflammatory, retinal and dry eye disease segments have been dominating the global ophthalmic drug market, owing to factors such as the increasing high prevalence and successful commercialisation of therapeutic medications of these diseases. However, only symptomatic relieving treatment options are available for eye conditions that do not typically cause vision impairment, including pterygium, pinguecula, DED and so on. Researches have demonstrated that the costly treatment of these conditions can pose a substantial economic burden on the patients and on society as a whole. In the future, unmet clinical demands for these conditions are expected to be ultimately solved.

Investigation on innovative drugs. Innovative ophthalmic medication, including novel drug mechanism, drug dosage forms and drug delivery routes, targeting a variety of ophthalmic diseases, are being developed across the globe, and together with new delivery system and forms of administration, it will help yield better effectiveness, compliance and safety. For instance, biologics involving anti-VEGF agents have shown high specificity. However, they are limited in treating posterior ophthalmic diseases as it is difficult for biologics to penetrate through vitreous humour and might require high frequency of intraocular injection that significantly impacts patient compliance. Innovative technical platforms may increase the response rate and efficacy in treating posterior ophthalmic diseases.

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Increasing penetration rate of eye care services. The prevalence of eye conditions and associated complications is affected by the affordability and accessibility of eye care services. For instance, the unmet clinical needs in ophthalmic clinical practice in China are attributed to the lack of ophthalmologists as well as affordable medication, which result in a large under-treated patient population. The number of ophthalmologic hospitals in China increased from 761 in 2018 to 1,203 in 2021, and the number of specialised doctors for ophthalmic diseases increased from approximately 14,024 in 2018 to 21,173 in 2021. Together with increased awareness of eye health and the increased disposable income, the penetration rate of eye care services will ultimately grow in the future.

Entry Barriers for the Global Ophthalmic Drug Market

Product development capabilities. The field of ophthalmology is highly specialised, and may not allow as much possibility of transferring the skillset from one specialty to another as some of the other therapeutic areas do. Therefore, domain-specific knowledge and skills are crucial for the effective development of ophthalmic drugs. The development of ophthalmic drugs is also knowledge-intensive, which creates a significant entry barrier for small or emerging businesses to enter into the ophthalmic drug industry.

Complicated therapeutic system design. Ophthalmic drug development is complicated and varies depending on the field of use with regard to successful formulation development and dosage forms. When taken as a whole, these characteristics provide a serious obstacle to the development of efficient ophthalmic treatment options.

Manufacturing and quality management capabilities. The ability to manufacture ophthalmic drugs has a direct impact on their effectiveness. It is essential for facilities to adhere to GMP standards, and equip themselves with skilled production team, validated production process and good quality management system. Significant entrance barriers are present for businesses lacking qualified manufacturing capabilities.

Brand recognition. Naturally, doctors and hospitals are more likely to suggest well-known drug products that have shown safe and efficient profiles. As a result, developing a well-known brand with substantial involvement among doctors and hospitals may take years of work, and substantial investment by new entrants.

DRUG APPLICATION PATHWAYS IN THE UNITED STATES AND CHINA

Drug Application Pathways in the United States

In the United States, the “new drug” is regarded as a drug that obtains its regulatory approval via submission of FDA Biologics License Application (“**BLA**”), or new drug application (“**NDA**”) under Section 505 of the Federal Food, Drug and Cosmetic Act (“**FDCA**”). BLAs are in connection with biological products, while NDAs generally pertain to traditional small molecule drugs. BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. For NDAs, there are three pathways to apply for approval of new drugs under Section 505 of the FDCA, Section 505(b)(1) is applicable to new molecular entities and requires full reports of investigations of safety and efficacy, whereas Section 505(b)(2) is applicable to modified new drugs and

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the applicant may rely on studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference in the full reports of investigation of safety and effectiveness. The third pathway is provided under section 505(j) for abbreviated new drug applications. The following chart sets out the drug application pathways via NDA in the United States:

Application Type	Drug Type	Application Pathway
NDA (new drug applications)	<ul style="list-style-type: none"> New molecular entities (NMEs) 	505(b)(1) An application that contains full reports of investigations of safety and efficacy.
	<ul style="list-style-type: none"> Modified new drug, including new dosage and formulation, new combination product, new indication, new route of administration, etc. 	505(b)(2) An application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.
ANDA (abbreviated new drug applications)	<ul style="list-style-type: none"> Generics 	505(j) An application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product.

Source: the FDA, F&S analysis

The 505(b)(2) Pathway

The regulatory pathway under Section 505(b)(2) of the FDCA (the “**505(b)(2) pathway**”) is a common R&D pathway adopted by ophthalmic biotechnology companies. It allows the applicant for an NDA to rely, in part, on the FDA’s previous findings of safety and efficacy for a similar product or published literature, which is a commonly-adopted de-risk approach for drug development in the United States and has been validated by successful launch and sale of many ophthalmic drugs with considerable sales revenue. The 505(b)(2) pathway was established to help avoid unnecessary and duplicative studies, including non-clinical and clinical studies, already performed on an existing or previously approved drugs, to fulfil various registration requirements. Thus, the 505(b)(2) pathway allows a less expensive and faster approval pathway and offers potential advantages over the 505(b)(1) pathway. Firstly, the 505(b)(2) pathway shortens the timeline and lowers the development costs because it could save the time to generate pre-clinical and clinical data required for approval. For example, the 505(b)(1) pathway normally takes ten to 15 years from the drug discovery stage to the approval stage, while the 505(b)(2) pathway normally only takes three to six years to the approval stage. Secondly, the 505(b)(2) pathway has a higher success rate from early stage of clinical trials to the approval stage, compared with the 505(b)(1) pathway, because the safety and efficacy profiles of the drug substance are typically well-characterised. Moreover, the 505(b)(2) pathway has a patent and market exclusivity of three years.

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The 505(b)(2) pathway also presents unique value for ophthalmic drug development in particular because ophthalmic drugs which are developed for topical use do not face any competition from their reference drugs which are in the form of oral medication. Due to blood-ocular barrier, oral drugs may deliver insufficient amount of active ingredient to the ocular surface due to poor bioavailability, or cause adverse effects to liver or kidney by increasing systemic drug dosage, due to relatively low blood flow to various targets of receptors in human eyes. As a result, none of the oral drugs which were used as the reference drugs in the 505(b)(2) pathway hold significant market share in drugs targeting ophthalmic diseases.

The following table sets out a list of all 27 new ophthalmic drugs approved in the United States from 1 January 2018 to 31 December 2023, and 15 of them were approved under the 505(b)(2) pathway:

Drug name	Indication	Approval year	Approval pathway	Reference drug
Cequa	Keratoconjunctivitis sicca (dry eye)	2018	Section 505(b)(2)	Neoral and Sandimmune
Inveltys	Post-operative inflammation and pain	2018	Section 505(b)(2)	Lotemax
Oxervate	Neurotrophic keratitis	2018	BLA	N/A
Xelpros	Reduction of intraocular pressure (“IOP”) in patients with open-angle glaucoma, or ocular hypertension	2018	Section 505(b)(2)	Xalatan
Yutiq	Chronic non-infectious uveitis	2018	Section 505(b)(1)	N/A
Dextenza	Ocular itching associated with allergic conjunctivitis	2018	Section 505(b)(2)	Maxidex
Beovu	Neovascular (Wet) Age-Related Macular Degeneration (AMD) and Diabetic Macular Edema (DME)	2019	BLA	N/A
Lotemax Sm	Post-operative inflammation and pain	2019	Section 505(b)(1)	N/A
Rocklatan	Reduction of IOP in patients with open-angle glaucoma, or ocular hypertension	2019	Section 505(b)(2)	Xalatan
Avaclyr	Acute herpetic keratitis	2019	Section 505(b)(2)	Zovirax
Durysta	Reduction of IOP in patients with open-angle glaucoma, or ocular hypertension	2020	Section 505(b)(1)	N/A
Eysuvis	Inflammation or injury	2020	Section 505(b)(2)	Lotemax
Tepezza	Thyroid Eye Disease	2020	BLA	N/A
Verkazia	Vernal keratoconjunctivitis	2021	Section 505(b)(2)	Not publicly disclosed
Vuity	Presbyopia	2021	Section 505(b)(2)	Not publicly disclosed
Acuvue Theravision with Ketotifen	Prevention of ocular itch	2022	Section 505(b)(2)	Not publicly disclosed
Atropine Sulfate Ophthalmic Solution	Dilation of the pupil before eye exams	2022	Section 505(b)(2)	Not publicly disclosed

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Drug name	Indication	Approval year	Approval pathway	Reference drug
Omlonti	Reduction of intraocular pressure in patients with open-angle glaucoma, or ocular hypertension	2022	Section 505(b)(1)	N/A
Kimmtrak	HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma	2022	BLA	N/A
Vabysmo	Neovascular (Wet) Age-Related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME)	2022	BLA	N/A
Miebo	DED	2023	Section 505(b)(1)	N/A
Vevye	DED	2023	Section 505(b)(2)	Cequa
Xdemvy	Demodex blepharitis	2023	Section 505(b)(1)	N/A
Izervay	Geographic atrophy secondary to age-related macular degeneration	2023	Section 505(b)(1)	N/A
Qlosi	Presbyopia	2023	Section 505(b)(2)	Not publicly disclosed
Ryzumvi	Pharmacologically-induced mydriasis produced by adrenergic agonists or parasympatholytic agents	2023	Section 505(b)(2)	Not publicly disclosed
Mydcombi	Pupil dilation	2023	Section 505(b)(2)	Not publicly disclosed

Source: the FDA, the CDER, F&S analysis

The top three ophthalmic drugs approved under the 505(b)(2) pathway with highest sales revenue worldwide in 2022 were Restasis, Lumigan and Combigan, which achieved sales revenue of US\$666 million, US\$514 million and US\$346 million, respectively.

Drug Application Pathways in China

According to the Requirements for Registration Classification and Application Dossiers of Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA in 2020, “new drug” refers to new chemical entities or improved new forms of known chemical entities that have never been marketed anywhere in the world, namely Class 1, 2 and 5.1. Class 1 and 2 are classified as innovative and improved new drugs, respectively, which have never been marketed within or outside China. Class 5.1 is classified as innovative drugs (including drug substances and preparations) that have been approved outside China. The table below sets out the details of such drug application pathways.

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Category	Classification	Definition/Scope
New drugs	Class 1 Innovative new drugs which have never been marketed within or outside China	Active ingredients and their formulations which bear clinical value and contain compounds with new structure and pharmacological effects
	Class 2 Improved new drugs which have never been marketed within or outside China	Class 2.1: Drug substances and preparations which contain optical isomers of the known active ingredients by using the splitting or the synthesis method; turn known active ingredients into ester or salt (including salt containing hydrogen bonds or coordination bonds); change the acid radical, alkali base or metal element of the known active ingredients of salts; or turn into other non-covalent bond derivatives (such as complex chelate or inclusion compound), which also have an obvious clinical advantage Class 2.2: New drug preparations using the new dosage form (including the new drug delivery system); the new prescription process or the administration route of known active ingredients, and which also have an obvious clinical advantage Class 2.3: New compound preparations of known active ingredients, which also have an obvious clinical advantage Class 2.4: New preparations of known active ingredients with new indications
	Class 5 Imported drugs which have been marketed outside China and are under application for being marketed in China domestic market	Class 5.1: Innovative drugs (including drug substances and preparations) that have been approved outside China Class 5.2: Non-innovative drugs (including drug substances and preparations) that have been approved outside China

From 1 January 2018 to 31 December 2023, eight ophthalmic drugs were newly approved in China.

PTERYGIUM

Overview

Pterygium is a benign proliferative ocular surface disease characterised mainly by wing-shaped and fibrovascular growth of the limbal and conjunctival tissue over the adjacent cornea. It leads to vision impairment due to its damage to the cornea. While pterygium remains on the sclera, the head of the pterygium advances unto the cornea. In most cases, pterygium may affect vision, cause general discomfort, and become a cosmetic nuisance. Exposure to ultraviolet light (“UVB”), e.g. sunlight, is generally believed to be a strong risk factor for the development of pterygium, and high risk groups of pterygium include populations with high exposure to sunlight. As a result of alterations in local ocular surface homeostasis, the main components of pterygium include proliferative clusters of limbal stem cells, active fibrovascular tissue, epithelial metaplasia, altered extracellular matrix with accumulation of collagen and elastin fibers and inflammatory infiltration.

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Some types of pterygium lesion progressively grow and affect vision, and other types grow slower. Both types of pterygium can cause severe symptoms, including foreign body sensation, hyperaemia, irritation and visual impairment due to lesion obscuration of the visual axis. In rare cases, pterygium could scar the cornea and lead to blindness if left untreated. In particular, pterygium can cause hyperaemia, growing onto the cornea, disrupting the normal tear film and leading to dryness and irritation. Hyperaemia can also be caused by the body's immune response to the pterygium, which can lead to inflammation and redness. The symptoms of pterygium-associated hyperaemia may include eye redness, irritation, tearing, and foreign body sensation in the eye.

The progression of pterygium can be categorised into three stages. In the first stage, the head of pterygia does not reach the midline between the limbus and pupillary margin. In the second stage, the head of pterygia passes the midline but does not reach the pupil, and in the third stage, it passes the pupillary margin. Asymptomatic, signs of dry eye such as burning, itching or tearing, and hyperemia associated eye redness, irritation, tearing, and a sensation of a foreign body in the eye are normally the symptoms of the first two stages. When pterygium reaches the third stage, visual symptoms due to induced astigmatism or direct encroachment onto the visual axis will appear.

Global Prevalence of Pterygium

Globally, the patient population of pterygium reached 974.1 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 1,017.8 million in 2028 and 1,058.9 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively.

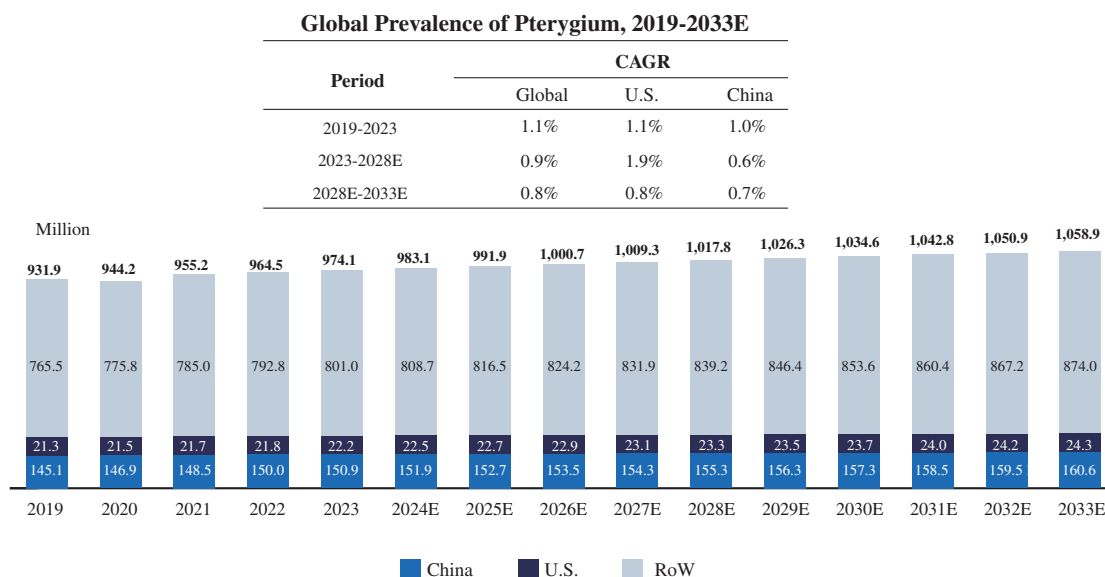
The patient population of pterygium in the United States reached 22.2 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 23.3 million in 2028 and 24.3 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively.

The patient population of pterygium in China reached 150.9 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 155.3 million in 2028 and 160.6 million in 2033, respectively, representing a CAGR of 0.6% from 2023 to 2028 and 0.7% from 2028 to 2033, respectively.

The patient population with pterygium remained relatively stable across the globe from 2019 to 2023 and is expected to remain relatively stable in the foreseeable future, mainly because the key factors that affected the incidence and prevalence of pterygium, such as UV radiation, environmental irritants, familial and hereditary factors, among others, remained persistent.

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The following chart sets out the global prevalence of pterygium from 2019 to 2033, with a breakdown showing prevalence in the United States, China and the rest of the world, respectively:



Source: literature review, expert interview, F&S analysis

Treatment Paradigm and Unmet Medical Needs

There is currently no approved drug therapy for the treatment of pterygium globally. The most common treatment option (i.e. the approach to directly address the disease of pterygium and promote healing) for pterygium that has caused visual disturbance is surgical excision which is usually used in combination with adjunctive therapy. Surgical excision offers a definitive solution by removing the abnormal tissue and has a long-standing history in clinical practice. While surgical intervention carries risks such as infection or recurrence, these are generally outweighed by its long-term effectiveness in restoring ocular health and appearance. Surgical excision is usually performed when the lesion encroaches on the visual axis, or less commonly, when hyperaemia and other bothersome symptoms are persistent. Surgical removal at the early stage of pterygium may be performed on patients who experience vision-impairing astigmatism before pterygium extends to the central corneal, and several surgical techniques have been developed over the years. When the traditional bare sclera excision technique is adopted, post-surgery recurrence was relatively high, at a rate of approximately 30% to 80% in the past. The wide range of recurrence rate is resulted from various preoperative features, including the patient's age, ethnicity and gender, as well as the size of the pterygium and the surgeon's skill level and previous experience. Modern surgical techniques, including various pharmaceuticals as the use of adjunct therapies such as mitomycin, anti-VEGF, cyclosporine A, beta irradiation, and subconjunctival bevacizumab injection, may lower the recurrence rate to approximately 10%. Conjunctival or conjunctiva-limbal autografting with intraoperative and postoperative mitomycin C ("MMC") remains the preferred method because it provides a lower recurrence rate and better cosmetic result. However, there will only be limited inhibition effects if these pharmaceuticals are used standalone, and additionally, none of such pharmaceuticals have entered into clinical trial stage to test their effects independent from the surgery. Adjunctive

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therapies accordingly cannot be used standalone and are always used in combination with surgery for the treatment of pterygium. Surgical complications occur relatively rarely with these modern techniques, but the high costs of surgical excision and its recurrence rate remain big concerns for doctors and patients. Among the patients with pterygium in the United States, approximately 60% use topical eye drops to manage symptoms (i.e. an intervention method focusing solely on alleviating symptoms associated with the disease without addressing the disease itself, which does not treat the disease directly), while approximately 5% opt for surgical excision, and approximately 30% do not seek any medical treatment because the symptoms are mild at early stage. Among the patients with pterygium in China, approximately 5% use topical eye drops to manage symptoms, while approximately 0.4% opt for surgical excision, and over 90% do not seek any medical treatment because early symptoms are mild and the disease awareness of some Chinese patients are relatively low.

More conservative off-label treatment options such as artificial tears, non-preserved lubricant eye ointment, or short-term anti-inflammatory eye drop, are available, but are mainly symptomatic and temporary, usually adopted in the early stages of the disease. To reduce significant inflammation and swelling, off-label drugs such as non-steroidal anti-inflammatory drugs or steroid eye drops may be used. The off-label drugs may be able to relieve some pterygium symptoms but their long-term use may raise safety and effectiveness concerns. For instance, the use of topical corticosteroids is limited for long-term use due to the concern for ocular complications such as glaucoma and cataract. The chart below sets out the current treatment regimen of pterygium drug therapies:

Method	Treatment Options	Mechanism of Action	Limitation	Penetration Rate	Cost
Pharmaceuticals	Artificial tears	Keep the eye lubricated and relieve minor discomfort	<ul style="list-style-type: none"> Off-label use Only for symptomatic and temporary use 	<ul style="list-style-type: none"> Approximately 60% in the United States Approximately 5% in China 	N/A ^(Note)
	Non-preserved lubricant eye ointment				
	Anti-inflammatory eye drops	Inhibit inflammatory reaction			
Surgery	Bare sclera	Excise the head and body of pterygium and allow the bare scleral bed to re-epithelialise	<ul style="list-style-type: none"> Common complications of surgical intervention include subconjunctival hemorrhage, graft edema, graft loss, retraction, graft sliding, and granuloma 	<ul style="list-style-type: none"> Approximately 5% in the United States Approximately 0.4% in China 	<ul style="list-style-type: none"> At chargemaster (a comprehensive list of hospitals' products, procedures and services) price of US\$5,000 - US\$10,000 in the U.S Approximately RMB3,000 in China
	Conjunctival or conjunctiva-limbal autografting	Obtain an autograft and suture the graft over the exposed scleral bed after excision			
	Amniotic membrane transplantation	Suture the amniotic membrane over the exposed scleral bed after excision			
Adjunctive therapy	Mitomycin-C ("MMC"), beta irradiation, anti-VEGF, cyclosporine A	Inhibit neovascular and inflammatory eye conditions			

Note: The off-label drug use is mainly for symptomatic relief with no therapeutic benefits. It is not applicable to calculate the annual cost per patient with off-label drug use, as the drug labels of such drugs do not provide clear recommendations on dosage and duration for its off-label use. For reference, the list price of Restasis and Xiidra in the United States is each in the approximate range of US\$600 to US\$700 per month/bottle. Normally the monthly subscription amount is one bottle.

Source: *Drug Discovery Today, F&S analysis*

In addition to the limited current treatment options, as it is difficult to detect pterygium at the early stage, especially for patients without proper awareness of disease prevention and control. Clinical examination by an ophthalmologist and anterior segment photographs are the main methods to detect pterygium. The condition of pterygium is often asymptomatic, especially early in its disease course. Additionally, the severity of pterygium is mainly based on the subjective evaluation of the ophthalmologists. However, due to the lack of ophthalmologists, screening for pterygium still faces a huge gap in remote or rural areas

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with relatively limited medical resources. Therefore, there are unmet clinical needs to develop a drug therapy to reduce pterygium associated hyperaemia and relieve relevant symptoms.

Global Competitive Landscape of Pterygium Drug Therapies

There is currently no approved drug therapy for the treatment of pterygium globally. The following table illustrates the competitive landscape of clinical-stage drug therapies indicated for pterygium globally as of the Latest Practicable Date:

Drug name/code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Active ingredients	Mechanism	Indications	First posted date ⁽²⁾
CBT-001	Our Group	The United States	Phase 3	Nintedanib	Tyrosine kinase inhibitor	Prevention of pterygium progression and reduction of conjunctival hyperaemia	13 July 2022
		China					4 September 2023
AG-86893	Allgenosis Biotherapeutics Inc	Australia	Phase 2	Nintedanib	Tyrosine kinase inhibitor	Prevention of pterygium progression and reduction of conjunctival hyperaemia	23 May 2018
RMP-A03	Suzhou Raymond Pharmaceuticals Company Ltd	The United States	Phase 2	Not publicly disclosed	Not publicly disclosed	Prevention of pterygium progression and reduction of conjunctival hyperaemia	3 April 2023

Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidate.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn.

Source: the CDE, ClinicalTrials.gov, F&S analysis

As confirmed by F&S, CBT-001 and AG-86893 are both Nintedanib, which have demonstrated the same mechanism of action. The active compound of RMP-A03 is not publicly disclosed. All the listed drug therapies for pterygium are administrated by topical routes. Nintedanib, also known as Ofev[®], is the reference listed drug for CBT-001 manufactured by Boehringer Ingelheim. Ofev[®], the active pharmaceutical ingredient of which is nintedanib monoethanesulphonate salt (the patent owner of which is also Boehringer Ingelheim and the expiry year of which is 2034), is an oral capsule approved by the FDA in 2014 for the treatment of idiopathic pulmonary fibrosis. In China, Ofev[®] has been included in the NRDL, and its end user price has been reduced to approximately RMB4,500 for a supply of 30 capsules. In the United States, the listed price of Ofev[®] oral capsule is approximately US\$13,695 for a supply of 60 capsules. The end user price of Ofev[®] in the United States varies, depending on different medical insurance plans and treatment plans adopted and different retail pharmacies, fully covered by relevant medical insurance plan or as high as US\$243 per capsule. Nintedanib is a small molecule that inhibits multiple receptor tyrosine kinases (“RTK”) and non-receptor tyrosine kinases. The RTKs inhibited by include platelet-derived growth factor receptor

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(“**PDGFR**”) α and β , fibroblast growth factor receptor 1-3, vascular endothelial growth factor receptor (“**VEGFR**”) 1-3, colony stimulating factor 1 receptor, and Fms-like tyrosine kinase-3 (“**FLT-3**”). These kinases except for FLT-3 have been implicated in pathogenesis of interstitial lung disease (“**ILD**”, lung conditions that cause scarring or fibrosis of lung tissues). Nintedanib binds competitively to the adenosine triphosphate binding pocket of these kinases and blocks the intracellular signalling cascades, which have been demonstrated to be involved in the pathogenesis of fibrotic tissue remodelling in ILD. Nintedanib, pharmacologically targeting the angiogenic and fibrotic pathogenesis of pterygium, has the potential to eliminate or postpone the need for surgery.

Market Size of Pterygium Drug Therapies

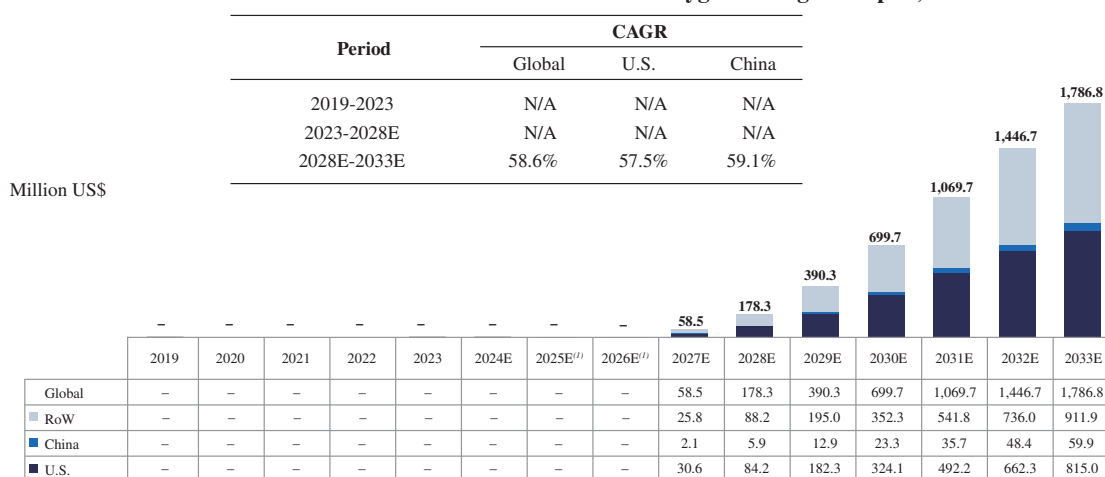
The global market size of pterygium drug therapies is expected to reach US\$178.3 million in 2028 and US\$1,786.8 million in 2033, representing a CAGR of 58.6%.

The market size of pterygium drug therapies in the United States is expected to reach US\$84.2 million in 2028 and US\$815.0 million in 2033, representing a CAGR of 57.5%.

The market size of pterygium drug therapies in China is expected to reach US\$5.9 million in 2028 and US\$59.9 million in 2033, representing a CAGR of 59.1%.

The following chart sets out the global market size of pterygium drug therapies from 2019 to 2033, with a breakdown showing market size in the United States, China and the rest of the world, respectively:

Historical and Forecasted Market Size of Global Pterygium Drug Therapies, 2019-2033E



Notes:

- (1) There is currently no approved drug therapy for the treatment of pterygium globally, and the first drug therapy indicated for pterygium is expected to be marketed in 2027.
- (2) The size and significant growth of pterygium drug therapy market in the United States, China and globally is estimated based on the following key assumptions:

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- (i) the expected prevalence of pterygium, which is based on analysis on and review of authoritative statistical data and of relevant literature. It was noted that the prevalence of pterygium is likely to experience a slight increase due to its primary risk factors, including aging populations and proximity to the equator (see “– Pterygium – Global Prevalence of Pterygium” in this section for details);
- (ii) the expected diagnosis and treatment rate of pterygium, estimated based on current diagnosis and treatment rate of surgery and anti-inflammatory drugs, which is approximately 3.0% and 0.6% in the United States and China, respectively. The diagnosis rate and treatment rate of pterygium is expected to reach 3.5% and 0.9% in the United States and China, respectively, in 2027; and 6.1% and 2.8% in the United States and China, respectively, in 2033. These estimates are based on analysis on relevant literature and insights gathered with industry experts, from which two major growth drivers were identified, including (a) enhanced healthcare awareness among patients combined with greater willingness to seek treatment; (b) expanded treatment options, particularly the emergence of targeted drug therapies, coupled with ongoing physician-patient education programs that are significantly improving clinical diagnosis and treatment rate;
- (iii) the expected penetration rate of pterygium drug therapies (representing the penetration rate of drugs with therapeutic effects on pterygium, typically CBT-001, among patients who currently require surgery or anti-inflammatory medication), estimated taking into consideration that (a) as more drugs indicated for pterygium will be launched and address the unmet clinical needs after regulatory approval, patients are expected to adopt these drugs and the number of treated patients will then grow rapidly, and (b) improved out-of-pocket healthcare spending capacity in the United States and China, leading to expected penetration rate of pterygium drug therapies being 0.5% and 0.2% in the United States and China, respectively, in 2027; and 7.6% and 1.5% in the United States and China, respectively, in 2033;
- (iv) the estimated annual costs per treatment, primarily based on the price of CBT-001 which is expected to be a strong indicator of the price range for other potential drugs that are going to be launched after CBT-001's launch. CBT-001 is planned to be priced competitively against certain existing off-label therapies, including Restasis priced at US\$638 or more and Xiidra priced at US\$693 or more in the United States (see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan- 4. Pricing Strategies” for details); and
- (v) that three drug candidates indicated for pterygium are expected to be approved and launched in 2027, 2029 and 2036, respectively. These will enhance the accessibility of pterygium drug therapies and promote its market growth. See “– Pterygium – Global Competitive Landscape of Pterygium Drug Therapies” in this section for details.

The growth rate of the expected market size for pterygium drug therapies was also benchmarked with that of the surging market size of anti-VEGF agents currently approved for retinal diseases, mainly because the market for anti-VEGF agents indicated for retinal diseases has observed several blockbuster drugs in recent years before there was no approved drug therapy. The similarity of such anti-VEGF agents with CBT-001 includes the following aspects: (a) comparable first-in-class potential/feature, (b) comparable disease nature, and (c) comparable drug price.

Source: literature review, expert interview, market survey, F&S analysis

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Key Growth Driver and Entry Barrier for Market of Drug Therapies Treating Pterygium

The growth in the market of pterygium drug therapies has primarily been driven by the following key factors:

Expanding patient pool. Pterygium is a common eye condition that affects millions of people worldwide. With rising prevalence of pterygium, there is an increasing demand for effective pharmaceutical treatment options. The growing prevalence creates a strong and growing demand for pharmaceutical companies to develop and commercialise new treatment options for pterygium with the growing number of affected individuals.

Unmet medical needs. Increasing awareness regarding eye health and the availability of treatment options is also contributing to the growth of the pterygium pharmaceuticals market. As more people become aware of pterygium and because of its potential impact on vision and quality of life, there is a growing demand for more effective pharmaceutical interventions, thereby creating a larger patient pool for pharmaceutical companies to target with their products. According to a survey conducted in the Brazilian Amazon region, the prevalence of pterygium as cause of visual impairment and blindness was reported as 14.3% and 3.9%, respectively.

Necessity of early-stage medication. There is currently no approved drug therapy for the treatment of pterygium globally. The most common treatment option for pterygium is surgical excision. The off-label drug use is mainly for symptomatic relief with no therapeutic benefits and may arise safety and effectiveness concerns for long-term use. However, modern surgical excision can still result in a recurrence rate of approximately 10%. By addressing pterygium in its early stages, patient outcomes can be significantly enhanced, thereby reducing the need for more invasive interventions.

Despite the relatively stable patient population as mentioned under “– Global Prevalence of Pterygium”, the market size of pterygium drug therapies is expected to expand, mainly because there is currently no approved pterygium drug therapy, and the other treatment options that are available currently, including surgical excision, and off-label drug use, have their respective limitations. As a result, once there is approved drug therapy available, a surging market size is expected, because such drug therapy will be able to enhance the clinical outcome of patients and reduce the need for more invasive intervention.

In addition to the general entry barriers for the global ophthalmic drug market as described in “– Overview of Ophthalmic Drug Market – Entry Barriers for the Global Ophthalmic Drug Market” above, the R&D obstacles of developing drug therapies indicated for pterygium also lie in identifying and developing appropriate (i) modality to target pathogenesis of the disease, (ii) drug delivery method and (iii) formulation for the delivery. Developing and obtaining patents for the method of use by inhibiting relevant growth factors to prevent pterygium growth and nano-emulsion as an eye drop to treat pterygium, based upon the fibrovascular nature of disease, could be an obstacle for other market players.

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JUVENILE MYOPIA

Overview

Juvenile myopia is also known as progressive myopia, or near-sightedness developing and progressing in children and adolescents. Myopia is believed to be caused by a combination of genetic and environmental factors, including spending long hours on close-up work such as reading or using electronic devices, insufficient outdoor time and exposure to bright light. It is caused by an increase in eye length or change in corneal curvature which directs light from distant objects to focus in front of the retina, and leads to blurred long-distance vision. Myopia generally characterised by a refractive error of 0.50 to -6.00 dioptres is considered as in low to moderate form, and it is considered as high myopia when exceeding -6.00 dioptres. Different from refractive myopia caused by ciliary muscle fatigue and ciliary contraction, juvenile myopia is characterised by rapid increase of the axial length (“AL”) and progressive elongation the eyeball. Even if the ciliary muscle is healthy, it cannot accurately focus. Juvenile myopia can lead to high myopia and to pathologic degenerative changes of the eyeball, and patients may suffer retinal choroidal atrophy, choroidal neovascularisation, macular hole and retinal detachment, which can cause severe and permanent damage to vision. Myopia is the leading cause of blindness. Therefore, children and adolescents with moderate to high myopia are in urgent need to effectively control the rapid increase of AL and prevent complications.

As children and adolescents aged between five and 19 are at a critical stage of visual development, myopia develops rapidly at this stage. If left uncorrected, myopia has been shown to have major consequences on children’s and adolescents’ level of education, quality of life, and personal and psychological well-being, and may even cause global potential productivity loss. High risk groups of myopia are children living in developed urban areas.

Global Prevalence of Juvenile Myopia

Globally, the patient population of juvenile myopia (i.e. myopia on the patient population aged between five and 19) reached 586.2 million in 2023, with a CAGR of 2.8% from 2019 to 2023. It is estimated to further grow to 653.6 million in 2028 and reach 688.2 million in 2033.

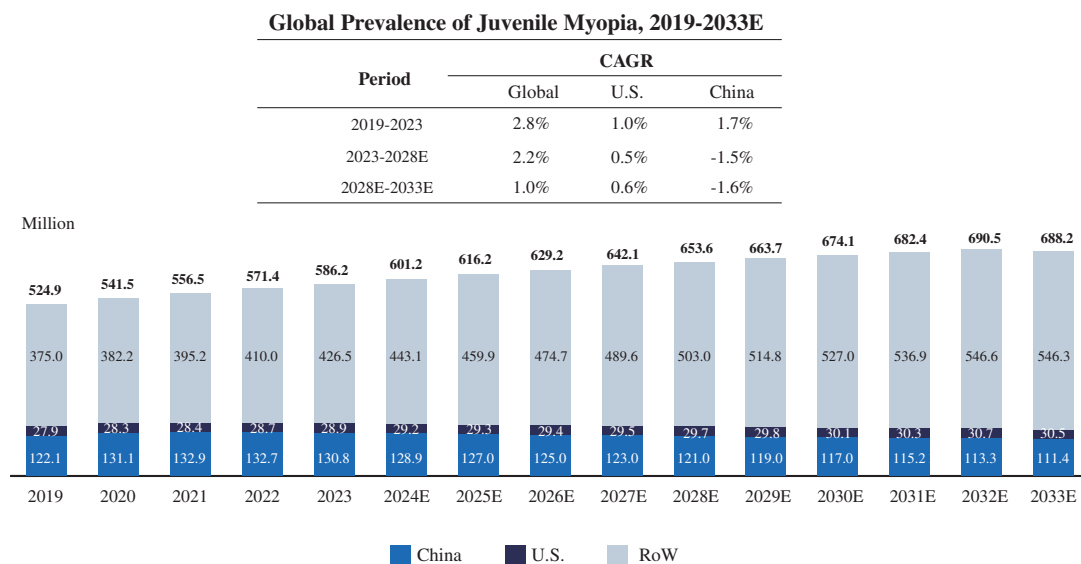
The patient population of juvenile myopia in the United States reached 28.9 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 29.7 million in 2028 and 30.5 million in 2033, respectively, representing a CAGR of 0.5% from 2023 to 2028 and 0.6% from 2028 to 2033, respectively.

The patient population of juvenile myopia in China reached 130.8 million in 2023, with CAGR of 1.7% from 2019 to 2023. It is estimated to reach 121.0 million in 2028 and 111.4 million in 2033, respectively, primarily taking into consideration of the Implementation Plan for Comprehensive Prevention and Control of Myopia among Children and Adolescents (“綜合防控兒童青少年近視實施方案”) (the “**Implementation Plan**”), which sets respective goals for the myopia rate for primary school students, middle school students and high school students in China till 2030. Upon the implementation of the Implementation Plan, the prevalence rate of progressive myopia among children and juvenile in China has decreased

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from 52.7% to 51.9% from 2020 to 2022. In the United States and other key regions, there was no similar initiative and thus change in prevalence rate on juvenile myopia was not seen in the same period of time. As a result, the prevalence of juvenile myopia in the United States and other key regions remained relatively stable from 2019 to 2023.

The following chart sets out the global prevalence of juvenile myopia from 2019 to 2033, with a breakdown showing prevalence in the United States, China and the rest of the world, respectively:



Note: The increase in patient population with myopia in China aged between five and 19 in 2020 is due to an increase in the overall population aged between five and 19 in 2020, which, according to the National Bureau of Statistics of China, is due to the fact that the population in 2019 was calculated based on a sample made from 2010 census data and therefore differ significantly from the 2020 census data.

Source: literature review, expert interview, F&S analysis

Treatment Paradigm and Unmet Medical Needs

Juvenile myopia, myopia in patients aged between five and 19, tends to progress rapidly. This disease has a considerable public health impact, and thus the field of juvenile myopia control has been developed rapidly. Current treatment options for preventing or reducing the progression of myopia mainly include optical correction, anticholinergics therapy and refractive surgery, all of which have certain limitations and thus present unmet medical needs worldwide.

According to the F&S Report, optical correction with spectacle lenses and contact lenses, and atropine eye drops as an anticholinergics therapy option are the major options for the treatment of myopia in children and adolescents. When patients aim to slow down the progression of juvenile myopia, they may opt for optical correction and atropine eye drops, and when patients would like to seek permanent vision correction, they may consider refractive surgery when they are older than 18 years of age. However, the efficacy of optical correction in delaying the progression of myopia is limited, and it has certain limitations.

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For example, spectacle lenses might exacerbate myopia because the peripheral vision will fall behind the retina and the axial length will increase. Wearing heavy spectacle lenses might also cause discomfort on patients, especially children. Contact lenses require regular maintenance to avoid eye infections and complications. Wearing contact lenses for a long time everyday might also cause corneal hypoxia. Additionally, contact lenses, especially daily disposable lenses and specialised lenses for certain eye conditions, can be costly.

In recent years, approximately 90% of patients with juvenile myopia opted for spectacle lenses in most countries, including the United States and China. The penetration rate of spectacle lenses is expected to remain high in the future. In recent years, the penetration rate of orthokeratology is approximately 5% and 2% in the United States and China, respectively. In the next 10 years, the penetration rate of orthokeratology is expected to reach over 15% and 10% in the United States and China, respectively.

In addition to the optical correction including spectacle lenses and orthokeratology, for atropine drug therapy, there was no such approved drug in the United States and China as of 31 December 2023, as a result, the historical proportion of approved atropine drug therapy is nil. The penetration rate of atropine among juvenile myopia patients group in the United States and China is expected to reach approximately 20% and 10% in 2033, respectively.

Atropine is the only treatment option that has been demonstrated to be consistently effective in slowing myopic progression and is the only anticholinergic that is recommended in the Guidelines for Appropriate Techniques for the Prevention and Control of Myopia in Children and Adolescents (《兒童青少年近視防控適宜技術指南》) in China. Higher concentrations of atropine such as 1% or 0.5% have been shown to be effective, but the high rate of photophobia as a side effect has been associated with high dropout rate. Patients may have various adverse reactions to atropine, even at low concentration, including photophobia, changes in intraocular pressure, rebound effect, local allergy and systemic adverse reactions, which may also lead to poor patient compliance. Photophobia is the most common adverse reaction in the use of atropine. The typical duration of treatment with atropine eye drops (including aqueous atropine eye drops and CBT-009) for juvenile myopia is at least two years, on the basis that after the treatment duration, the progression of myopia will be effectively controlled, and no significant rebound effect would be observed one year after the cessation of the treatment.

Currently, aqueous atropine eye drops is used in some countries to treat juvenile myopia, and they have certain advantages including effective hydration to the eyes and easier distribution evenly across the ocular surface, and easy application and good tolerance by most individual patients. However, the limited shelf life due to atropine's instability in the aqueous formulation has prevented aqueous atropine eye drops from being widely recognised as a treatment option. CBT-009 as a non-aqueous atropine eye drop, differ from aqueous atropine eye drops in nature. Firstly, non-aqueous atropine eye drops have higher stability as their non-aqueous solutions are without free hydroxide ions, which can (i) significantly reduce the degradation of atropine and thus results in a decrease in the production of impurities, and (ii) prevent the growth of bacteria, so no preservatives or single dose-packaging will be needed. In contrast, preservatives are commonly used to solve the issue of microbial growth in aqueous atropine eye drops. Secondly, non-aqueous atropine eye drops have higher bioavailability, as the low volume drop which leads to low surface tension between the drug and the eye surface

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will increase the drug’s residence time. Subject to ongoing stability studies, CBT-009 is currently expected to have a shelf life of at least two years. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009 – Current Therapies and Limitations” in this prospectus for details. The shelf life of Eikance approved in Australia in March 2021 is three years and that of Xingqi Meioupin approved in China in March 2024 is 18 months, and the expiry time for Ryjusea approved in Japan in December 2024 and in the EU in June 2025 is three months after opening, all of which are approved aqueous-based atropine eye drops.

Refractive surgery mainly consists of non-laser surgery and laser surgery, and laser surgery includes excimer laser and femtosecond laser. Laser-assisted in situ keratomileusis (“**LASIK**”) is the most commonly performed refractive surgery. In clinical practices, small incision lenticule extraction (“**SMILE**”) and other refractive surgery procedures are only recommended for patients above 18 years old after their eye visions have stabilised. Eligibility for refractive surgery is determined by several factors, including age, corneal thickness, pupil diameter and ophthalmic disease history. Only approximately 60% of the patients who meet the criteria are eligible for surgery. Refractive surgery can generally be performed once and the surgery effect might be offset by the progression of myopia over time or future presbyopia. In addition, the costs of refractive surgery can be high and not all health insurance plans in the United States and China cover such costs. For example, the average cost of LASIK eye surgery for both eyes is US\$4,400 in the United States and ranges from RMB4,000 to RMB6,000 in China. The chart below sets out the current treatment regimen of juvenile myopia drug therapies:

Method	Treatment options	Subtypes	Indications	Mean difference in refraction change, dioptre/year	Mean difference in axial change, mm/year	Annual cost per patient in the United States and China	Limitations	Strengths
Lifestyle Intervention	Environmental Interventions	Time spent outdoors: exposure to more than two hours of outdoor activity per day, or more than ten hours of outdoor activity per week	Limited efficacy	N/A	N/A	N/A	N/A	N/A
Pharmaceuticals Intervention	Anticholinergics	Low-dose 0.01% (standard amount) ⁽¹⁾ atropine	Slow the progression myopia in children aged from six to 12 years old, have a refraction of -0.75D to -4.00D	0.53	-0.15	U.S.: approximately US\$660 China: RMB3,600	Adverse reaction, including photophobia, vision blurring, changes in intraocular pressure (IOP), rebound effect, local allergy, and systemic reactions Possible myopic rebound if atropine usage is stopped suddenly terminated	Clear effects in myopia control, better outcome than spectacle lenses and contact lenses.
		High-dose 1% or tropicamide ⁽²⁾ etc.		N/A ⁽³⁾	N/A ⁽³⁾			
Optical Correction	Spectacle lenses	Bifocal or multifocal spectacles	Myopia with fast refractive progression	0.26	-0.08	U.S.: US\$200 - US\$400 China: RMB500 - RMB2,000	Myopia exacerbation. The corneal is aspherical, peripheral vision will fall behind the retina and the axial length increases. Distort vision at the edge of the lens if astigmatism exists. Discomfort Poor aesthetics	Large field of view, less chromatic aberrations, and high affordability
		Progressive spectacles		0.17	-0.05			
	Contact lenses	Soft hydrophilic contact lens	Slow the progression of myopia in children aged from eight to 12 at the initiation of treatment, have a refraction of -0.75D to -4.00D (spherical equivalent) with ± 0.75 dioptres of astigmatism	0.06	-0.01	U.S.: US\$200 - US\$1,000 China: RMB1,000 - RMB7,000	Inconvenience Long time wearing, or non-fit contact lens may cause problems related to corneal hypoxia, eyelid and eye dryness. Potential risk of infection and complications High expense	More natural vision compared to glasses Cosmetically acceptable, more easily handled, and more convenient for daily activities
		Orthokeratology ⁽⁴⁾	Slow the progression of myopia in children up to about -6.00D of myopia and no more than -1.75D of astigmatism	N/A ⁽⁵⁾	-0.15			
		Rigid gas permeable contact lenses	Correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eye	-0.03	0.02			
Refractive Surgery	Laser Surgery	Excimer laser Femtosecond laser	Stable eye prescription for normally -0.5D to -8.0D myopia	N/A ⁽⁶⁾	N/A ⁽⁶⁾	U.S.: approximately US\$4,400 China: RMB4,000 - RMB6,000	Refractive surgery has age limit - not suggested for patients under 18 years old Refractive surgery can only be performed once, and it is possible of future myopia. Also, myopia progression aging, and presbyopia will all offset the surgery effect. High surgery expense	Short procedure time with lasting vision improvement

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Notes:

- (1) As low dose of 0.01% is more well-tolerated by patients, it is used by two of the three approved eye drops indicated for juvenile myopia (i.e. Eikance and Xingqi Meioupin) and is regarded across the industry as the standard amount.
- (2) There is currently no approved high-dose atropine product, as a result, mean difference in refraction change and mean difference in axial change for this is not available.
- (3) Anticholinergics (and in particular tropicamide) are not comparable with atropine-based eye drops in terms of their effectiveness on treatment of myopia, because they actually have different indications and therapeutic effects on myopia progression, in that atropine has been shown to be able to slow down the axial elongation of the eye and the increase in refractive error, whereas tropicamide is mainly used for diagnostic purposes (instead of treatment purposes) due to lack of sufficient evidence on myopia control by using tropicamide. In addition, atropine has longer half-life as compared to tropicamide, which may help lower the frequency of dosing and improve patient compliance by longer duration of action.
- (4) Other than atropine, orthokeratology is the most effective treatment method for juvenile myopia. In the United States and China, the penetration rate of orthokeratology has reached 5% and 2% respectively, and is expected to reach over 15% and 10% in the next ten years respectively.
- (5) Orthokeratology reshapes the surface of the cornea through night-time wear in order to temporarily reduce myopia. The metric used to evaluate its effectiveness is more focused on its immediate effect, rather than long-term refraction changes as the metric for other treatment options. As a result, data on mean difference of refraction change is not available.
- (6) The clinical endpoint for refractive surgery is normally the percentage of distance uncorrected visual acuity, so the data on mean difference in refraction change or axial change is not of clinical comparability and thus not available.

Source: China Ministry of Education, Eye (Lond), F&S analysis

Global Competitive Landscape of Juvenile Myopia Drug Therapies

Eikance 0.01% eye drop approved by the Australia Therapeutic Goods Administration (“TGA”) is the first available and commercialised prescription for children aged between four and 14 years old as a treatment option to slow down the progression of myopia. Eikance 0.01% approved by TGA is only available and commercialised in Australia and New Zealand as of the Latest Practicable Date. The listed price of Eikance in Australia is approximately AU\$40 and the annual cost per patient is estimated to be approximately AU\$480. Eikance 0.01% eye drop has been approved by New Zealand Medicines and Medical Devices Safety Authority and has been available on prescription from pharmacies in New Zealand commencing from the end of June 2024. In addition to Eikance, Xingqi Meioupin 0.01% eye drop was approved by the NMPA in China in March 2024 for children aged between six and 12 years old as a treatment option to slow down the progression of myopia. In December 2024 and June 2025, Ryjusea 0.025% eye drop was approved in Japan and in the EU for children aged between five and 15 years old as a treatment option to slow down the progression of myopia. There is currently no approved atropine drug therapy for the treatment of juvenile myopia in the United States and Hong Kong. Also, low-dose atropine eye drops are commonly prescribed in off-label uses.

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The following table illustrates the competitive landscape of clinical-stage drug therapies indicated for juvenile myopia globally as of the Latest Practicable Date, divided by those in non-aqueous formulation and aqueous formulation:

Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Dosage ⁽⁴⁾	Indications	First posted date/Approved date ⁽²⁾
<i>In non-aqueous formulation</i>						
CBT-009	Our Group	Australia	Phase 1/2	Not publicly disclosed	Juvenile myopia	13 May 2022
<i>In aqueous formulation⁽³⁾</i>						
Eikance	Aspen Pharmacare Australia Pty Ltd	Australia	Approved	0.01%	Juvenile myopia	19 March 2021
Xingqi Meioupin	Shenyang Xinqi Pharmaceutical Co Ltd	China	Approved	0.01%	Juvenile myopia	12 March 2024
Ryjusea	Santen Pharmaceutical Co., Ltd.	Japan/EU	Approved	0.025%	Juvenile myopia	27 December 2024
NVK-002	Vyluma, Inc., Syneos Health, and Nevakar, Inc.	the United States	NDA	0.01%	Juvenile myopia	N/A
HR19034	Chengdu Suncadia Pharmaceuticals Co., Ltd.	China	NDA	Not publicly disclosed	Juvenile myopia	N/A
NVK-002	Zhaoke Ophthalmology Ltd	China	NDA	Not publicly disclosed	Juvenile myopia	N/A
SYD-101	Sydnexis, Inc.	the United States	Phase 3	0.01%/0.03%	Juvenile myopia	18 April 2019
Atropine	Bausch & Lomb Incorporated	the United States	Phase 3	0.01%	Juvenile myopia	8 May 2019
OT-101	Ocumension (Hong Kong) Limited/ ORA, Inc./ Statistics & Data Corporation	the United States	Phase 3	0.01%	Juvenile myopia	25 February 2021
Not publicly disclosed	Shenyang Xinqi Pharmaceutical Co., Ltd.	China	Phase 3	0.02%/0.04%	Juvenile myopia	27 September 2021
OT-101	Ocumension Therapeutics/ Lyophilization Technology, Inc	China	Phase 3	0.01%	Juvenile myopia	17 December 2021
Atropine Sulfate	LitePharmTech Co., Ltd.	Korea	Phase 3	Not publicly disclosed	Juvenile myopia	6 September 2022
ARVN002	Arctic Vision Shanghai Biotechnology Co Ltd/ Alcami Corporation	China	Phase 3	0.01%	Juvenile myopia	14 September 2022
QLM3004	Qilu Pharmaceutical Co Ltd	China	Phase 3	0.01%/0.02%/0.04%	Juvenile myopia	2 August 2023
Not publicly disclosed	Zhejiang Shapuaisi Pharmaceutical Co., Ltd.	China	Phase 3	0.02%	Juvenile myopia	27 November 2023
Not publicly disclosed	BrightGene Pharmaceutical Co., Ltd	China	Phase 3	0.01%/0.02%	Juvenile myopia	15 March 2024
Not publicly disclosed	Seefunge Pharmaceutical Technology Co., Ltd.	China	Phase 3	0.01%/0.02%	Juvenile myopia	27 November 2024
Alleeance®	Laboratorios Sophia S.A de C.V.	Not publicly disclosed	Phase 3	0.01%	Juvenile myopia	29 April 2024
DE-127	Santen Pharmaceutical Co Ltd	China	Phase 2/3	0.025%	Juvenile myopia	28 March 2022
Not publicly disclosed	Hangzhou Hels Technology	China	Phase 2/3	Not publicly disclosed	Juvenile myopia	23 April 2023
SHJ002	Sunhawk Vision Biotech, Inc.	Taiwan	Phase 2	Not publicly disclosed	Juvenile myopia	30 August 2024
BHVI	Hai Yen Eye Care, and Brien Holden Vision Institute	Vietnam	Phase 1/2	0.02%	Juvenile myopia	10 March 2020

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Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Dosage ⁽⁴⁾	Indications	First posted date/Approved date ⁽²⁾
IVMED-85	iVeena Delivery Systems, Inc.	Not publicly disclosed	Phase 1/2	Not publicly disclosed	Juvenile myopia	9 March 2023
Not publicly disclosed	Aier Health Ophthalmology (Liaoning) Co., Ltd	China	Phase 1	Not publicly disclosed	Juvenile myopia	27 October 2022
STN1013400	Santen Pharmaceutical Co., Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	27 March 2023
DA001	Wuhan Docan Pharmaceutical Co., Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	22 November 2023
GPN00884	Ebe Pharmaceutical Co., Ltd./ Grand Pharmaceutical Co., Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	23 April 2024
Not publicly disclosed	Lepu Medical	China	Phase 1	0.01%/0.03%	Juvenile myopia	10 May 2024

Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidate.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn. Approved date denotes the date on which the relevant drug products (i.e., Eikance, Xingqi Meioupin and Ryjusea) were approved by the regulatory authorities in the relevant authorities.
- (3) Drug candidates in aqueous formulation are included for information. CBT-009 adopts non-aqueous formulation, which is expected to improve patient tolerability, safety and product stability as compared with existing aqueous-based formulations based on pre-clinical and clinical studies conducted by us or our CROs. In addition, all the drug candidates listed in the table above are atropine-based, but the exact mechanism of action of topical atropine is still unknown, according to the F&S Report.
- (4) The active pharmaceutical ingredient of all drug candidates in this table is atropine sulphate, with different level of dosages. The dosage of approved drug therapies (i.e., Eikance, Xingqi Meioupin and Ryjusea) refers to the dosage approved by the relevant regulatory authority, and the dosage of drug candidates at clinical trial stages refers to the dosage amount tested in the respective clinical trial.

Source: *ClinicalTrials.gov, F&S analysis*

The reference drug for CBT-009 is atropine, which has been approved by the FDA for ocular use. Atropine sulfate solution (1%) was approved by the FDA for ocular use with the brand names of Atropine Sulfate and Isopto Atropine[®] indicated for mydriasis, cycloplegia, and penalisation of the healthy eye in the treatment of amblyopia. Multiple drugs have adopted Atropine Sulfate as the active ingredient. As to the reference listed drug of Isopto Atropine[®] approved by the FDA in 2016 with atropine sulfate as the active compound, Alcon is the manufacturer and the patent holder with the relevant patent expiry year being 2030.

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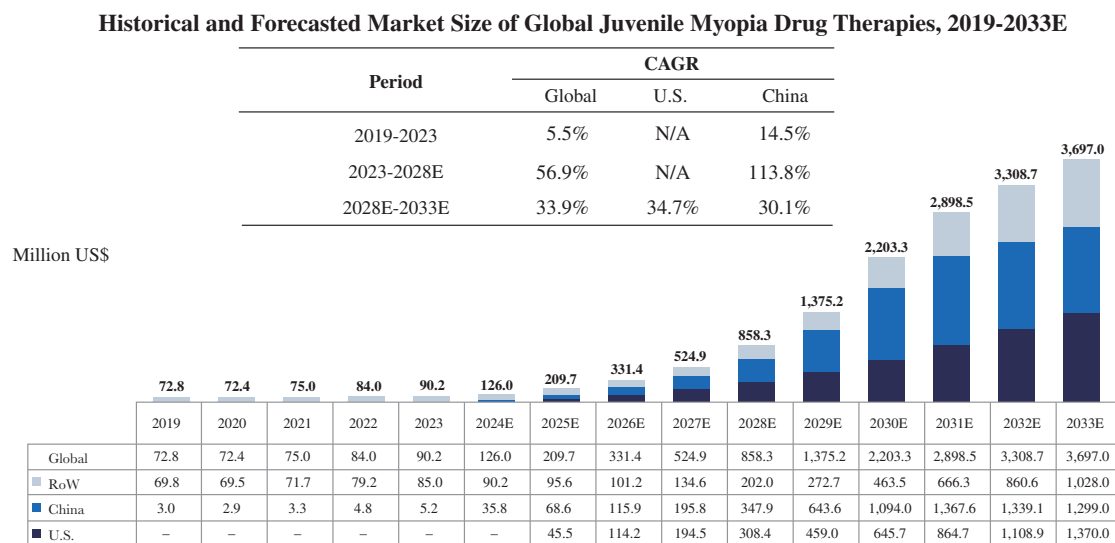
Market Size of Juvenile Myopia Drug Therapies

The global market size of juvenile myopia drug therapies increased from US\$72.8 million in 2019 to US\$90.2 million in 2023, with a CAGR of 5.5%. It is expected to reach US\$858.3 million in 2028 and US\$3,697.0 million in 2033, representing a CAGR of 56.5% from 2023 to 2028 and 33.9% from 2028 to 2033, respectively.

There has been no approved drug therapy for the treatment of juvenile myopia in the United States. The market size of juvenile myopia drug therapies in the United States is expected to reach US\$308.4 million in 2028 and US\$1,370.0 million in 2033, representing a CAGR of 34.7%.

The market size of juvenile myopia drug therapies in China increased from US\$3.0 million in 2019 to US\$5.2 million in 2023, with a CAGR of 14.5%. It is expected to reach US\$347.9 million in 2028 and US\$1,299.0 million in 2033, representing a CAGR of 113.8% from 2023 to 2028 and 30.1% from 2028 to 2033, respectively.

The following chart sets out the global market size of juvenile myopia drug therapies from 2019 to 2033, with a breakdown showing market size in the United States, China and the rest of the world, respectively:



Source: literature review, expert interview, market survey, F&S analysis

Note: The size and significant growth of juvenile myopia drug therapy market in the United States, China and globally is estimated based on the following key assumptions:

- (i) the expected prevalence of juvenile myopia, which is based on analysis on and review of from authoritative statistical data and relevant literature, and has taken into consideration the fact that a number of previously expected approvals for drug pipelines, such as NVK-002, SYD-101, OT-101 and HR19034, had not materialised as of the Latest Practicable Date (see “ – Juvenile Myopia – Global Prevalence of Juvenile Myopia” in this section for details);

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- (ii) the current diagnosis and treatment rate of juvenile myopia, estimated based on current diagnosis and treatment rate which is 90%, because in recent years, around 90% of juvenile myopia patients wear spectacle lenses in most countries, including in the United States and China. Other than optical correction including spectacle lenses and orthokeratology, there was no approved drug therapy indicated for juvenile myopia in the United States and China till December 2023. As a result, the historical market size of drug therapies for juvenile myopia was small. As more drugs indicated for juvenile myopia will be launched and address the unmet clinical needs after regulatory approval, patients are expected to adopt these drugs and the number of treated patients will then grow rapidly. The penetration rate of myopia drug therapies (representing the penetration rate of myopia drug therapies among patients who currently require optical correction and refractive surgery) among juvenile myopia patient group was nil up to 2023 in the United States and China, and is expected to reach approximately 10.2% and 8.9% in 2033, respectively. These estimates are based on analysis on relevant literature and insights gathered with industry experts, from which three major growth drivers were identified, including (a) the approval of Xinqi Meioupin in China, and other atropine drug therapies in the U.S. and China that are expected to be approved in the following years, (b) China's 14th Five-Year National Eye Health Plan, which has incorporated myopia prevention into local government performance evaluations, and other similar public education and awareness campaigns on myopia prevention in the United States and China which raise awareness about juvenile myopia and its early intervention, and (c) growing parents' willingness to invest in vision care solutions for their children in the U.S. and China; and
- (iii) the estimated annual costs per treatment. For reference, the annual cost of juvenile myopia drug therapies in the United States and China is estimated to be around US\$600 based on the price of Eikance and several in-hospital preparations and RMB3,600 based on the price of Xinqi Meioupin, respectively. The annual cost of Ryjusea approved in Japan in December 2024 and in the EU in June 2025 had not been publicly available as of the Latest Practicable Date.

Key Growth Driver and Entry Barrier for Market of Drug Therapies Treating Juvenile Myopia

The growth in the market of juvenile myopia drug therapies has primarily been driven by the following key factors:

Expansion of myopic population. Myopia has emerged as a major public health issue worldwide. The prevalence of juvenile myopia, particularly in East Asia, has significantly increased over the past half-century due to factors such as urbanisation, lifestyle changes, and longer periods of study. The growing number of myopic children and adolescents creates a strong and growing demand for pharmaceuticals that target the slowing progression of myopia in addition to conventional measures, thereby promoting the growth of juvenile myopia pharmaceutical market.

National strategy for myopia prevention. It is indicated that myopia may become one of the most common causes of irreversible vision loss among east Asians. With China being the world's most populous country, the prevalence of myopia among the younger generation is of significant interest and importance. The Implementation Plan for Comprehensive Prevention and Control of Myopia among Children and Adolescents sets targets for myopia rates among primary, middle, and high school students to be below 38%, 60%, and 70%, respectively, by 2030. These policies will raise the awareness of myopia control and facilitate the overall growth myopia pharmaceutical market.

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Proven efficacy of atropine eye drop. Currently, only a limited number of non-atropine-based drug therapies have been approved globally for delaying myopia progression, and their effectiveness in slowing the progression of myopia is still limited. Extensive research has shown that atropine eye drop have promising clinical outcomes and a good tolerance profile even during long-term follow-up periods. Additionally, topical low-dose atropine has been used off-label globally for decades and incorporated into routine myopia management. The Guidelines for Appropriate Techniques for the Prevention and Control of Myopia in Children and Adolescents in China has recommended 0.01% atropine eye drop as an additional therapy conventional optical correction in addition to conventional optical correction as such low dose has limited side effects for children and adolescents. The proven efficacy of these pharmacological agents, combined with their increasingly wider adoption in clinical practice once approved, will ultimately sustain the development of the myopia pharmaceutical market.

Despite the relatively stable patient population in the United States and other key regions and the decreasing number of patient population in China as mentioned under “– Global Prevalence of Juvenile Myopia”, the market size of juvenile myopia drug therapies is expected to expand, mainly because as mentioned above, slowing progression of myopia is a considerable public health impact, and the field of myopia control has been developed rapidly. Among the current treatment options, atropine is the only medication that has been demonstrated to be consistently effective in slowing myopia progression. Also, topical low-dose atropine has been used off-label globally for decades and incorporated into the routine management of myopia. Since 2019, 0.01% atropine eye drops has been applied as in-house preparation of medical institutions to slow down the progression of myopia in China.

In addition to the general entry barriers for the global ophthalmic drug market as described in “ – Overview of Ophthalmic Drug Market – Entry Barriers for the Global Ophthalmic Drug Market” above, the R&D obstacles of developing drug therapies indicated for juvenile myopia also lie in developing appropriate formulation to overcome the instability of atropine in aqueous formulations, commonly used as commercial eye drop products, to maintain reasonable drug product shelf life. Due to the chemical structure of atropine with internal ester bond linkage, atropine molecule tends to decompose in water. In addition, unlike aqueous formulation which is generally compatible and well-tolerated by the eye and therefore less likely to cause irritation, atropine aqueous formulation tends to cause eye irritation which could have an impact on patient compliance for chronic usage in children and adolescent, the target patient population. Developing and obtaining patents for the non-aqueous formulation as an eye drop to potentially overcome the instability of atropine, and adopting an approved artificial tear as the major excipient of the non-aqueous formulation which could potentially increase the comfort level of eyes, could be an obstacle for other market players.

INDUSTRY OVERVIEW

MEIBOMIAN GLAND DYSFUNCTION (“MGD”) ASSOCIATED DRY EYE DISEASE (“DED”)

Overview

Meibomian glands are large sebaceous glands present in eyelids which secrete lipids that form the superficial layer of tear film to protect evaporation of the aqueous phase. MGD is a chronic diffuse abnormality of the meibomian glands which secrete complex lipids named meibum onto the ocular surface. These complex lipids form the outermost layer of the tear film to prevent water evaporation and thus maintain tear film stability. MGD is characterised by blockage or other abnormalities of the meibomian glands that result in impaired lipid secretion, leading to evaporative dry eye. Multiple subtypes of MGD have been identified and as shown by previous studies, all subtypes of MGD can lead to various symptoms of MGD. The symptoms of MGD can be observed in the forms of tear abnormalities, which can cause evaporative DED (i.e., MGD associated DED), ocular surface irritation, inflammation, or ocular surface disease. MGD is the leading cause of evaporative DED, as meibomian glands play an important role in providing lipids to the tear film, which helps to retard the evaporation of tears from the ocular surface. MGD also commonly occurs with an eyelid problem called blepharitis, which causes inflamed eyelids and a crusty discharge at the base of the eyelashes. High risk groups of MGD include female and aged population.

According to the F&S Report, MGD is a contributing factor in 70% to 86% of DED cases globally, and DED is a common public health concern with a prevalence rate of approximately 10% out of total global population. DED could also result in severe consequences as it progresses, such as visual disruption or reduction in visual function.

DED is a multifactorial disease of the tear film, characterised by increased tear film osmolarity, ocular inflammation, deterioration of ocular surface and neurosensory abnormalities, can cause some ocular symptoms such as ocular discomfort and visual disturbance. Patients are diagnosed with DED based on their symptoms and tear film stability. Patients with moderate to severe dry eye symptoms often complain of significant itching and limitation of daily activities which may lead to deterioration in quality of life and even depression. Patients with clogged meibomian glands and mites have less stable tear film. Therefore, preventing and relieving meibomian glands clog and mites are effective ways to avoid the development of DED. At present, mild DED is generally managed with artificial tears in addition to education and environmental modifications. As severity progresses, additional strategies such as anti-inflammatory therapies (e.g. topical cyclosporine, steroids, lifitegrast), lid hygiene, punctal occlusion, thermal pulsation, amniotic membrane bandage, autologous serum, and in the most severe cases, surgery may be required to treat DED. Current treatment options for DED mainly include drug therapies, therapeutic devices and surgery, most of which have certain limitations and thus present unmet medical needs worldwide.

INDUSTRY OVERVIEW

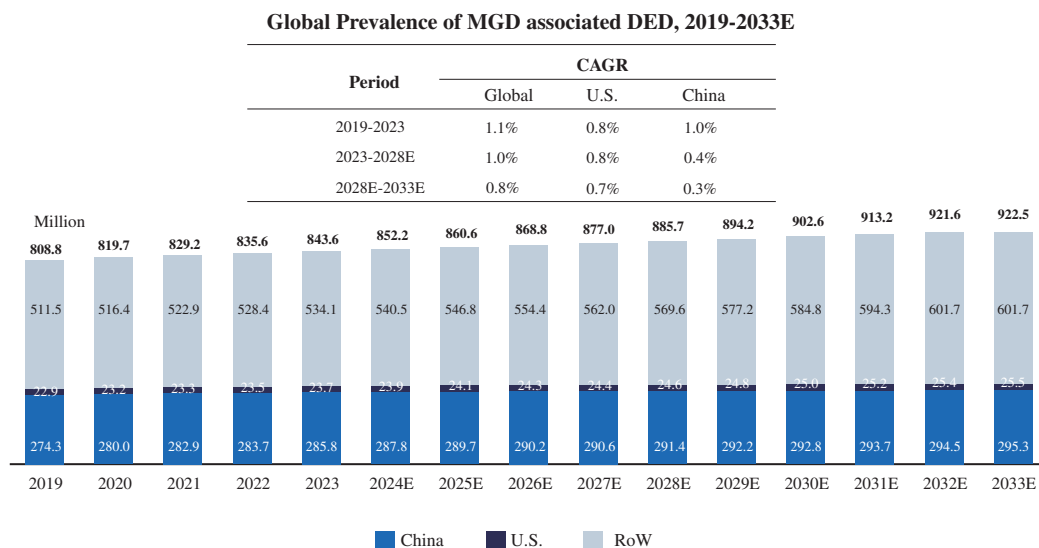
Global Prevalence of MGD associated DED

According to the F&S Report, MGD is a contributing factor in 70% to 86% of DED cases globally. Globally, the patient population of MGD associated DED reached 843.6 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 885.7 million in 2028 and will reach 922.5 million in 2033, respectively, representing a CAGR of 1.0% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively.

The patient population of MGD associated DED in the United States reached 23.7 million in 2023, with a CAGR of 0.8% from 2019 to 2023. It is estimated to reach 24.6 million in 2028 and 25.5 million in 2033, respectively, representing a CAGR of 0.8% from 2023 to 2028 and 0.7% from 2028 to 2033, respectively.

The patient population of MGD associated DED in China reached 285.8 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 291.4 million in 2028 and 295.3 million in 2033, respectively, representing a CAGR of 0.4% from 2023 to 2028 and 0.3% from 2028 to 2033, respectively.

The following chart sets out the global prevalence of MGD associated DED from 2019 to 2033, with a breakdown showing prevalence in the United States, China and the rest of the world, respectively:



Source: literature review, expert interview, F&S analysis

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Treatment Paradigm and Unmet Medical Needs

Tear film evaporation causes tear film instability, tear hyperosmolarity, and ocular surface inflammation and cell apoptosis, resulting in a continuing cycle of DED. The primary goal of treating MGD associated DED is to restore the tear film lipid layer and decrease evaporation, thereby reducing ocular signs and relevant symptoms. Current treatment options for MGD associated DED mainly include drug therapies, therapeutic devices and surgery, most of which have certain limitations and thus present unmet medical needs worldwide.

Various mechanisms exist for the treatment of DED, including artificial tears, anti-inflammatory drugs, corneal repair, stimulating mucoprotein secretion, mite removal and reducing evaporation. Artificial tears may be prescribed for patients with mild DED to replenish tears, lubricate the ocular surface, and dilute the soluble inflammatory mediators on the surface, but they may cause temporary blurry vision and lacrimal gland malfunction in the long term. Anti-inflammatory agents may be prescribed to treat mild or moderate DED but it may cause ocular surface pain and require long-term use. Other unconventional drug therapies, such as corneal repair drugs or mucoprotein secretion-stimulating drugs, are not stable for long-term storage. The option of mite removal wipes normally requires an overall treatment period of one to two months, and is difficult to achieve a satisfying therapeutic effect in the short term.

The diagram below sets out the current treatment and management regimen for MGD associated DED.

Stage	Clinical Description	Pharmacological Intervention	Other Intervention
1	<ul style="list-style-type: none"> No symptoms of ocular discomfort, itching, or photophobia No ocular surface staining 	N/A	<ul style="list-style-type: none"> Improvement of diet and environment
2	<ul style="list-style-type: none"> Minimal to mild symptoms of ocular discomfort, itching, or photophobia Scattered lid margin features None to limited ocular surface staining 	<ul style="list-style-type: none"> Artificial lubricants Topical azithromycin Topical emollient lubricant or liposomal spray Consider oral tetracycline derivatives 	<ul style="list-style-type: none"> All the above Palpebral physical therapy Advise improving ambient humidity, optimising workstations, and increasing dietary omega-3 fatty acid intake
3	<ul style="list-style-type: none"> Moderate symptoms of ocular discomfort, itching, or photophobia with limitations of activities Plugging lid margin Mild to moderate conjunctival and peripheral corneal staining 	<ul style="list-style-type: none"> All the above Oral tetracycline derivatives Lubricant ointment at bedtime Anti-inflammatory therapy for dry eye Therapy targeting tear evaporation 	<ul style="list-style-type: none"> All the above
4	<ul style="list-style-type: none"> Marked symptoms of ocular discomfort, itching or photophobia with definite limitation of activities Dropout lid margin Increased conjunctival and corneal staining including central staining 	<ul style="list-style-type: none"> All the above 	<ul style="list-style-type: none"> All the above

Source: the American Academy of Ophthalmology, literature review, F&S analysis

INDUSTRY OVERVIEW

Therapeutic devices for the treatment of MGD associated DED mainly include soft therapeutic contact lenses and therapeutic neurostimulation devices. Soft therapeutic contact lenses may be used for MGD associated DED with corneal injury, but it may cause corneal edema and hyperaemia when being worn for long hours. Therapeutic neurostimulation devices might cause nasal irritation and lower the comfort level for patients.

Lacrimal duct surgery is performed to embolise lacrimal duct to keep tears and artificial tears on eyes and relieve the symptoms of MGD associated DED. While lacrimal duct surgery is believed to be generally effective and safe, it brings adverse reactions like rejection, local inflammation, redness and pain during the procedure. It might also induce chronic ophthalmic disease such as chronic dacryoadenitis when the tear duct is blocked for a long time and bacteria and tear fluids gathered in the tear sac. In addition, patients with inflammation in eyes and poor duct conditions, such as ectropion and narrow duct, may not be suitable for lacrimal duct surgery.

Global Competitive Landscape of Drug Therapies Treating MGD associated DED

There is a wide range of treatment options for DED. Among them, Miebo™ (perfluorohexyloctane ophthalmic solution), indicated for the treatment of the signs and symptoms of DED and approved by the FDA on 18 May 2023, was the first and only FDA-approved drug therapy for DED that directly targets tear evaporation, which is often led by MGD, as of the Latest Practicable Date. Before the approval of Miebo™ by the FDA, topical ophthalmic prescription drug therapies would only attempt to alter various factors that may contribute to DED, such as inflammation, bacterial growth, inadequate tear production. These drug therapies do not target the key driver of the disease (i.e., excessive evaporation).

The following table illustrates the competitive landscape of drug therapies indicated for MGD associated DED globally as of the Latest Practicable Date:

Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Indications	Active ingredients	Mechanism	First posted date ⁽²⁾	Annual cost per patient in US\$	Patent expiry date
Miebo™ (NOV03) ⁽³⁾	Bausch & Lomb Inc. ⁽⁴⁾	The United States and the EU	Approved	DED ⁽⁵⁾	Perfluorohexyloctane ⁽⁵⁾	Not publicly disclosed	N/A	9,252	21 June 2037
SHR8058 eye drops/ NOV03 eye drop ⁽⁶⁾	Jiangsu HengRui Pharmaceuticals Co Ltd	China	NDA	MGD associated DED	Perfluorohexyloctane ⁽⁷⁾	Not publicly disclosed	N/A	N/A	N/A
AZR-MD-001	Azura Ophthalmics Ltd/ ORA, Inc.	The United States	Phase 3	MGD associated DED	Selenium Disulfide ⁽⁸⁾	Keratolytic agent	26 March 2024	N/A	N/A
HY02	Hovione Scientia Ltd	The United States	Phase 2	MGD associated DED	Minocycline ⁽⁸⁾	Not publicly disclosed	25 March 2019	N/A	N/A
AXR-270	AxeroVision, Inc.	The United States	Phase 2	MGD associated DED	Not publicly disclosed	Glucocorticoid receptor agonist ⁽⁸⁾	14 July 2020	N/A	N/A
TP-03	Tarsus Pharmaceuticals, Inc.	The United States	Phase 2	MGD associated DED	Lotilaner	Non-competitive gamma-aminobutyric acid receptor antagonist ⁽⁹⁾	12 July 2022	N/A	N/A
CBT-006	Our Group	The United States	Phase 2	MGD associated DED	Cyclodextrin	Supramolecular catalysts	12 May 2021	N/A	N/A

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Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidate.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn.
- (3) The price of Miebo™ is US\$771 for one month's supply, and the patent expiry date is 21 June 2037. Perfluorohexyloctane, the active ingredient of Miebo™, forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce the evaporation. The product label of Miebo does not clarify the recommended duration of administration.
- (4) Bausch & Lomb Inc. acquired the rights to develop and commercialise NOV03 from Novaliq GmbH in the United States and Canada in December 2019.
- (5) Although on FDA approved label, the indication of Miebo™ is DED (i.e. all types of DED), the patients from the clinical trials of Miebo™ were patients with MGD associated DED only.
- (6) Novaliq GmbH entered into a strategic collaboration arrangement with Jiangsu Hengrui Pharmaceuticals to develop, manufacture and commercialise NOV03 for the treatment of MGD associated DED in Greater China.
- (7) Perfluorohexyloctane is a novel substance that has been approved as a medical device NovaTears(r), which is a nonblurring wetting agent for the ocular surface.
- (8) AZR-MD-001, HY02, and AXR-270 are anti-inflammatory antibiotics.
- (9) TP-03 is an antiparasitic agent.

Source: the FDA, the CDE, ClinicalTrials.gov, F&S analysis

Market Size of Drug Therapies Treating MGD associated DED

According to the F&S Report, the global market size of drug therapies treating MGD associated DED is expected to reach US\$3,784.8 million in 2028 and US\$8,543.8 million in 2033, representing a CAGR of 17.7%.

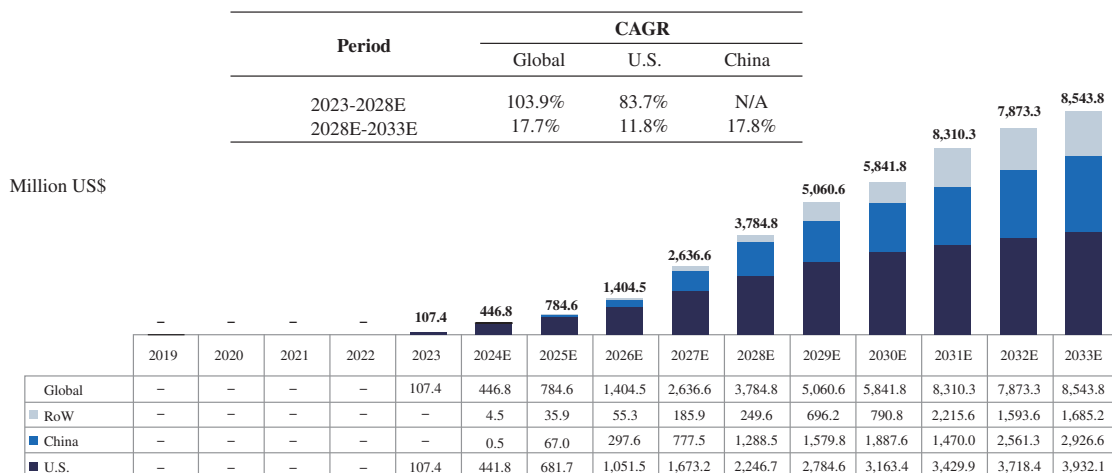
The market size of drug therapies treating MGD associated DED in the United States is expected to reach US\$2,246.7 million in 2028 and US\$3,932.1 million in 2033, representing a CAGR of 11.8%.

The market size of drug therapies treating MGD associated DED in China is expected to reach US\$1,288.5 million in 2028 and US\$2,926.6 million in 2033, representing a CAGR of 17.8%.

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The following chart sets out the global market size of drug therapies treating MGD associated DED from 2019 to 2033, with a breakdown showing market size in the United States, China and the rest of the world, respectively:

Historical and Forecasted Market Size of Global MGD associated DED Drug Therapies, 2019-2033E



Source: literature review, expert interview, market survey, F&S analysis

Key Growth Driver and Entry Barrier for Market of Drug Therapies Treating MGD associated DED

The growth in the market of drug therapies treating MGD associated DED has primarily been driven by the following key factors:

Expansion of MGD associated DED population. MGD has a high prevalence, leading to increased awareness of the condition among both patients and healthcare professionals. This has driven the demand for effective pharmaceutical treatments. Studies have shown that MGD is a contributing factor in 70% to 86% of DED cases globally. There is a growing demand for pharmaceutical treatments that target the underlying causes of MGD and provide relief for those affected by this condition.

Cognitive enhancement in causes of disease. In addition to the high prevalence of MGD associated DED, there is also a growing understanding of the underlying causes of the condition, which will continuously boost the market growth of pharmaceutical treatments for MGD associated DED. In the past, DED patients were mainly diagnosed and treated based on their unstable tear film. However, in recent years, DED has been recognised as a multifactorial disease and has been clearly classified into two major subtypes: aqueous-deficient DED and evaporative dry eye. This increased understanding has led to a greater focus on developing drug therapies that specifically target these underlying causes, offering more targeted and effective solutions for patients.

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Significant shift in treatment approach. There has been a notable shift in the approach to treating MGD in recent years. While conventional treatments primarily focused on symptom management, there is now a greater emphasis on addressing the underlying causes of the condition. This change has generated a demand for pharmaceuticals that not only offer symptomatic relief but also target the fundamental mechanisms of MGD, providing more comprehensive and sustainable solutions for patients. In 2023, a significant milestone was achieved with the FDA approval of Miebo™, marking it as the first and only FDA-approved drug therapy for DED that targets tear evaporation, which is often led by MGD. According to the financial report of Bausch & Lomb Inc. in the third quarter of 2023, the total number of Miebo™ prescriptions, including initial prescriptions and refills, reached 9,600 within the first month following its launch. This data underscores the high demand and positive reception of this innovative treatment option among healthcare professionals and patients alike.

In addition to the general entry barriers for the global ophthalmic drug market as described in “ – Overview of Ophthalmic Drug Market – Entry Barriers for the Global Ophthalmic Drug Market” above, the R&D obstacles of developing drug therapies indicated for MGD associated DED also lie in the lack of clear understanding on the pathogenesis of the disease and appropriate method to address the underlining cause of disease. Discovering and obtaining patents for the mechanism of action to dissolve cholesterol, the key component believed to contribute to the lipid accumulation at meibomian gland orifice, could be an obstacle for other market players.

PINGUECULA

Overview

Pinguecula is a round, yellowish, elevated tissue that develops on the conjunctiva adjacent to the cornea. Pinguecula is characterised as raised yellow-white fibrovascular growth of the interpalpebral bulbar conjunctiva that does not involve the cornea and represents elastotic degeneration of subepithelial collagen with hyalinized connective tissue. In general, an asymptomatic pinguecula requires no treatment, but its yellowish and raised contour can cause mechanical or poor tear film-related ocular surface irritation. Pinguecula may cause cosmetic blemish or irritation if vascularised due to inflammation. When the lesion becomes vascularised and/or inflamed, it may lead to symptoms of ocular hyperaemia, discomfort, pain, foreign body sensation, tearing, and itching. Environmental irritants such as wind and dust, exposure to UVB and aging are considered to be some of the possible causes leading to pinguecula. Pinguecula is distinguished from pterygium by the lack of corneal invasion of the former.

As pinguecula is a raised bump, it causes the natural tear film to spread unevenly over the surface of the eye, and thus causing a break in the tear film. Symptoms of pinguecula include dry eyes, burning sensation, itching, constant rubbing of the eyes due to foreign body sensation, blurry vision and stinging.

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Global Prevalence of Vascularised Pinguecula

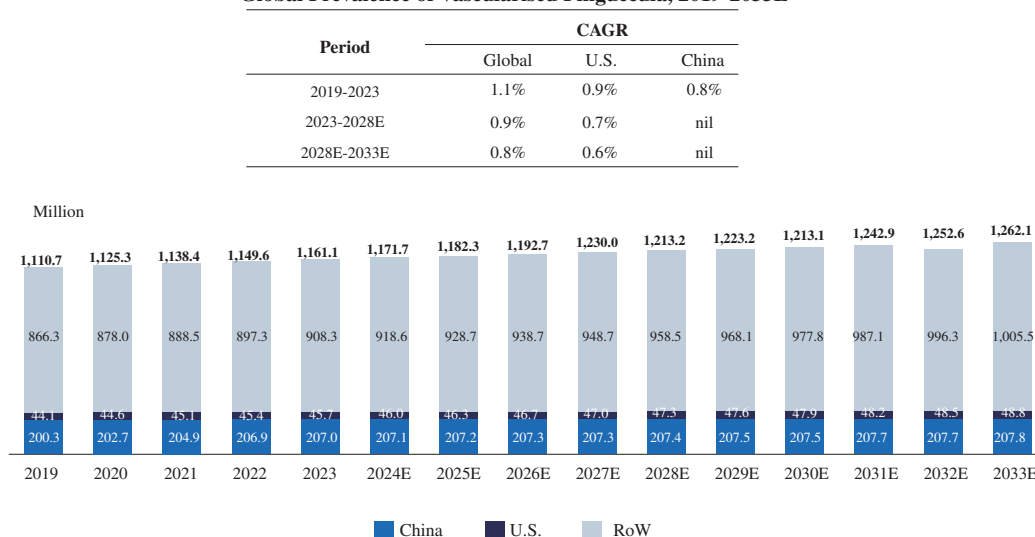
The global patient population of vascularised pinguecula reached 1,161.1 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 1,213.2 million in 2028 and 1,262.1 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively.

The patient population of vascularised pinguecula in the United States reached 45.7 million in 2023, with a CAGR of 0.9% from 2019 to 2023. It is estimated to reach 47.3 million in 2028 and 48.8 million in 2033, respectively, representing a CAGR of 0.7% from 2023 to 2028 and 0.6% from 2028 to 2033, respectively.

The patient population of vascularised pinguecula in China reached 207.0 million in 2023, with a CAGR of 0.8% from 2019 to 2023. It is estimated to remain relatively stable at 207.4 million in 2028 and 207.8 million in 2033, respectively.

The following chart sets out the global prevalence of vascularised pinguecula from 2019 to 2033, with a breakdown showing prevalence in the United States, China and the rest of the world, respectively:

Global Prevalence of Vascularised Pinguecula, 2019-2033E



Source: literature review, expert interview, F&S analysis

Treatment Paradigm and Unmet Medical Needs

There is currently no approved drug therapy for the treatment of vascularised pinguecula globally. Nevertheless, there exist two major intervention methods (rather than treatment options) to manage pinguecula, which are pharmacological intervention and surgical intervention, both of which have certain limitations and thus present unmet medical needs worldwide.

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Pharmacological intervention such as artificial tears and ointment is mainly symptomatic and temporary, usually adopted in mild cases of dryness or foreign body sensation. If inflammation is more severe, a short course of topical steroids or topical antibiotic-steroid in tapering dose may be indicated. Topical non-steroidal anti-inflammatory drugs are also effective for pinguecula. However, long-term use of topical steroid therapy might cause adverse side effects, such as IOP elevation, cataract formation, and increased risk of infection. Surgical intervention, including conjunctival autografting, argon laser photocoagulation, cryotherapy and adjunctive therapy is usually considered only for cosmetic reasons. Common complications of surgical intervention include recurrence of pinguecula and pigmentary changes at the site of removal. Moreover, the costs of surgeries for vascularised pinguecula and associated treatment are relatively high in the United States and China. The chart below sets out the current treatment regimen of vascularised pinguecula drug therapies:

Method	Treatment Options	Mechanism of Action	Limitation	Cost
Pharmaceuticals	Artificial tears	Keep the eye lubricated and relieve minor discomfort	<ul style="list-style-type: none"> Off-label use Only for symptomatic and temporary use 	N/A ^(Note)
	Non-preserved lubricant eye ointment			
	Anti-inflammatory drugs	Inhibit inflammatory reaction		
Surgery	Conjunctival autografting	Obtain an autograft and suture the graft over the exposed scleral bed after excision	<ul style="list-style-type: none"> Common complications of surgical intervention include recurrence of pinguecula and pigmentary changes at the site of removal 	<ul style="list-style-type: none"> US\$1,000 - US\$1,600 in the U.S. Approximately RMB2,000 in China
	Argon laser photocoagulation	Provide control of the extent and depth of removal of tissue		
	Cryotherapy	Suture the amniotic membrane over the exposed scleral bed after excision		
Adjunctive therapy	Topical antibiotic-steroid eye drops	Inhibit neovascular and inflammatory eye conditions		

Note: The off-label drug use is mainly for symptomatic relief with no therapeutic benefits. It is not applicable to calculate the annual cost per patient with off-label drug use, as the drug labels of such drugs do not provide clear recommendations on dosage and duration for its off-label use.

Source: the NVISION, F&S analysis

Global Competitive Landscape of Pinguecula Drugs Therapies

There is currently no approved drug therapy for the treatment of vascularised pinguecula globally. As of the Latest Practicable Date, CBT-004 was the only clinical-stage drug therapy indicated for vascularised pinguecula globally. According to the F&S Report, Inlyta (axitinib), manufactured by Pfizer, is the reference listed drug for CBT-004, which was approved by the FDA in 2012 and is indicated for the treatment of advanced renal cell carcinoma. Axitinib, patent holder of which is PF PRISM CV and the expiry year of which is 2037, is a small molecule multi-receptor tyrosine kinase inhibitor. It has the advantage of blocking VEGF receptors, and blocking platelet derived growth factor receptors, which contributes to neovascularisation and pathologic angiogenesis.

Market Size of Vascularised Pinguecula Drug Therapies

According to the F&S Report, the global market size of vascularised pinguecula drug therapies is expected to reach US\$255.8 million in 2028 and US\$1,539.3 million in 2033, representing a CAGR of 43.2%.

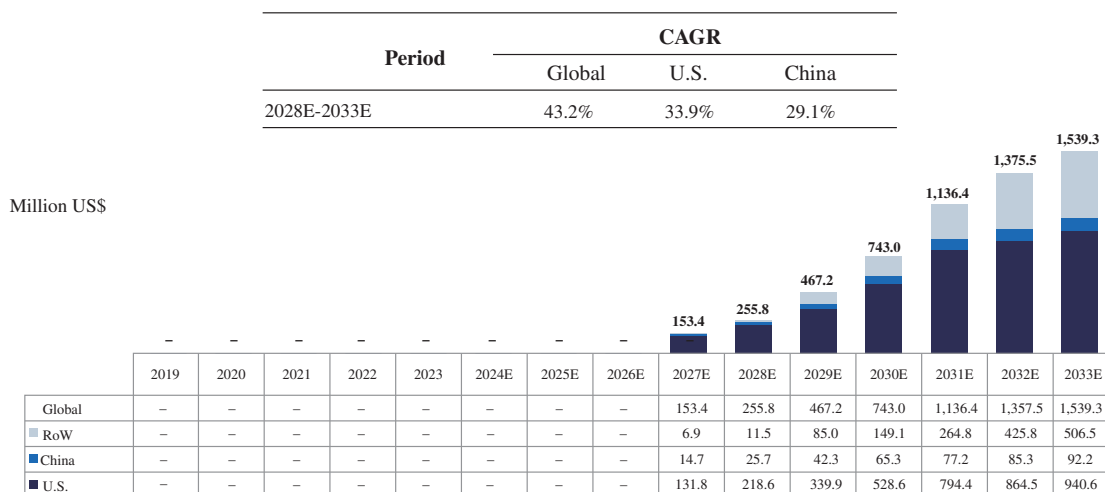
INDUSTRY OVERVIEW

The market size of vascularised pinguecula drug therapies in the United States is expected to reach US\$218.6 million in 2028 and US\$940.6 million in 2033, representing a CAGR of 33.9%.

The market size of vascularised pinguecula drug therapies in China is expected to reach US\$25.7 million in 2028 and US\$92.2 million in 2033, representing a CAGR of 29.1%.

The following chart sets out the global market size of vascularised pinguecula drug therapies from 2019 to 2033, with a breakdown showing market size in the United States, China and the rest of the world, respectively:

Historical and Forecasted Market Size of Global Vascularised Pinguecula Drug Therapies, 2019-2033E



Source: literature review, expert interview, market survey, F&S analysis

Key Growth Driver and Entry Barrier for Market of Drug Therapies Treating Vascularised Pinguecula

The growth in the market of vascularised pinguecula drug therapies has primarily been driven by the following key factors:

Enlarging patient pool. Vascularised pinguecula is a prevalent condition commonly observed in individuals who have been exposed to prolonged periods of ultraviolet light, dust, wind, and other environmental factors. The substantial number of patients affected by vascularised pinguecula provides an opportunity for additional research and clinical intervention to enhance the understanding of the underlying mechanisms, and to develop more effective treatment strategies.

Unmet medical needs. There is currently no approved drug therapy for the treatment of vascularised pinguecula globally. The existing treatment options for vascularised pinguecula are limited, often focusing on alleviating symptoms rather than addressing the underlying disease pathogenesis. Consequently, there is a distinct requirement for innovative therapeutic interventions that directly address the angiogenesis and inflammation associated with vascularized pinguecula. Advancements in this field have the potential to greatly

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enhance the quality of life for individuals affected by this condition, offering hope for more effective management and even potential resolution option for this challenging ocular disorder.

In addition to the general entry barriers for the global ophthalmic drug market as described in “ – Overview of Ophthalmic Drug Market – Entry Barriers for the Global Ophthalmic Drug Market” above, the R&D obstacles of developing drug therapies indicated for vascularised pinguecula also lie in identifying appropriate (i) modality to target pathogenesis of the disease, (ii) drug delivery method and (iii) formulation for the delivery. Developing and obtaining patents for the method of use by inhibiting relevant growth factors to reduce vascularised pinguecula, and appropriate formulation as an eye drop to treat the disease, based upon the vascular nature of disease, could be an obstacle for other market players.

GLAUCOMA

Overview

Glaucoma is a group of ophthalmic diseases that are usually characterised by progressive structural and functional changes of the optic nerve, leading to glaucomatous appearing optic disc and visual field damage if untreated. Glaucoma is often associated with a long and asymptomatic initial phase, and is usually unnoticed until its later stages. Worldwide, glaucoma is the one of the leading causes of blindness second only to cataracts.

There are two categories of glaucoma, namely, primary glaucoma and secondary glaucoma. Risks of glaucoma include elevated intraocular pressure, ethnic background, aged over 60, special eye conditions, eye injuries or certain eye surgeries and prolonged corticosteroid use.

Glaucoma is one of the leading causes of blindness in both the developed and developing world with a blind rate of up to 38.3%. On top of the significant clinical impact of glaucoma, the associated economic, psychological and social burden caused by such disease is substantial.

Global Prevalence of Glaucoma

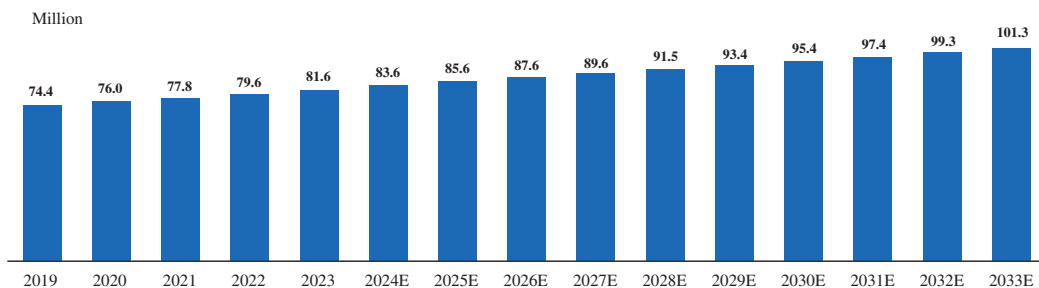
Globally, the patient population of glaucoma reached 81.5 million in 2023, with a CAGR of 2.3% from 2019 to 2023. It is estimated to reach 91.5 million in 2028 and 101.3 million in 2033, respectively, representing a CAGR of 2.3% from 2023 to 2028 and 2.1% from 2028 to 2033, respectively.

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The following chart sets out the global prevalence of glaucoma from 2019 to 2033:

Global Prevalence of Glaucoma, 2019-2033E

Period	CAGR
2019-2023	2.3%
2023-2028E	2.3%
2028E-2033E	2.1%



Source: literature review, F&S analysis

Treatment Paradigm and Unmet Medical Needs

The dominant treatment option for glaucoma includes pharmacologic therapy, laser therapy and conventional surgery. The ultimate goal of glaucoma treatment is to preserve enough vision during the patient's lifetime to meet functional needs. Treatment aim to delay, stop, and ideally reverse the damage to the optic nerve and ganglion cell layer. The only clinically proven way to slow down or stop damage from progressing is to reduce and maintain IOP at an optimal level to avoid further damage to optic nerves. Therefore, the overarching principle for glaucoma treatment is to set a target IOP.

Market Size of Glaucoma Drug Therapies

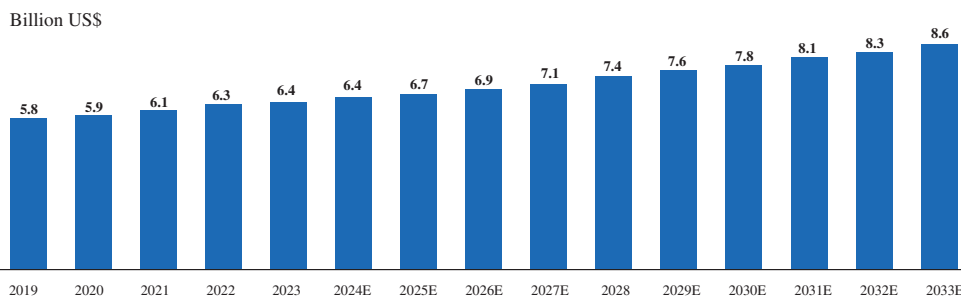
According to the F&S Report, the global market size of glaucoma drug therapies reached US\$6.4 billion in 2023. It is expected to reach US\$7.4 billion in 2028 and US\$8.6 billion in 2033, representing a CAGR of 2.7% from 2023 to 2028 and 3.2% from 2028 to 2033, respectively.

INDUSTRY OVERVIEW

The following chart sets out the global market size of glaucoma drug therapies from 2019 to 2033:

Historical and Forecasted Market Size of Global Glaucoma Drug Therapies, 2019-2033E

Period	CAGR
2019-2023	2.8%
2023-2028E	2.7%
2028E-2033E	3.2%



Source: literature review, expert interview, annual reports published by market players, market survey, F&S analysis

PRESBYOPIA

Overview

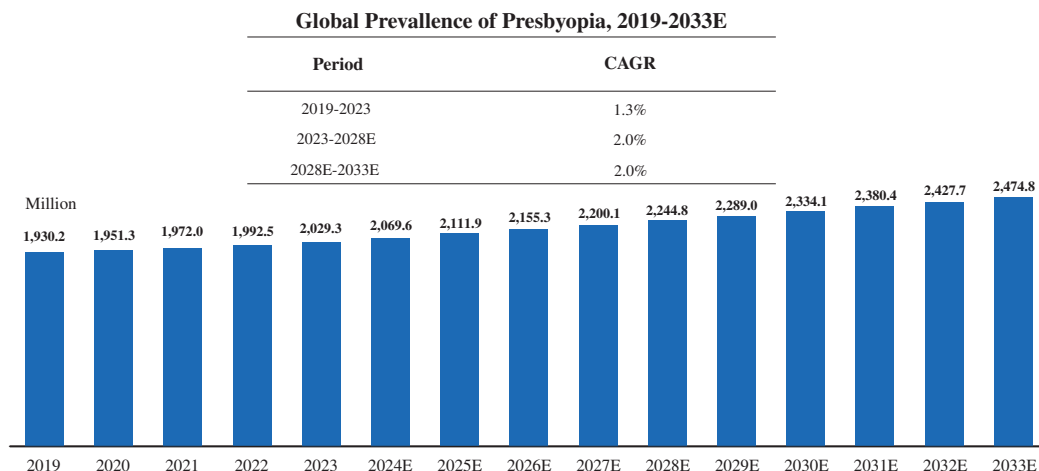
During the aging process, the lens in the eyes would gradually become thicker and lose flexibility. With less elasticity, it is difficult for the eyes to focus up close. Presbyopia is a refractive condition, whereby the progressive loss of accommodation results in loss of the visual ability to focus on objects located at different distance. Symptoms begin to appear after the age of 40. As the world's population is aging, presbyopia is one of the most pressing visual concerns in the future. The mechanism of pharmacological presbyopia treatment is (i) pinhole effect, which increases the depth of focus, and (ii) lens softening to alleviate or reduce the impact on vision loss caused by presbyopia.

Global Prevalence of Presbyopia

Globally, the patient population of presbyopia reached 2,029.2 million in 2023, with a CAGR of 1.3% from 2019 to 2023. It is estimated to reach 2,244.8 million in 2028 and 2,474.8 million in 2033, respectively, representing a CAGR of 2.0% from 2023 to 2028 and 2.0% from 2028 to 2033, respectively.

INDUSTRY OVERVIEW

The following chart sets out the global prevalence of presbyopia from 2019 to 2033:



Source: literature review, F&S analysis

Treatment Paradigm and Unmet Medical Needs

Current treatment options for presbyopia include optical correction, drug therapies and refractive surgery. Spectacles and contact lenses are two major options for optical correction, both of which may limit the use for some patients. Current drug therapies indicated for presbyopia may lead to adverse reaction, including chronic inflammation, stimulation of the fixed pupils, posterior contractions of the iris, pigment dispersion and myopic shift. However, they are only able to improve the vision, but not able to cure presbyopia. Refractive surgery includes the options of laser surgery, intracorneal inlays, and intraocular lens implantation. Some of the options are irreversible, or have late complications, or may lead to prolonged postoperative recovery.

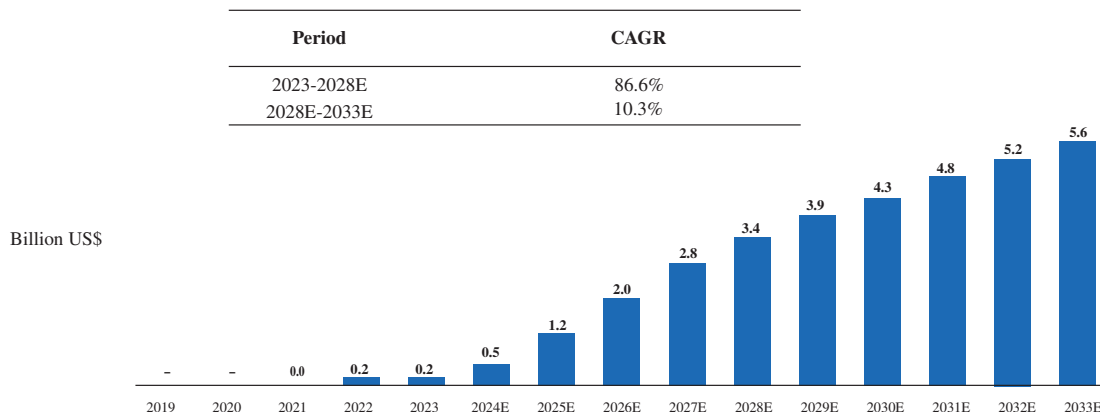
Market Size of Presbyopia Drug Therapies

According to the F&S Report, the global market size of presbyopia drug therapies reached US\$0.2 billion in 2023. It expected to reach US\$3.4 billion in 2028 and US\$5.6 billion in 2033, representing a CAGR of 86.6% from 2023 to 2028 and 10.3% from 2028 to 2033, respectively.

INDUSTRY OVERVIEW

The following chart sets out the global market size of presbyopia drug therapies from 2019 to 2033:

Forecasted Market Size of Global Presbyopia Drug Therapies, 2019-2033E



Source: literature review, expert interview, annual reports published by market players, market survey, F&S analysis

SOURCE OF INFORMATION

In connection with the Global Offering, we have commissioned Frost & Sullivan, an Independent Third Party, to conduct a detailed analysis and to prepare an industry report on the global ophthalmic drug markets as well as in the United States and China. The F&S Report has been prepared by Frost & Sullivan independent from our influence. We have agreed to pay Frost & Sullivan a fee of RMB690,091 for the preparation of the F&S Report which we consider is in line with the market rates. Except as otherwise noted, all data and forecasts in this section are derived from the F&S Report. Our Directors confirm that, after taking reasonable care, there is no adverse change in the market information since the date of the F&S Report which may qualify, contradict or have an impact on the information disclosed in this section in any material respect.

Frost & Sullivan prepared its report based on its in-house database, Independent Third Party reports and publicly available data from reputable industry organisations. To prepare the F&S Report, Frost & Sullivan also conducted analysis on projected figures based on historical data, macroeconomic data and specific industry related drivers, and reviewed annual reports of listed companies in the global, the United States and China ophthalmic drug markets. In compiling and preparing the F&S Report, Frost & Sullivan has adopted the following assumptions: (i) the social, economic and political environments of the United States and China will remain stable during the forecast period, which will ensure a sustainable and steady development of the United States and China healthcare industry; (ii) both the United States and China healthcare markets will grow as expected due to rising healthcare demand and supply; and (iii) both the United States and the Chinese governments will continue to support healthcare reform.

REGULATORY OVERVIEW

REGULATIONS RELATING TO THE PRC

Drug Administration

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**Innovation Opinion**”) to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing.

The PRC Drug Administration Law (《中華人民共和國藥品管理法》), promulgated by the Standing Committee of the National People’s Congress (全國人民代表大會常務委員會) (the “**SCNPC**”) on 20 September 1984, last amended on 26 August 2019 and effective from 1 December 2019, and the Regulations for the Implementation of the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》), promulgated by the State Council on 4 August 2002, last amended on 6 December 2024 and effective from 20 January 2025, establishes the legal framework for the administration of pharmaceutical products, including the research, development, manufacturing and business operation of new drugs, and provides regulations applicable to the administration of pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The latest amendment on the PRC Drug Administration Law implements sweeping changes to the previous laws, which includes without limitation: (1) improving the supervision system for the entire drug approval process; (2) clarifying the responsibilities in drug supervision; (3) strengthening the punishment of illegal behavior; (4) implementing the marketing authorisation holder system; (5) reforming the drug approval system; (6) cancellation of the good manufacturing practice (the “**GMP**”) certifications for drugs and good supply practice certifications for pharmaceutical products; and (7) replacement of approval by registration of clinical trial organisations and improvement of the approval procedure for clinical trials. Drug Registration Regulation (《藥品註冊管理辦法》), promulgated by the National Medical Products Administration (國家藥品監督管理局) (the “**NMPA**”) on 30 October 2002, last amended by the State Administration of Market Regulation (國家市場監督管理總局) (the “**SAMR**”) on 22 January 2020 and effective from 1 July 2020, further stipulates regulations governing clinical trial applications, marketing approval, and post-approval amendment and renewal.

Drug Clinical Trial

Drug Clinical Trial Approval

The Administration of Quality of Drug Clinical Practice (《藥物臨床試驗質量管理規範》), promulgated by the China Food and Drug Administration (國家食品藥品監督管理總局) (the “**CFDA**”, revoked on 18 March 2018) on 6 August 2003, last amended by NMPA and the National Health Commission (國家衛生健康委員會) (the “**NHC**”) on 23 April 2020 and effective from 1 July 2020, refines and specifies the responsibility requirements for all parties involved in drug clinical trials. It also emphasises on the importance of essential

REGULATORY OVERVIEW

documents of a clinical trial as checked by the sponsor and drug administration authorities and as the basis for confirming the authenticity of the implementation of the clinical trial and the completeness of the data collected. The Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), promulgated by NMPA and NHC on 29 November 2019 and effective from 1 December 2019, specifies all clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed.

Pursuant to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on 11 November 2015, an umbrella approval would be issued by NMPA for all phases of a new drug clinical trial, instead of obtaining approvals phase by phase. Pursuant to the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》), both promulgated by NMPA on and effective from 24 July 2018, applicants could proceed with their clinical trials if they have not received any denial or query from the Center for Drug Evaluation of NMPA (國家藥監局藥審中心) (the “CDE”) within 60 business days after the application has been accepted and the relevant application fees have been paid. The PRC Drug Administration Law further stipulates that the CDE shall within 60 working days from the date on which the application for a clinical trial is accepted, decide whether to approve such application and then notify the clinical trial applicant. Failure by CDE to notify the applicant within the prescribed time limit shall be deemed as approval of the application. Pursuant to the Announcement of the Opinions on Handling Issues Related to Verification of Drug Clinical Trial Data (《關於藥物臨床試驗數據核查有關問題處理意見的公告》), both promulgated by CFDA on and effective from 22 May 2017, if the clinical trial data is incomplete, ill-formed and insufficient to prove the safety and efficacy of the drug, the registration application of the drug will be rejected.

Drug Clinical Trial Registration

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme of the clinical trial and other information on the drug clinical trial registration and information platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall continuously update registered information, and finalise information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. Pursuant to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), both promulgated by CFDA on and effective from 6 September 2013, for all clinical trials approved and conducted in China shall be published through the drug clinical trial registration and information platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial’s unique registration number and shall complete certain follow-up information and complete the first submission for publication before the first subject’s enrolment in the trial. If the forementioned publication has not been submitted within one year after applicant’s obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

REGULATORY OVERVIEW

Conducting Clinical Trial

Pursuant to the Drug Registration Regulation, a clinical trial principally consists of four phases and biosimilar trial. Based on the characteristics of drugs and research objective, the researching content include clinical pharmacology research, exploratory clinical trials, confirmatory clinical trials and post-marketing research. In order to conduct a clinical trial in China, NMPA requires the sponsor to apply for ethics committee's approval and comply with the relevant requirements of quality management standards for clinical trial of drugs in China. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

Pursuant to the Administration of Quality of Drug Clinical Practice, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution.

Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. Compliance with quality control regulations would be inspected by relevant authorities. The protocol of a clinical trial must be approved by the ethics committee.

Pursuant to the PRC Drug Administration Law and the Regulations on the Administration of Drug Clinical Trial Institutions, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required to perform filing procedures.

Human Genetic Resources Approval

Pursuant to the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) (the “**Human Genetic Resource Regulation**”), promulgated by the PRC State Council on 28 May 2019, effective from 1 May 2024, and last amended on 10 March 2024, human genetic resource includes human genetic resource materials and information. Human genetic resource materials shall refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information shall refer to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalised the specific requirements to obtain approval relating to research collaborations between Chinese and foreign entities. Utilisation of China's human genetic resources in internally cooperative clinical trial with the purpose of obtaining marketing licenses for drugs and medical devices, which involves no export or emigration of human genetic resources, is not subject to relevant approval. However, parties to such internationally cooperative clinical trial shall submit a filing about the category, quantity, usage of human genetic resources. Foreign organisations, individuals

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and institutions established or actually controlled by foreign organisations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

New Drug Application and Approval

Pursuant to the PRC Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognised as a holder of the drug sales approval and responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the PRC Drug Administration Law. The holder of the drug sales approval may engage in manufacturing or distribution on their own, or to entrust a licensed third party. At the time of application for drug sales approval, the applicant and the manufacturing enterprise shall have held the corresponding permission for pharmaceutical manufacturing.

Pursuant to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug sales approval, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organise pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. It also stipulates the review procedure for drugs of breakthrough therapy, conditional approval procedure, priority review procedure and special approval procedure. The following illustrates the drug registration approval procedures pursuant to the New Registration Administrative Measures.

Pursuant to the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), both promulgated by NMPA on and effective from 11 November 2015, provides fast-track clinical trial approvals and drug registration pathways for the specific category of new drug applications. In addition, the Circular on Issues Concerning Optimising Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), both promulgated by NMPA and NHC on and effective from 17 May 2018, further simplifies and accelerates the approval process of specific kind of drugs.

Drug Production

Drug Manufacturing Permit

Pursuant to the PRC Drug Administration Law and the Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》), promulgated by the NMPA on 11 December 2002, last amended on 22 January 2020 and effective on 1 July 2020, a drug manufacturer must obtain the permission for drug manufacturing from the provincial authorities related to medical products before it commences to manufacture drug products. Prior to granting such permit, the relevant government authority will inspect the applicant's

REGULATORY OVERVIEW

production facilities and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards. Each Drug Manufacturing Permit will be valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

Good Manufacturing Practice

Pursuant to the Norms on Good Manufacturing Practices (《藥品生產質量管理規範》), issued by the Ministry of Health (revoked on 10 March 2013) on 28 December 1992 and last amended on 17 January 2011 and effective from 1 March 2011, sets out the basic standard for the manufacture of pharmaceuticals products, which includes the production facilities, the qualification of the management personnel, production plant and facilities, documentation, material packaging and labelling, inspection, production management, sales and return of products and customers' complaints.

Contract Manufacturing of Drug

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drug (《藥品委託生產監督管理規定》), promulgated by CFDA on 14 August 2014 and effective from 1 October 2014, in the event that a drug manufacturer in China that has obtained a drug marketing authorisation temporarily lacks manufacturing conditions as a result of technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, it can entrust the manufacturing of that drug to another domestic drug manufacturer. Such contract manufacturing arrangements needs to be approved by the provincial branch of NMPA. It further prohibits the contract manufacturing arrangement of certain special drugs, including narcotic drugs, psychoactive drugs, biochemical drugs and active pharmaceutical ingredients.

Pursuant to the PRC Drug Administration Law, a drug manufacturer can entrust the manufacturing of drug to another qualified drug manufacturer. Entrusted manufacturing of blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals is prohibited, unless otherwise stipulated by the drug administrative department of the State Council. The PRC Drug Administration Law specifies that a holder of drug sales approval may produce drugs by itself or may entrust other drug manufacturers. A holder of drug sales approval that intends to manufacture drugs on its own shall obtain a drug manufacturing permit, or if the holder intends to entrust a third-party to manufacture, it shall entrust a qualified drug manufacturer. The holder of drug sales approval and the commissioned manufacturer shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations pursuant to such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the drug administrative department of the State Council.

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Export of Drug

Pursuant to the Reply by NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), both promulgated on and effective from 20 September 1999, enterprise's right to operate import and export of pharmaceutical products and the qualification shall be decided by the foreign trade authority. Export of pharmaceutical products shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the NMPA would support the export in principal based on the national policy of encouraging exports. However, pursuant to the PRC Drug Administration Law, the export license issued by NMPA is required for the export of narcotics and psychotropic drugs prescribed by the PRC.

Regulations relating to Personal Information and Data Protection

Cybersecurity

On 7 November 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the “**Cybersecurity Law**”), which became effective on 1 June 2017. The Cybersecurity Law requires network operators to comply with laws and regulations and fulfill their obligations to safeguard security of the network when conducting business and providing services. The Cybersecurity Law further requires network operators to take all necessary measures in accordance with applicable laws, regulations and compulsory national standards to safeguard the safe and stable operation of the networks, respond to cybersecurity incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data.

The Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “**MCR**”) were promulgated jointly by the Cyberspace Administration of China (“**CAC**”) and the other 12 governmental authorities, and became effective on 15 February 2022. The MCR stipulates that the operators carrying out data processing activities that affect or may affect national security, shall conduct cyber security review. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad (國外上市).

Data Security

The Data Security Law of the PRC (《中華人民共和國數據安全法》), promulgated by the SCNPC on 10 June 2021, and effective from 1 September 2021, stipulates that entities engaged in data processing activities must comply with laws and regulations. These entities are required to establish and improve a comprehensive data security management system the data processing lifecycle, strengthen the risk monitoring mechanism, conduct regular risk assessments, and report to the relevant authorities.

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Personal Information Protection

On 20 August 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the “**Personal Information Protection Law**”), which came into effect on 1 November 2021. The law stipulates certain important concepts with respect to personal information processing activities: (i) “personal information” refers to all kinds of information related to identified or identifiable natural persons recorded by electronic or other means, excluding the information processed anonymously; (ii) “personal information processing activities” include the collection, storage, use, processing, transmission, provision, disclosure and deletion, etc. of personal information; and (iii) “personal information processor” refers to an organisation or individual that independently determines the purpose and methods in the processing of personal information.

Data Cross-border Transfer

On 7 July 2022, the CAC promulgated the Measures for the Security Assessment of Data Cross-border Transfer (《數據出境安全評估辦法》), which took effect on 1 September 2022. The Measures for the Security Assessment of Data Cross-border Transfer requires the data processor providing data overseas and falling under any of the following circumstances apply for the security assessment of cross-border data transfer by the national cybersecurity authority through its local counterpart: (i) where the data processor intends to provide important data overseas; (ii) where the critical information infrastructure operator and any data processor who has processed personal information of more than 1,000,000 people intend to provide personal information overseas; (iii) where any data processor who has provided personal information of 100,000 people or sensitive personal information of 10,000 people to overseas recipients accumulatively since 1 January of the last year intends to provide personal information overseas; and (iv) other circumstances where the security assessment of data cross-border transfer is required as prescribed by the CAC.

On 22 February 2023, the CAC promulgated Measures for the Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), which came into effect on 1 June 2023. Pursuant to Measures for the Standard Contract for Outbound Transfer of Personal Information, personal information processor transferring personal information abroad shall conclude Standard Contract if satisfy all the following conditions: (1) the data processor who intends to transfer personal information abroad is not a critical information infrastructure operator; (2) the data processor processes personal information of less than one million individuals; (3) the data processor has cumulatively transferred abroad the personal information of less than 100,000 individuals since 1 January of the previous year; and (4) the data processor has cumulatively transferred abroad the sensitive personal information of less than 10,000 individuals since 1 January of the previous year. The Measures for the Standard Contract for Outbound Transfer of Personal Information came into effect on 1 June 2023, and a six-month grace period is provided. Any violation of the Standard Contract Measures shall be punished in accordance with the Personal Information Protection Law and other laws and regulations.

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On 22 March 2024, the CAC issued the Provisions on Facilitating and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》) (the “**Cross-Border Data Flows Provisions**”), which provides the following circumstances under which data processors shall, through the local cyberspace administration at the provincial level, apply to the national cyberspace administration for security assessment of cross-border data transfer: (i) critical information infrastructure operators providing personal information or important data overseas; and (ii) data processors other than critical information infrastructure operators providing important data overseas, or cumulatively providing overseas personal information (excluding sensitive personal information) of more than 1 million individuals or sensitive personal information of more than 10,000 individuals since 1 January of the current year. The Cross-Border Data Flows Provisions also provides that, where the data processors other than critical information infrastructure operators provide personal information (excluding sensitive personal information) overseas of not less than 100,000 but not more than one million individuals, or the sensitive personal information of not more than 10,000 individuals, cumulatively as of 1 January of the current year, it shall conclude a standard contract with overseas recipients or pass the authentication on personal information protection. Articles 3 to 6 of the Cross-Border Data Flows Provisions mainly provide the exemptions from applying for the security assessment or authentication, and filing the standard contracts. Exemptions include but are not limited to international trade, cross-border transportation, academic cooperation, transactional manufacturing, marketing and other activities that do not involve personal information or important data, among others. Any failure to comply with such requirements may subject us to, among others, suspension of services, fines, revoking relevant business permits or business licenses and penalties.

Regulations relating to Company Law and Foreign Investment

Principal Foreign Investment Administration

The establishment, operation and management of corporate entities in the PRC is governed by the Company Law of PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was issued by the SCNPC on 29 December 1993, the latest effective amendment of which became effective from 1 July 2024. Limited liability companies and stock limited companies established in the PRC shall be subject to the Company Law. A foreign-invested company is also subject to the Company Law unless otherwise provided by the foreign investment laws.

On 1 January 2020, the PRC Foreign Investment Law (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) promulgated by the NPC and the Regulations for Implementation of the PRC Foreign Investment Law (《中華人民共和國外商投資法實施條例》) promulgated by the State Council came into effect and became the principal laws and regulations governing foreign investment in the PRC, replacing three previous major laws regulating foreign investment in the PRC, namely, the PRC Sino-foreign Equity Joint Venture Enterprise Law (《中華人民共和國中外合資經營企業法》), the PRC Sino-foreign Cooperative Joint Venture Enterprise Law (《中華人民共和國中外合作經營企業法》), and the PRC Wholly Foreign-invested Enterprise Law (《中華人民共和國外資企業法》), together with their implementation rules and ancillary regulations.

REGULATORY OVERVIEW

Pursuant to the Foreign Investment Law, “foreign investment” shall refer to the investment activities conducted directly or indirectly by foreign individuals, enterprises or other entities in the PRC, including the following circumstances: (i) the establishment of foreign-invested enterprises in the PRC by foreign investors solely or jointly with other investors; (ii) a foreign investor’s acquisition of shares, equity interests, property portions or other similar rights and interests of enterprises in the PRC; (iii) investment in new projects in the PRC by foreign investors solely or jointly with other investors; and (iv) investments made by foreign investors through means provided in laws, administrative regulations, or other methods prescribed by the State Council. The Foreign Investment Law and the Regulations for Implementation of the Foreign Investment Law provide that a system of pre-entry national treatment and negative list shall apply to the administration of foreign investment, where “pre-entry national treatment” means that the treatment given to foreign investors and their investments at market entry stage is no less favourable than that given to domestic investors and their investments, and “negative list” means the special administrative measures for foreign investment’s entry to specific fields or industries. Foreign investments not in the fields of the negative list will be granted national treatment. Foreign investors shall not invest in the prohibited fields as specified in the negative list, and foreign investors who invest in the restricted fields shall comply with certain special requirements on shareholding and senior management personnel, etc.

Industry Catalogue of Foreign Investment

Investments in the PRC by foreign investors and foreign-invested enterprises were regulated by the Catalogue of Industries for Guiding Foreign Investment (《外商投資產業指導目錄》), later replaced by the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2019 Version) (《外商投資准入特別管理措施(負面清單)(2019年版)》) (the “**Negative List 2019**”) and the Catalogue of Industries for Encouraging Foreign Investment (2019 Version) (《鼓勵外商投資產業目錄(2019年版)》) (the “**Encouraging Catalogue 2019**”) which were promulgated by the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會) (the “**NDRC**”) and the MOFCOM on 30 June 2019 and became effective from 30 July 2019. On 23 June 2020, the NDRC and the MOFCOM promulgated the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020 Version) (《外商投資准入特別管理措施(負面清單)(2020年版)》) (the “**Negative List 2020**”), which became effective from 23 July 2020 and replaced the Negative List 2019. On 27 December 2020, the NDRC and the MOFCOM promulgated the Catalogue of Industries for Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) (the “**Encouraging Catalogue 2022**”), which became effective from 1 January 2023 and replaced the Encouraging Catalogue 2019. On 27 December 2021, the NDRC and the MOFCOM promulgated the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2021 Version) (《外商投資准入特別管理措施(負面清單)(2021年版)》) (the “**Negative List 2021**”), which became effective from 1 January 2022 and replaced the Negative List 2020. On 6 September 2024, the NDRC and the MOFCOM promulgated the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the “**Negative List 2024**”), which became effective from 1 November 2024 and replaced the Negative List 2021. Pursuant to the Encouraging Catalogue 2022 and the Negative List 2024, foreign-invested projects are categorised as encouraged, restricted and prohibited.

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Foreign Investment Information Report

On 30 December 2019, the MOFCOM and SAMR jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), which became effective from 1 January 2020. Pursuant to the measures, where a foreign investor directly or indirectly carries out investment activities within PRC, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department through the enterprise registration system and the national enterprise credit information publicity system.

Foreign Exchange

Pursuant to the PRC Foreign Currency Administration Rules (《中華人民共和國外匯管理條例》) promulgated by the State Council on 29 January 1996 and last amended on 5 August 2008 and various regulations issued by the State Administration of Foreign Exchange (國家外匯管理局) (the “SAFE”) and other relevant PRC government authorities, RMB is generally freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan, or investment in securities outside the PRC, unless the prior approval by the SAFE or its local counterparts is obtained.

On 4 July 2014, the SAFE promulgated the Notice of State Administration of Foreign Exchange on Issues Relating to Foreign Exchange Control for Overseas Investment and Financing and Round-tripping by Chinese Residents through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “SAFE Circular No. 37”), which regulates foreign exchange matters in relation to the use of special purpose vehicles by PRC residents or entities to seek offshore investment and financing or conduct round trip investment in China. Pursuant to SAFE Circular No. 37, a “special purpose vehicle” shall refer to an offshore entity established or controlled, directly or indirectly, by PRC residents or entities for the purpose of seeking offshore financing or making offshore investment, using legitimate onshore or offshore assets or interests, and “round trip investment” shall refer to direct investment in China by PRC residents or entities through special purpose vehicles, namely, establishing foreign-invested enterprises to obtain ownership, control rights, and management rights. SAFE Circular No. 37 provides that, before making a contribution into a special purpose vehicle, PRC residents or entities are required to complete foreign exchange registration with SAFE or its local branch. On 13 February 2015, the SAFE promulgated the Notice of the SAFE on Further Simplifying and Improving the Foreign Currency Management Policy on Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), effective from 1 June 2015, which further amended SAFE Circular No. 37 by requiring PRC residents or entities to register with qualified banks rather than the SAFE or its local branches in connection with their establishment of an offshore entity established for the purpose of overseas investment or financing.

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Tax

Enterprise Income Tax

The PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) and Regulations for the Implementation of the PRC Enterprise Income Tax (《中華人民共和國企業所得稅法實施條例》) (collectively, the “**EIT Laws**”) were promulgated on 16 March 2007 and 6 December 2007, respectively, and were amended on 29 December 2018 and 23 April 2019, respectively. Pursuant to the EIT Laws, taxpayers consist of resident enterprises and non-resident enterprises. Resident enterprises are defined as enterprises that are established in China in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered within China. Non-resident enterprises are defined as enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside China, but have established institutions or premises in China, or have no such established institutions or premises but have income generated from inside China. Pursuant to the EIT Laws and relevant implementing regulations, a uniform EIT rate of 25% is applicable. However, if non-resident enterprises have not formed permanent establishments or premises in China, or if they have formed permanent establishment institutions or premises in China but there is no actual relationship between the relevant income derived in China and the established institutions or premises set up by them, the enterprise income tax is, in that case, set at the rate of 10% for their income sourced from inside China.

Value Added Tax

The PRC Interim Value-added Tax Regulations (《中華人民共和國增值稅暫行條例》) (the “**VAT Regulations**”) was promulgated by the State Council on 13 December 1993 and last amended on 19 November 2017. Pursuant to the VAT Regulations, value added tax is imposed on goods sold in or imported into the PRC and on processing, repair and replacement services provided within the PRC.

Intellectual Property Rights

Patent

Patents are protected by the PRC Patent Law (《中華人民共和國專利法》) which was promulgated on 12 March 1984 and last amended on 17 October 2020 taking effect from 1 June 2021. The Patent Office pursuant to the National Intellectual Property Administration is responsible for receiving, examining, and approving patent applications. According to the PRC Patent Law, the patent right protection period is 20 years for an invention patent, 10 years for a utility model patent and 15 years for a design patent (10 years for a design patent filed on or before 31 May 2021), counted from the date of filing. Except under certain specific circumstances provided by law, any party seeking to use a patent owned by another party shall obtain consent or a proper license from the patent owner, or else the use will constitute an infringement of the rights of the patent owner.

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Trademark

Trademarks are protected by the PRC Trademark Law (《中華人民共和國商標法》) which was promulgated on 23 August 1982 and last amended on 23 April 2019 as well as the Regulation for Implementation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) which was promulgated by the State Council on 3 August 2002 and amended on 29 April 2014. In China, registered trademarks include commodity trademarks, service trademarks, collective marks, and certification marks. The PRC Trademark Office of National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout the PRC, and grants a term of ten years to registered trademarks. Trademarks are renewable every ten years where a registered trademark needs to be used after the expiration of its validity term. A registration renewal application shall be filed within twelve months prior to the expiration of the term. A trademark registrant may license its registered trademark to another party by entering into a trademark license contract. The licensor shall supervise the quality of the commodities on which the trademark is used, and the licensee shall guarantee the quality of such commodities. The PRC Trademark Law has adopted a “first come, first file” principle with respect to trademark registration. Where trademark for which a registration application has been made is identical or similar to another trademark which has already been registered or been subject to a preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right first obtained by others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use.

Copyright

The PRC Copyright Law (《中華人民共和國著作權法》), which was promulgated by the SCNPC on 7 September 1990 and amended on 11 November 2020, provides that Chinese citizens, legal persons, or other organisations shall, whether published or not, enjoy copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology, and computer software.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網絡域名管理辦法》) promulgated by the Ministry of Information Industry on 24 August 2017 and effective from 1 November 2017, “domain name” shall refer to the character mark of hierarchical structure, which identifies and locates a computer on the internet and corresponds to the Internet protocol (IP) address of such computer. The principle of “first come, first served” applies to domain name registration service. After completing the domain name registration, the applicant will become the holder of the registered domain name. Furthermore, the holder shall pay operation fees for registered domain names on schedule. If the domain name holder fails to pay corresponding fees as required, the original domain name registry shall deregister the relevant domain name and notify the holder of deregistration in written forms.

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Employment and Social Welfare

The Labour Contract Law

Pursuant to the PRC Labour Law (《中華人民共和國勞動法》) promulgated on 5 July 1994 and last amended on 29 December 2018, enterprises and institutions shall establish and improve their system of workplace safety and sanitation, strictly abide by state rules and standards on workplace safety, educate labourers in labour safety and sanitation in China. Labour safety and sanitation facilities shall comply with state-fixed standards. Enterprises and institutions shall provide labourers with a safe workplace and sanitation conditions which are in compliance with state stipulations and the relevant articles of labour protection. The PRC Labour Contract Law (《中華人民共和國勞動合同法》), which was promulgated on 29 June 2007, amended on 28 December 2012 and effective from 1 July 2013, is primarily aimed at regulating employee/employer rights and obligations, including matters with respect to the establishment, performance and termination of labour contracts. Pursuant to the PRC Labour Contract Law, labour contracts shall be concluded in writing if labour relationships are to be or have been established between enterprises or institutions and the labourers. Enterprises and institutions are forbidden to force labourers to work beyond the time limit and employers shall pay labourers for overtime work in accordance with the laws and regulations. In addition, labour wages shall not be lower than local standards on minimum wages and shall be paid to labourers in a timely manner.

Social Insurance and Housing Fund

As required pursuant to the Regulation of Insurance for Labour Injury (《工傷保險條例》) promulgated on 27 April 2003, amended on 20 December 2010 and effective from 1 January 2011, the Provisional Measures for Maternity Insurance of Employees of Corporations (《企業職工生育保險試行辦法》) effective from 1 January 1995, the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance for Employees of Corporations of the State Council (《國務院關於建立統一的企業職工基本養老保險制度的決定》) promulgated on 16 July 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (《國務院關於建立城鎮職工基本醫療保險制度的決定》) promulgated on 14 December 1998, the Unemployment Insurance Measures (《失業保險條例》) promulgated on 22 January 1999, and the PRC Social Insurance Law (《中華人民共和國社會保險法》) promulgated on 10 October 2010, amended and effective from 29 December 2018, enterprises are obliged to provide their employees in China with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, labour injury insurance, and medical insurance. These payments are made to local administrative authorities and any employer that fails to contribute may be fined and ordered to make up within a prescribed time limit. In accordance with the Regulations on the Management of Housing Funds (《住房公積金管理條例》) which was promulgated by the State Council on 3 April 1999 and last amended on 24 March 2019, enterprises must register at the competent managing centre for housing funds and upon the examination by such managing centre of housing funds, these enterprises shall complete procedures for opening an account at the relevant bank for the deposit of employees' housing funds. Enterprises are also required to pay and deposit housing funds on behalf of their employees in full and in a timely manner.

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Environmental Protection

Pursuant to the PRC Environmental Protection Law (《中華人民共和國環境保護法》) promulgated by the SCNPC on 26 December 1989 and amended on 24 April 2014, the PRC Environmental Impact Assessment Law (《中華人民共和國環境影響評價法》) promulgated by the SCNPC on 28 October 2002 and respectively amended on 2 July 2016 and 29 December 2018, the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》) promulgated by the State Council on 29 November 1998 and amended on 16 July 2017, and other relevant environmental laws and regulations, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

Enterprises generating environmental pollution in the PRC must comply with the PRC Law on the Prevention from Water Pollution (《中華人民共和國水污染防治法》) promulgated by the SCNPC on 11 May 1984, and last amended on 27 June 2017, the PRC Law on the Prevention from Atmospheric Pollution (《中華人民共和國大氣污染防治法》) promulgated by the SCNPC on 5 September 1987, and last amended on 26 October 2018, the PRC Law on the Prevention from Noise Pollution (《中華人民共和國噪聲污染防治法》) promulgated by the SCNPC on 24 December 2021 and effective from 5 June 2022, and the PRC Law on the Prevention from Environmental Pollution of Solid Waste (《中華人民共和國固體廢物污染環境防治法》) promulgated by the SCNPC on 30 October 1995, and last amended on 29 April 2020. The abovementioned laws regulate extensive issues in relation to the environment protection including waste water discharge, air pollution control, noise emission and solid waste pollution control. Pursuant to these laws, all the enterprises that may cause environmental pollution in the course of their production and business operation shall introduce environmental protection measures in their plants and establish a reliable system for environmental protection.

Fire Protection

Pursuant to the PRC Fire Prevention Law (《中華人民共和國消防法》), which was promulgated on 29 April 1998 and last amended on 29 April 2021, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. Pursuant to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) promulgated by the Ministry of Housing and Urban-Rural Development of the PRC on 1 April 2020 and last amended on 21 August 2023, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

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M&A Rules

Pursuant to the Regulations on Merger with and Acquisition of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the “**M&A Rules**”) jointly promulgated by the MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the SAT, the China Securities Regulatory Committee (the “**CSRC**”), the State Administration for Industry and Commerce and the SAFE on 8 August 2006, effective from 8 September 2006 and amended on 22 June 2009, a foreign investor is required to obtain necessary approvals when it (i) acquires the equity of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (ii) subscribes the increased capital of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (iii) establishes a foreign-invested enterprise to purchase the assets of a domestic enterprise and operates these assets; or (iv) purchases the assets of a domestic enterprise, and then invests such assets to establish a foreign-invested enterprise. The M&A Rules, among other things, further purport to require that an offshore special vehicle, or a special purpose vehicle, established for listing purposes and controlled directly or indirectly by PRC companies or individuals, shall obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle’s shares on an overseas stock exchange, especially in the event that the special purpose vehicle acquires shares of or equity interests in the PRC companies in exchange for the shares of offshore companies.

Overseas Listing

On 6 July 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly promulgated the Opinions on Strictly Cracking Down on Illegal Securities Activities in accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》) (the “**Opinions on Securities Activities**”). The Opinions on Securities Activities emphasizes the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

Furthermore, on 17 February 2023, the CSRC promulgated Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”) and five relevant guidelines, which became effective from 31 March 2023. Pursuant to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, shall complete the filing procedures and report relevant information to the CSRC. The Overseas Listing Trial Measures provide that if the issuer meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as an indirect overseas offering subject to the filing procedure: (i) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the issuer’s business activities are substantially conducted in mainland China, or its primary place(s) of business are located in mainland China, or the senior managers in charge of its business operations and management

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are mostly Chinese citizens or domiciled in mainland China. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted.

At a press conference held for these new regulations, officials from the CSRC clarified that the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures shall be deemed as the existing issuers (“**Existing Issuers**”). Existing Issuers are not required to complete the filing procedures immediately, but they should file with the CSRC when subsequent corporate actions such as refinancing are involved. Domestic companies that have obtained approval from overseas regulatory authorities or securities exchanges (for example, a contemplated offering and/or listing in Hong Kong has passed the hearing of the Stock Exchange) for their indirect overseas offering and listing prior to the effective date of the Overseas Listing Trial Measures but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from 31 March 2023. Those who complete their overseas offering and listing within such six-month period are deemed as Existing Issuers and are not required to file with the CSRC for their overseas offering and listing. Within such six-month transition period, however, if such domestic companies need to reapply for offering and listing procedures to the overseas regulatory authority or securities exchanges (such as requiring a new hearing for the listing application of its shares on the Stock Exchange), or if they fail to complete their indirect overseas issuance and listing, such domestic companies shall complete the filing procedures with the CSRC. On 17 February 2023, the CSRC also promulgated the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which clarifies that on or prior to the effective date of the Overseas Listing Trial Measures, domestic companies that have already submitted valid applications for overseas offering and listing but have not obtained approval from overseas regulatory authorities or stock exchanges may reasonably arrange the timing for submitting their filing applications with the CSRC, and must complete the filing before the completion of their overseas offering and listing.

We have submitted a filing to the CSRC on 4 December 2023 pursuant to the filing procedures as stipulated in the Overseas Listing Trial Measures in connection with the Listing. The CSRC issued the Notice of Filing on 10 December 2024 for the Global Offering and for the listing of the Shares on the Stock Exchange.

On 24 February 2023, the CSRC promulgated the Provisions on Strengthening Confidentiality and Archives Administration in Respect of Overseas Issuance and Listing of Securities by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Confidentiality Provisions**”), which became effective from 31 March 2023. Pursuant to the Confidentiality Provisions, domestic joint-stock enterprises listed in overseas markets via direct offering and domestic operational entities of enterprises listed in overseas markets via indirect offering must obtain approval and complete filing or other requirements before they publicly disclose any documents and materials that contain state secrets or government work secrets or that, if divulged, will jeopardise China’s national security or public interest, or before they provide such documents or materials to entities or individuals such as securities companies, securities service providers and overseas regulators.

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REGULATIONS RELATING TO THE UNITED STATES

U.S. Regulation of Pharmaceutical Product Development and Approval

In the United States, the Food and Drug Administration, or the FDA, regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and the Public Health Service Act, or the PHSA, and their implementing regulations. The process of obtaining approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement correspondence, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the U.S. Department of Justice, or the DOJ, or other governmental entities. Drugs are also subject to other federal, state and local statutes and regulations.

Our drug candidates must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's good laboratory practice regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- Institutional Review Board, or the IRB, approval before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with study protocols, good clinical practice, or GCP, and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;
- preparation and submission to the FDA of an NDA;

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- a determination by the FDA within 60 days of its receipt of an NDA whether the NDA is acceptable for filing; if the FDA determines that the NDA is not sufficiently complete to permit substantive review, it may request additional information and decline to accept the application for filing until the information is provided;
- in-depth review of the NDA by the FDA, which may include review by a scientific advisory committee;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient and finished drug product are produced to assess compliance with the FDA's current good manufacturing practice requirements, or cGMP;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA;
- payment of user fees and the FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, such as a Risk Evaluation and Mitigation Strategy, or REMS, and post-approval studies required by the FDA.

Pre-clinical Studies

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, or NCEs, the pre-clinical development stage generally involves synthesising the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including good laboratory practices. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorisation from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor must resolve with the FDA any outstanding concerns or questions before the clinical trial can begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begin, issues will not arise that could cause the trial to be suspended or terminated.

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Clinical Studies

The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that, in general, all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimised and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. For example, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their [ClinicalTrials.gov](https://clinicaltrials.gov) website.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

- Phase I: In a standard Phase I clinical trial, the drug is initially introduced into a small number of subjects who are initially exposed to a range of doses of the drug candidate.

The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, appropriate dosing, side effect tolerability and safety of the drug.

- Phase Ib: Although Phase I clinical trials are not intended to treat disease or illness, a Phase Ib trial is conducted in patient populations who have been diagnosed with the disease for which the study drug is intended. The patient population typically demonstrates a biomarker, surrogate, or other clinical outcome that can be assessed to show "proof-of-concept." In a Phase Ib study, proof-of-concept typically confirms a hypothesis that the current prediction of a biomarker, surrogate or other outcome benefit is compatible with the mechanism of action of the study drug.
- Phase I/II: A Phase I and Phase II trial for the same treatment is combined into a single study protocol. The drug is administered first to determine a maximum tolerable dose, and then additional patients are treated in the Phase II portion of the study to further assess safety and/or efficacy.

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- Phase II: The drug is administered to a limited patient population to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.
- Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labelling of the drug product. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA. A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase IV clinical trials, are conducted after initial regulatory approval, and they are used to collect additional information from the treatment of patients in the intended therapeutic indication or to meet other regulatory requirements. In certain instances, the FDA may mandate the performance of Phase IV clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCPs and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organised by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorisation for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalise a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive

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and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and the FDA Review Process

Following trial completion, trial results and data are analysed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labelling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support regulatory approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the FDA. Under federal law, the submission of most NDAs is subject to the payment of application user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Paediatric Research Equity Act of 2003, or the PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant paediatric subpopulations and to support dosing and administration for each paediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Under the Prescription Drug User Fee Act, or the PDUFA, as amended, each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through 30 September 2024, the user fee for an application requiring clinical data, such as an NDA, is US\$4,048,695. The PDUFA also imposes a program fee for prescription human drugs US\$416,734. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months

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from the filing date for a “priority review” NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by the FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug’s identity, strength, quality and purity. The FDA may refer applications for drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may re-analyse the clinical trial data, which can result in extensive discussions between the FDA and us during the review process.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its active pharmaceutical ingredient will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorises commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a drug receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labelling or may condition the approval of the NDA on other changes to the proposed labelling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug’s safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialised. The FDA may also place other conditions on approvals including the

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requirement for a REMS to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimisation tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Section 505(b)(2) NDAs

The FDA is authorised to approve an alternative type of NDA under Section 505(b)(2) of the FDCA, based on safety and effectiveness data that were not developed by the applicant. Section 505(b)(2) allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which at least some of the information required to show that the drug is safe and effective for the intended use comes from investigations that "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

505(b)(2) NDAs may provide an alternate and potentially more expeditious pathway to the FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain pre-clinical or clinical studies of the new product. The FDA may also require companies to perform additional studies to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, Congress authorised the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the pre-clinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of

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the drug do not show a significant difference from the rate and extent of absorption of the listed drug.” The Generic Drug User Fee Act, or the GDUFA, as reauthorised, sets forth performance goals for the FDA to review standard ANDA’s within 10 months of their submission, and priority ANDA’s within eight months of their submission if they satisfy certain requirements.

Upon approval of an ANDA, the FDA indicates that the generic product is “therapeutically equivalent” to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider an “AB” therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of an “AB” rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Paediatric Trials

Under the PREA, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant paediatric subpopulations, and to support dosing and administration for each paediatric subpopulation for which the product is safe and effective. With the enactment of the FDASIA, a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Paediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the paediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of paediatric assessments or a full or partial waiver of the requirement to provide data from paediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the paediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials, and/or other clinical development programs. The law requires the FDA to send non-compliance letters to sponsors who do not submit their paediatric assessments as required.

Under the Best Pharmaceuticals for Children Act, or the BPCA, certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor submits information requested by the FDA, relating to the use of the active moiety of the product candidate in children. Although the FDA may issue a written request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a paediatric population, or part of the paediatric population, may produce health benefits in that population.

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The FDASIA permanently reauthorised the PREA and the BPCA, modifying some of the requirements under these laws, and established priority review vouchers for rare paediatric diseases. Pursuant to the Consolidated Appropriations Act of 2021, the FDA's authority to award rare paediatric disease vouchers has been extended until 30 September 2024, and until 30 September 2026 for products that receive Rare Paediatric Disease designation by 30 September 2024.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labelling (known as "**off-label use**"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Modifications or enhancements to the drug or its labelling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Any distribution of prescription drugs and pharmaceutical samples also must comply with the U.S. Prescription Drug Marketing Act, a part of the FDCA.

In the United States, once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that drugs be manufactured in specific approved facilities and in accordance with cGMP. Applicants may also rely on third parties for the production of clinical and commercial quantities of drugs, and these third parties must operate in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organisational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using third-party contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the

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FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase IV testing, risk minimisation action plans and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labelling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centres for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act. If drugs are made available to authorised users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorised sale of pharmaceutical drugs.

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The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with the FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labelling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In 2018, the FDA advanced policies aimed at promoting drug competition and patient access to generic drugs, such as issuing guidance about making complex generic drugs and the circumstances in which approval of a generic product application may be delayed.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed

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with the FDA by the innovator NDA holder. Specifically, the applicant must certify with respect to each relevant patent that: the required patent information has not been filed; the listed patent has expired; the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the notice of the Paragraph IV certification, expiration of the patent, or a decision in the infringement case that is favourable to the ANDA applicant. To the extent that the Section 505(b)(2) applicant relies on the prior FDA findings of safety and efficacy, the applicant is required to certify to the FDA concerning any patents listed for the previously approved product in the Orange Book to the same extent that an ANDA applicant would.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Paediatric exclusivity is another type of regulatory market exclusivity in the United States. Paediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a paediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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We are an innovation-driven clinical-stage ophthalmology biotechnology company dedicated to the development of novel and differentiated treatments. Throughout the years, we have been focusing on the in-house discovery, development and commercialisation of first-in-class and best-in-class ophthalmic therapies. Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on 20 November 2020 and is the holding company of our Group.

The history of our Group can be traced back to September 2015, when Cloudbreak USA (one of our operating subsidiaries) was founded in the U.S. by Dr. Ni (our Single Largest Shareholder, chairman of the Board, Executive Director and chief executive officer) together with other co-founders, namely, Mr. Dinh (our Executive Director) and Dr. Li (our Non-executive Director). Dr. Ni became acquainted with Mr. Dinh during their career at Allergan, having worked alongside each other for over 15 years. Dr. Ni became acquainted with Dr. Li through business and personal contacts in the scientific field in California, the United States, and our founders subsequently became acquainted with each other. In 2015, leveraging on their expertise and knowledge in ophthalmology, they further decided to jointly found Cloudbreak USA, our first principal operating entity.

KEY MILESTONES

The following table summarises various key milestones in our corporate and business development.

Year	Milestone
September 2015	Cloudbreak USA, our first principal operating entity, was incorporated in the United States
December 2016	CBT-001: IND application submitted in the United States, and the FDA did not raise any objection against proceeding with phase 2 clinical trial during the 30-day review period of the IND application
April 2017	CBT-001: commenced phase 2 clinical trial in the United States
April 2018	CBT-001: completed phase 2 clinical trial in the United States
May 2019	CBT-001: FDA did not raise any objection to proceed with phase 3 clinical trial in the EOP2 meeting
April 2020	CBT-001: entered into an exclusive commercialisation licensing arrangement with Grand Pharma
November 2020	Our Company was incorporated in the Cayman Islands
February 2021	CBT-004: IND approval obtained to proceed with phase 2 clinical trial in the United States
May 2022	CBT-006: completed phase 2 clinical trial in the United States
November 2022	CBT-001: IND application submitted in the PRC
January 2023	CBT-009: completed phase 1/2 clinical trial in Australia

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
March 2023	CBT-001: NMPA approval obtained to commence phase 3 MRCT in the PRC
May 2023	Commenced operations of our first pilot production facility in Suzhou, Jiangsu, the PRC
September 2023	CBT-009: FDA did not raise any objection to proceed with phase 3 clinical trial in preliminary responses to our Pre-IND application
August 2024	We entered into an exclusive license agreement with Santen Pharmaceutical Co., Ltd.
September 2024	CBT-009: IND approval obtained to proceed with phase 3 clinical trial in the United States
May 2025	CBT-004: completed phase 2 clinical trial in the United States

OUR CORPORATE DEVELOPMENT AND SHAREHOLDING CHANGES

Our Group comprises our Company, six operating subsidiaries and five investment holding subsidiaries. Set out below is information and the major corporate development history of members of our Group:

Our Operating Subsidiaries

We set forth below certain information on our operating subsidiaries (all of which are our major subsidiaries that made material contributions to our results of operations during the Track Record Period and up to the Latest Practicable Date, save for Cloudbreak Yixing and Cloudbreak Wenzhou which have not yet commenced operations):

No.	Name	Date of incorporation/ establishment/ formation	Ownership as of the Latest Practicable Date	Issued capital / Registered capital	Principal activities	Place of incorporation/ establishment/ formation
1.	Cloudbreak USA	14 September 2015	100%	Not applicable ⁽¹⁾	Research and development of therapeutic drugs, and a holding entity of our patents material to our clinical-stage drug candidates	California, USA
2.	ADS USA	16 January 2017 (subsequently converted to a LLC in Delaware, USA on 16 November 2020)	100%	100 units	Research and development of therapeutic drugs and biologics, and a holding entity of our patents material to our clinical-stage drug candidates	Formed as an LLC in Nevada, USA, subsequently converted to an LLC in Delaware, USA

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

No.	Name	Date of incorporation/ establishment/ formation	Ownership as of the Latest Practicable Date	Issued capital / Registered capital	Principal activities	Place of incorporation/ establishment/ formation
3.	Cloudbreak Guangzhou	30 September 2018	100%	RMB10,970,620	Research and development of therapeutic drugs, and a holding entity of our patents material to our clinical-stage drug candidates in the PRC	PRC
4.	ADS Australia	20 November 2020	100%	100 shares of A\$0.01 each	Clinical development of therapeutic drugs	Australia
5.	Cloudbreak Suzhou	27 September 2021	100%	US\$40 million	Research and pre-clinical and clinical development of therapeutic drugs and operation of production facility	PRC
6.	Cloudbreak Yixing ⁽²⁾	5 September 2023	100%	US\$35 million	Research and pre-clinical and clinical development of therapeutic drugs and biologics	PRC
7.	Cloudbreak Wenzhou ⁽²⁾	11 June 2024	100%	RMB10,000,000	Research and pre-clinical and clinical development of therapeutic drugs and biologics	PRC

Notes:

- (1) According to the fifth amended and restated operating agreement of Cloudbreak USA dated 3 December 2021, our Company was admitted as its sole member.
- (2) As of the Latest Practicable Date, Cloudbreak Yixing and Cloudbreak Wenzhou had not yet commenced operations.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Our Investment Holding Subsidiaries

Set out below are the details of our investment holding subsidiaries:

No.	Name	Date of incorporation	Ownership as of the Latest Practicable Date	Issued capital	Principal activities	Place of incorporation
1.	Cloudbreak Cayman	1 November 2019	100%	240,403 ordinary A shares, 152,484,600 ordinary B shares, 8,873,587 series A preferred shares, and 81,707,570 series B preferred shares, with par value of US\$0.0001 each	Investment holding	Cayman Islands
2.	Cloudbreak BVI	18 November 2019	100%	1 ordinary share of US\$1 each	Investment holding	BVI
3.	Cloudbreak HK	28 November 2019	100%	1 ordinary share of HK\$1 each	Investment holding and trademarks holding	Hong Kong
4.	Cloudbreak Pharma HK	13 June 2022	100%	10,000 ordinary share of HK\$1 each	Investment holding	Hong Kong
5.	Cloudbreak Germany	4 November 2021	100%	25,000 shares of EUR1 each	Investment holding	Germany

MAJOR SHAREHOLDING CHANGES OF OUR GROUP

1. Cloudbreak USA

(a) Formation of Cloudbreak USA

Cloudbreak USA (our first principal operating entity) was formed by Dr. Ni (our Single Largest Shareholder, chairman of the Board, Executive Director and chief executive officer) as a limited liability company under the laws of the state of California of the U.S. on 14 September 2015. Dr. Ni, together with Mr. Dinh (our Executive Director) and Dr. Li (our Non-executive Director) are considered as co-founders of Cloudbreak USA and our Group.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(b) Investment by Bright Future

On 18 November 2015, Cloudbreak USA and Bright Future Pharmaceutical Laboratories Ltd. (“**Bright Future**”) entered into a cooperation agreement, pursuant to which, Bright Future agreed to invest US\$2 million into Cloudbreak USA by subscribing for 30% of its membership interest. Such investment amount was determined based on arm’s length negotiations. Pursuant to the operating agreement and the members agreement of Cloudbreak USA each dated 4 December 2015, Dr. Ni, Bright Future, Mr. Dinh and Dr. Li held 30%, 30%, 15%, and 10% of the issued and outstanding membership interest of Cloudbreak USA, respectively, while the remaining 15% of the issued and outstanding membership interest was unassigned. The aggregate investment amount of US\$2 million was fully settled by 15 February 2017. Bright Future is a Hong Kong incorporated research-based multinational pharmaceutical company focused on skin health, pediatrics, respiratory and pain management. Prior to such investment, Bright Future was an Independent Third Party, and it is now one of our substantial Shareholders.

(c) Investment by Saier Holdings and Brillimedical and Issuance to Whitcup Life

On 8 May 2016, each of Saier Holdings (Asia) Company Limited (“**Saier Holdings**”) and Brillimedical International Corporation (“**Brillimedical**”) invested US\$1.25 million into Cloudbreak USA, by way of capital contribution to the membership interest of Cloudbreak USA. Such investment amount was determined based on arm’s length negotiations. The aggregate investment amount of US\$2.5 million was fully settled on 5 August 2016. Saier Holdings is engaged in investment holding. Brillimedical is an investment firm wholly owned by Mr. Jay Jiang, an Independent Third Party, and focused on medical devices and healthcare companies. Each of Saier Holdings and Brillimedical is an Independent Third Party.

According to the amended and restated operating agreement of Cloudbreak USA dated 10 May 2017: (i) 500 class A units of Cloudbreak USA were assigned to each of Saier Holding and Brillimedical for each of its US\$1.25 million capital contribution; and (ii) 500 class A units were assigned to Whitcup Life Sciences LLC (“**Whitcup Life**”) for nil consideration. Whitcup Life is a company wholly-owned by Dr. Scott Whitcup, who was our senior scientific adviser at that time and now the chairman of our scientific advisory board, and such units were issued to Whitcup Life as incentive for Dr. Scott Whitcup to be our scientific adviser. Whitcup Life is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the abovementioned issuance of units, the issued membership interest of Cloudbreak USA as of 10 May 2017 was as follows:

Name	Class A units	Percentage interest
Dr. Ni	2,800	29.68%
Bright Future	2,800	29.68%
Mr. Dinh	1,400	14.85%
Dr. Li	933	9.89%
Saier Holdings	500	5.30%
Brillimedical	500	5.30%
Whitcup Life	500	5.30%
Total	9,433	100%

(d) Investment by Beijing Join and grants of profits interest units awards

On 29 December 2017, Cloudbreak USA issued 800 class A units to Beijing Join Medical Technology Co., Ltd. (北京九潤達醫療科技有限公司) (“**Beijing Join**”) for a capital contribution of US\$6 million. Such investment amount was determined based on arm’s length negotiations. However, it was subsequently agreed that Beijing Join’s entitlement would be proportionately adjusted to approximately 533 class A units of Cloudbreak USA for a capital contribution of US\$4 million. Such investment amount was settled on 9 January 2018. Beijing Join is a Beijing-based company mainly engaged in sales of medical device and medical technology services. It is an Independent Third Party.

To recognise the contribution of certain officers, employees, advisers, and shareholders of Cloudbreak USA in connection with the submission of CBT-001 IND application and the completion of CBT-001 phase 2 clinical trial in the U.S., Cloudbreak USA awarded profits interest units to the following participants in December 2017 and June 2018, respectively:

Participants	Number of profits interest units awarded in December 2017	Number of profits interest units awarded in June 2018
Dr. Yang	200	50
Dr. Ni	127	100
Brillimedical	200	–
Mr. Dinh	20	50
Whitcup Life	10	10
Dr. Li	10	–
Dr. John Hovanesian	–	23

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

As of 1 June 2018, the membership interest in Cloudbreak USA was as follows:

Name	Class A units	Profits interest units	Percentage interest
Dr. Ni	2,800	227	28.12%
Bright Future	2,800	–	26.01%
Mr. Dinh	1,400	70	13.65%
Dr. Li	933	10	8.76%
Brillimedical	500	200	6.50%
Beijing Join	533	–	4.95%
Whitcup Life	500	20	4.83%
Saier Holdings	500	–	4.65%
Dr. Yang	–	250	2.32%
Dr. John Hovanesian	–	23	0.21%
Total	9,966	800	100%

(e) Transfer of units by Brillimedical and Beijing Join, further grant of profits interest units awards and other membership interest restructuring changes

To recognise the contribution of certain officers and employees in connection with obtaining FDA consent for CBT-001 to conduct phase 3 clinical trial in the U.S., on 1 May 2019, Cloudbreak USA awarded profits interest units to the investment holding companies of Dr. Ni, Mr. Dinh and Dr. Yang:

Participants	Number of profits interest units awarded
Water Lily Consultants	112
VD&TL	17
YDD Consulting	14

According to the fourth amended and restated operating agreement of Cloudbreak USA dated 29 December 2019:

- (a) Brillimedical transferred 500 class A units and 200 profits interest units to Dr. Li for nil consideration in order for those units to be held by Dr. Li as trustee and nominee of Brillimedical, pursuant to a declaration of trust dated 25 December 2019 between Dr. Li and Brillimedical (“**Brillimedical Trust Arrangement**”). The Brillimedical Trust Arrangement was put in place for administrative convenience. Such arrangement was terminated in November 2023 when Dr. Li transferred his interests in our Company to Brillimedical;

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (b) Beijing Join transferred 330.46 class A units and 202.54 class A units to K. RUI International Ltd. (“**K. RUI**”) and Renfu Zhou Ltd. (“**Renfu Zhou Ltd.**”) for US\$2.48 million and US\$1.52 million, respectively. K. RUI is engaged in investment and investment consulting. Renfu Zhou is engaged in investment holding. K. RUI and Renfu Zhou Ltd. are alternative investment vehicles of the shareholders of Beijing Join, and are Independent Third Parties;
- (c) Whitcup Life was awarded 280 class A units for nil consideration as recognition of Dr. Scott Whitcup’s contribution to the development progress of CBT-001;
- (d) Dr. Ni transferred 2,800 class A units and 227 profits interests units to Water Lily Consultants (his wholly-owned investment holding company);
- (e) Mr. Dinh transferred 1,400 class A units and 70 profits interests units to VD&TL (his wholly-owned investment holding company); and
- (f) Dr. Yang transferred 250 profits interests units to YDD Consulting (his wholly-owned investment holding company).

Upon completion of the abovementioned changes, according to the fourth amended and restated operating agreement of Cloudbreak USA dated 29 December 2019, the membership interest in Cloudbreak USA as of 29 December 2019 was as follows:

Name	Class A units	Profits interest units	Percentage interest
Water Lily Consultants	2,800	339	28.05%
Bright Future	2,800	–	25.02%
Dr. Li <i>(Note)</i>	1,433	210	14.69%
VD&TL	1,400	87	13.29%
Whitcup Life	780	20	7.15%
Saier Holdings	500	–	4.47%
K. RUI	330.46	–	2.95%
YDD Consulting	–	264	2.36%
Renfu Zhou Ltd.	202.54	–	1.81%
Dr. John Hovanesian	–	23	0.21%
Total	10,246	943	100%

Note: As of 29 December 2019, Dr. Li held 500 class A units and 200 profits interest units as trustee and nominee of Brillimedical, pursuant to the Brillimedical Trust Arrangement.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(f) Share swap with our Company

On 24 November 2021, our Company and Cloudbreak USA underwent a share swap as part of the group restructuring to establish our Company as the holding company of all Group companies (the “**Group Restructuring**”), as a result of which the then shareholders of Cloudbreak USA would hold their interest through our Company instead, and Cloudbreak USA would become a direct wholly-owned subsidiary of our Company. For details, see “– Major Shareholding Changes of Our Group – 5. Our Company – (d) Share swap with Cloudbreak USA and allotment of shares in connection with the Series B Equity Incentive Arrangement” in this section.

2. ADS USA

(a) Formation of ADS USA

ADS USA was formed as a limited liability company in the State of Nevada, USA on 16 January 2017. Upon its formation, Dr. Ni held 70,000 units, and each of Ms. Leng, Mr. Dinh and Dr. Yang held 10,000 units of ADS USA, representing 70%, 10%, 10% and 10% of the membership interest, respectively.

(b) Intellectual property assignment by Cloudbreak USA, conversion and formation in Delaware and dissolution in Nevada, and transfer of units by members

Pursuant to an intellectual property assignment and an asset transfer agreement both dated 29 September 2020 entered into by ADS USA and Cloudbreak USA, Cloudbreak USA transferred all of its rights, title and interest in certain CBT compounds for certain indications to ADS USA in consideration of ADS USA issuing 142,718 limited liability company units to Cloudbreak USA. Such consideration was determined based on arm’s length negotiations. As a result, ADS USA became a non wholly-owned subsidiary of Cloudbreak USA.

On 16 November 2020, ADS USA was dissolved as a limited liability company in the State of Nevada, USA, and converted into a limited liability company in the State of Delaware, USA.

On the same day, each of Dr. Ni, Ms. Leng, Mr. Dinh and Dr. Yang transferred his/her respective units held in ADS USA to his/her investment holding vehicles.

Upon completion of all the actions mentioned above, according to the limited liability company agreement of ADS USA dated 16 November 2020 and as further agreed under the joint consent of the members and board of managers of ADS USA dated 28 December 2020, Cloudbreak USA, Water Lily Consultants, Ice Tree LLC, VD&TL and YDD Consulting held approximately 58.82%, 28.82%, 4.12%, 4.12% and 4.12% of the membership interest, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(c) Merger with ADS Biotechnology and registration in California

On 4 January 2021, ADS USA merged with ADS Biotechnology LLC (our wholly-owned subsidiary) (“**ADS Biotechnology**”), and ADS USA became the surviving entity and a wholly-owned subsidiary of our Company (the “**Merger**”). For details, see “– Major Shareholding Changes of our Group – 5. Our Company – (b) Merger between ADS USA and ADS Biotechnology” in this section. On 10 June 2021, ADS USA registered as a foreign limited liability company in the State of California, USA.

3. Cloudbreak Guangzhou

(a) Establishment of Cloudbreak Guangzhou

Cloudbreak Guangzhou was established under the laws of the PRC as a sino-foreign equity joint venture enterprise on 30 September 2018, with an initial registered capital of RMB10,200,000. Upon establishment, Cloudbreak Guangzhou was owned as to 62.50% by Dr. Ni and 37.50% by Cloudbreak USA. Both Dr. Ni and Cloudbreak USA contributed intellectual property rights as registered capital, which was fully settled on 31 December 2018.

On 30 September 2018, Dr. Ni entered into an option agreement and proxy with each of Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants (collectively, the “**Shareholders Option Agreements**”). Pursuant to the Shareholders Option Agreements, Dr. Ni agreed to irrevocably and unconditionally grant to each of Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants the option to purchase approximately 37.5%, 10.38%, and 2.07% equity interests in Cloudbreak Guangzhou owned by him, respectively, at the purchase price of US\$1.00.

On the same day, Cloudbreak Guangzhou and Dr. Ni entered into an option agreement and proxy (“**ESOP Proxy Agreement**”), pursuant to which, Dr. Ni agreed that approximately 12.55% equity interests in Cloudbreak Guangzhou were held by him for the purpose of an employee equity incentive plan to be formulated and implemented by Cloudbreak Guangzhou.

(b) Capital injection by Yunxin Partnership

As part of the Series A Financing, Shanghai Yunxin Venture Capital Management Partnership (Limited Partnership) (上海雲鋅創業投資管理合夥企業(有限合夥)) (currently known as Shanghai Yunxin Venture Capital Partnership (Limited Partnership) (上海雲鋅創業投資合夥企業(有限合夥))) (“**Yunxin Partnership**”) and Cloudbreak Guangzhou entered into an investment agreement dated 29 October 2018 and a supplemental investment agreement dated 14 January 2019, pursuant to which Yunxin Partnership agreed to invest an aggregate of RMB10,000,000 into Cloudbreak Guangzhou. Such investment was conducted by way of capital injection by Yunxin Partnership in two steps.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

On 17 May 2019, Yunxin Partnership contributed RMB5,000,000 to the capital of Cloudbreak Guangzhou, of which RMB197,000 was credited to its registered capital and RMB4,803,000 was credited to its capital reserve. Upon completion, the registered capital of Cloudbreak Guangzhou increased from RMB10,200,000 to RMB10,397,000, and Cloudbreak Guangzhou was owned as to approximately 61.32% by Dr. Ni, 36.79% by Cloudbreak USA and 1.89% by Yunxin Partnership.

On 28 June 2019, Yunxin Partnership contributed RMB5,000,000 to the capital of Cloudbreak Guangzhou, of which RMB188,310 was credited to its registered capital and RMB4,811,690 was credited to its capital reserve. Upon completion, the registered capital of Cloudbreak Guangzhou increased from RMB10,397,000 to RMB10,585,310, and Cloudbreak Guangzhou was owned as to approximately 60.23% by Dr. Ni, 36.13% by Cloudbreak USA and 3.64% by Yunxin Partnership.

For details of the Series A Financing, see “– Pre-IPO Investment – Series A Financing” in this section.

(c) Acquisition by Cloudbreak HK

As part of the Group Restructuring, on 27 December 2019, Dr. Ni, Cloudbreak USA and Cloudbreak HK (which was then indirectly wholly-owned by Cloudbreak Cayman) entered into a share transfer agreement (“**2019 Share Transfer Agreement**”) (and as supplemented thereafter), pursuant to which Cloudbreak HK acquired 60.23% and 36.13% equity interest in Cloudbreak Guangzhou from Dr. Ni and Cloudbreak USA, at a consideration of the US\$ equivalent of RMB10,958,246 and RMB6,573,492, respectively, which was determined based on the then value of all shareholders’ equity in Cloudbreak Guangzhou. Such consideration amount was fully settled on 12 June 2020. As a result, Cloudbreak Guangzhou became a non wholly-owned subsidiary of Cloudbreak HK.

Upon completion of such share transfer, the arrangements under the Shareholders Option Agreements and the ESOP Proxy Agreement were terminated. At the time of termination of the ESOP Proxy Agreement, Cloudbreak Guangzhou has not yet implemented any employee equity incentive plan. As further agreed under the supplemental agreement to the 2019 Share Transfer Agreement, Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants were entitled to receive from Dr. Ni the US\$ equivalent of RMB8,461,301, RMB2,081,029 and RMB415,914, respectively. The corresponding amount was paid to Cloudbreak USA on 25 June 2020, and Dr. Ni held the relevant amounts for Water Lily Consultants and Ice Tree Consultants on their behalf.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

In connection with the Series A Financing and as part of the Group Restructuring, pursuant to the share transfer agreement dated 5 August 2020 and the supplemental share transfer agreement dated 6 August 2020, Yunxin Partnership transferred its 3.64% equity interest in Cloudbreak Guangzhou to Cloudbreak HK for a consideration of the US\$ equivalent to RMB662,261.6. Such consideration was determined based on the then value of all shareholders' equity in Cloudbreak Guangzhou. Such consideration amount was fully settled on 7 December 2020. For details of the Series A Financing, see “– Pre-IPO Investments – Series A Financing” in this section.

Upon completion of the abovementioned share transfers on 21 October 2020, Cloudbreak Guangzhou became a limited liability company (Taiwan, Hong Kong or Macau legal person sole proprietorship) (台港澳法人獨資) and was wholly-owned by Cloudbreak HK. At the time, Cloudbreak HK was wholly-owned by Cloudbreak BVI, which was in turn indirectly wholly-owned by our Company through Cloudbreak Cayman.

In connection with its acquisition of Cloudbreak Guangzhou, Cloudbreak HK contributed RMB10 million in cash to Cloudbreak Guangzhou, of which, RMB385,310 was credited to its registered capital while the remaining amount of RMB9,614,690 was credited to its capital reserve. Such capital contributions were fully settled on 22 February 2021. Upon completion of the capital contribution, the registered capital of Cloudbreak Guangzhou increased from RMB10,585,310 to RMB10,970,620.

Our PRC Legal Advisers have confirmed that all approvals and filings in relation to the equity transfers in the PRC as described above have been obtained and the procedures involved have been carried out in accordance with the PRC laws and regulations.

4. Cloudbreak Cayman

(a) Incorporation of Cloudbreak Cayman and its subsequent shareholding restructuring

Cloudbreak Cayman was incorporated as a limited liability company in the Cayman Islands on 1 November 2019, with a share capital of US\$50,000 divided into 500,000,000 shares of a par value of US\$0.0001 each. Upon incorporation, one subscriber share, credited as fully paid at par, was issued to the initial subscriber, after which a shareholding restructuring was carried out.

On 27 March 2020, Cloudbreak Cayman entered into a share subscription agreement with Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants, pursuant to which, Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants, subscribed for 130,769,200, 18,096,199, and 3,619,200 ordinary shares of Cloudbreak Cayman, for a consideration of the US\$ equivalent of RMB15,035,000, RMB2,081,000, and RMB416,000, respectively. Upon completion of such share subscription, Cloudbreak Cayman was held as to approximately 85.76% by Cloudbreak USA, 11.87% by Water Lily Consultants and 2.37% by Ice Tree Consultants.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(b) Series B Financing, Group Restructuring, and allotment and re-designation of shares of Cloudbreak Cayman

Between April 2020 to July 2020, Cloudbreak Cayman underwent a Group Restructuring step in connection with the Series A Financing and the Series B Financing. For details, see “– Pre-IPO Investments – Series A Financing” and “– Pre-IPO Investments – Series B Financing” in this section.

In connection with the Series B Financing, pursuant to a share purchase agreement dated 1 July 2020 entered into by, among others, Cloudbreak Cayman, Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants, Cloudbreak Cayman issued and allotted 205,984, 28,649 and 5,770 ordinary A shares to Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants on 27 August 2020, for a consideration of approximately US\$20.60, US\$2.86 and US\$0.58, respectively. Such consideration was determined based on the par value of US\$0.0001 per share, and was fully settled on 27 August 2020.

According to the shareholders resolutions of Cloudbreak Cayman dated 27 August 2020, 130,769,200, 18,096,200 and 3,619,200 ordinary shares then held by Cloudbreak USA, Water Lily Consultants, and Ice Tree Consultants, respectively, were re-classified and re-designated as ordinary B shares of Cloudbreak Cayman.

Upon completion of the Group Restructuring in connection with the Series A Financing and the Series B Financing, the shareholding of Cloudbreak Cayman was as follows:

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name	Ordinary A shares	Ordinary B shares	Series A preferred shares	Series B preferred shares	Percentage interest
Cloudbreak USA	205,984	130,769,200	–	–	53.83%
Water Lily Consultants	28,649	18,096,200	–	–	7.45%
Ice Tree Consultants	5,770	3,619,200	–	–	1.49%
Series A Investor <i>(Note)</i>					
Yunxin Holdings Limited ("Yunxin Holdings")	–	–	8,873,587	–	3.65%
Series B Investors					
Yicun Holdings Limited ("Yicun Holdings")	–	–	–	46,881,393	19.27%
Grand Diamond Limited ("Grand Diamond")	–	–	–	26,789,367	11.01%
Zhongyin Health Holdings Limited ("Zhongyin Health")	–	–	–	8,036,810	3.30%
Total	<u>240,403</u>	<u>152,484,600</u>	<u>8,873,587</u>	<u>81,707,570</u>	<u>100%</u>

Note: Yunxin Holdings is a company incorporated under the laws of the BVI, and is controlled by Yunxin Partnership. For details, see "– Major Shareholding Changes of Our Group – 3. Cloudbreak Guangzhou – (b) Capital injection by Yunxin Partnership", "– Pre-IPO Investments – Series A Financing", and "– Pre-IPO Investments – Information regarding the Pre-IPO Investors" in this section.

(c) Share exchange between Cloudbreak Cayman and our Company

On 28 December 2020, a share exchange between Cloudbreak Cayman and our Company was carried out as part of the Group Restructuring, as a result of which the then shareholders of Cloudbreak Cayman would become shareholders of our Company, while Cloudbreak Cayman would become directly wholly-owned by our Company. For details, see "– Major Shareholding Changes of our Group – 5. Our Company – (c) Share exchange between Cloudbreak Cayman and our Company" in this section.

5. Our Company

(a) Incorporation of our Company

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on 20 November 2020, with an initial authorised share capital of US\$50,000 divided into 500,000,000 ordinary shares, each with a par value of US\$0.0001. As of the Latest Practicable Date, our Company is the holding company of our Group, and its principal business activity is investment holding.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon its incorporation, our Company issued one subscriber Share, credited as fully paid at par, to Maples Corporate Services Limited, an Independent Third Party. On the same day, such one subscriber Share was transferred to Water Lily Consultants.

(b) Merger between ADS USA and ADS Biotechnology

As part of the Group Restructuring, pursuant to the agreement and plan of merger dated 4 January 2021 entered into by ADS USA, our Company and ADS Biotechnology, ADS USA and ADS Biotechnology (which was wholly-owned by our Company prior to the Group Restructuring) underwent the Merger. It was agreed that each unit of membership interest in ADS USA that was issued and outstanding immediately prior to the Merger shall be cancelled and extinguished and converted automatically into the right to receive 468,8139 validly issued, fully paid and non-assessable shares of our Company, rounded off to the nearest whole number of shares of our Company.

On 13 January 2021, in connection with the Merger, and in order to reflect the membership interest of ADS USA immediately prior to the Merger, Water Lily Consultants surrendered its one share in our Company, and our Company issued and allotted (i) 66,973,418 Class A Ordinary Shares to Cloudbreak USA, (ii) 32,816,975 Class A Ordinary Shares to Water Lily Consultants, (iii) 4,688,139 Class A Ordinary Shares to Ice Tree LLC, (iv) 4,688,139 Class A Ordinary Shares to VD&TL, and (v) 4,688,139 Class A Ordinary Shares to YDD Consulting. Upon completion of the Merger and such allotment of shares, our Company was held as to approximately 58.82% by Cloudbreak USA, 28.82% by Water Lily Consultants, and 4.12% by each of Ice Tree LLC, VD&TL and YDD Consulting.

(c) Share Exchange between Cloudbreak Cayman and our Company

On 28 December 2020, a share exchange between Cloudbreak Cayman and our Company was carried out as part of the Group Restructuring, as a result of which the then shareholders of Cloudbreak Cayman would hold their interests through our Company instead, and Cloudbreak Cayman would become a wholly-owned subsidiary of our Company. Pursuant to a share exchange agreement dated 28 December 2020 entered into by the then shareholders of Cloudbreak Cayman and our Company (“**Share Exchange Agreement**”), it was agreed that all issued shares of Cloudbreak Cayman shall be acquired by our Company from the then shareholders of Cloudbreak Cayman, while corresponding shares in our Company shall be issued and allotted to them in return (“**Share Exchange**”). For details of the shareholding of Cloudbreak Cayman prior to the Share Exchange, see “– 4. Cloudbreak Cayman – (b) Series B Financing, Group Restructuring, and allotment and re-designation of shares of Cloudbreak Cayman” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Details of the Share Exchange are as follows:

Name	Number of Class A Ordinary Shares newly issued and allotted	Number of Class B Ordinary Shares newly issued and allotted	Number of Series A Preferred Shares newly issued and allotted	Number of Series B Preferred Shares newly issued and allotted
Cloudbreak USA	205,984	130,769,200		
Water Lily Consultants	28,649	18,096,200	–	–
Ice Tree Consultants	5,770	3,619,200	–	–
Series A Investor <i>(Note)</i>				
Yunxin Holdings	–	–	8,873,587	–
Series B Investors				
Yicun Holdings	–	–	–	46,881,393
Grand Diamond	–	–	–	26,789,367
Zhongyin Health	–	–	–	8,036,810
Total	240,403	152,484,600	8,873,587	81,707,570

Note: Yunxin Holdings is a company incorporated under the laws of the BVI, and is controlled by Yunxin Partnership. For details, see “– Major Shareholding Changes of Our Group – 3. Cloudbreak Guangzhou – (b) Capital injection by Yunxin Partnership”, “– Pre-IPO Investments – Series A Financing”, and “– Pre-IPO Investments – Information regarding the Pre-IPO Investors” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Share Exchange on 12 March 2021, Cloudbreak Cayman became a wholly-owned subsidiary of our Company, and details of our Company's shareholding were as follows:

Name	Class A Ordinary Shares	Class B Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Percentage interest
Cloudbreak USA	67,179,402	130,769,200	–	–	55.42%
Water Lily Consultants	32,845,624	18,096,200	–	–	14.26%
Ice Tree LLC	4,688,139	–	–	–	1.31%
VD&TL	4,688,139	–	–	–	1.31%
YDD Consulting	4,688,139	–	–	–	1.31%
Ice Tree Consultants	5,770	3,619,200	–	–	1.02%
<i>Series A Investor</i>					
Yunxin Holdings	–	–	8,873,587	–	2.49%
<i>Series B Investors</i>					
Yicun Holdings	–	–	–	46,881,393	13.13%
Grand Diamond	–	–	–	26,789,367	7.50%
Zhongyin Health	–	–	–	8,036,810	2.25%
Total	<u>114,095,213</u>	<u>152,484,600</u>	<u>8,873,587</u>	<u>81,707,570</u>	<u>100%</u>

(d) Share swap with Cloudbreak USA and allotment of shares in connection with the Series B Equity Incentive Arrangement

As part of the Group Restructuring, our Company underwent the following steps for the then shareholders of Cloudbreak USA to hold their interest through our Company instead, and Cloudbreak USA would become a subsidiary of our Company (“**Share Swap**”).

On 24 November 2021, our Company and Cloudbreak USA entered into a contribution commitment agreement, pursuant to which, Cloudbreak USA distributed Ordinary Shares held by it to the then members of Cloudbreak USA approximately on a pro rata basis in proportion to their then membership interest in Cloudbreak USA (the “**Distribution**”), such that they would directly hold the Class A Ordinary Shares and Class B Ordinary Shares after the Distribution. Details of the Distribution are set out below:

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name	Distribution by Cloudbreak USA	
	Class A Ordinary Shares	Class B Ordinary Shares
Water Lily Consultants	18,846,176	36,685,342
Bright Future	16,810,861	32,723,465
Dr. Li	9,864,373	19,201,662
VD&TL	8,927,768	17,378,497
Whitcup Life	4,803,103	9,349,562
Saier Holdings	3,001,940	5,843,476
K. RUI	1,985,282	3,864,485
YDD Consulting	1,585,024	3,085,355
Renfu Zhou Ltd.	1,216,786	2,368,556
Dr. John Hovanesian	138,089	268,800
Total	67,179,402	130,769,200

On the same day, our Company and Cloudbreak USA entered into a contribution and exchange agreement, pursuant to which, the then members of Cloudbreak USA contributed, assigned, transferred and conveyed all issued and outstanding units in Cloudbreak USA to our Company, in exchange for which our Company issued and allotted certain Class C Ordinary Shares and certain portion of our Company's promissory note with a principal sum of US\$30,000,000 ("**Promissory Note**") to each of them (the "**Contribution and Exchange**") approximately on a pro rata basis in proportion to their then membership interest in Cloudbreak USA. Details of the Contribution and Exchange are set out below:

Name	Membership interests in Cloudbreak USA transferred to our Company		Issuance by our Company	
	Class A units	Profits interest units	Class C Ordinary Shares	Portion of Promissory Note
Water Lily Consultants	2,800	339	51,519,363	US\$8,234,387.35
Bright Future	2,800	–	45,955,468	US\$8,082,903.79
Dr. Li	1,433	210	26,966,012	US\$4,230,554.06
VD&TL	1,400	87	24,405,636	US\$4,080,328.21
Whitcup Life	780	20	13,130,134	US\$2,260,603.14
Saier Holdings	500	–	8,206,334	US\$1,443,375.68
K. RUI	330.46	–	5,427,121	US\$ 954,552.26
YDD Consulting	–	264	4,332,944	US\$ 117,969.50
Renfu Zhou Ltd.	202.54	–	3,326,301	US\$ 585,048.37
Dr. John Hovanesian	–	23	377,491	US\$ 10,277.64
Total	10,246	943	183,646,804	US\$ 30,000,000

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

On 27 October 2022, the entire principal sum of US\$30,000,000 under the Promissory Note was repaid in full by our Company using the funds raised from the Series C Financing. For details of the Series C Financing, see “– Pre-IPO Investments – Series C Financing” in this section.

Pursuant to the Series B Equity Incentive Arrangement, on 24 November 2021, an aggregate of 9,732,246 Class A Ordinary Shares were allotted and issued to Water Lily Consultants, Ice Tree LLC, VD&TL and YDD Consulting. For details, see “– Equity Incentive Arrangements” in this section and “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.

Upon completion of the Share Swap and allotment of shares in connection with the Series B Equity Incentive Arrangement, Cloudbreak USA became a wholly-owned subsidiary of our Company, and details of our Company’s shareholding were as follows:

Name	Class A Ordinary Shares	Class B Ordinary Shares	Class C Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Percentage interest
Water Lily Consultants	55,592,019	54,781,542	51,519,363	–	–	29.41%
Bright Future	16,810,861	32,723,465	45,955,468	–	–	17.34%
VD&TL	15,559,916	17,378,497	24,405,636	–	–	10.42%
Dr. Li ^(Note)	9,864,373	19,201,662	26,966,012	–	–	10.18%
Whitcup Life	4,803,103	9,349,562	13,130,134	–	–	4.96%
Saier Holdings	3,001,940	5,843,476	8,206,334	–	–	3.10%
YDD Consulting	8,217,172	3,085,355	4,332,944	–	–	2.84%
K. RUI	1,985,282	3,864,485	5,427,121	–	–	2.05%
Renfu Zhou Ltd.	1,216,786	2,368,556	3,326,301	–	–	1.26%
Ice Tree LLC	6,632,148	–	–	–	–	1.20%
Ice Tree Consultants	5,770	3,619,200	–	–	–	0.66%
Dr. John Hovanesian	138,089	268,800	377,491	–	–	0.14%
Series A Investor						
Yunxin Holdings	–	–	–	8,873,587	–	1.61%
Series B Investors						
Yicun Holdings	–	–	–	–	46,881,393	8.52%
Grand Diamond	–	–	–	–	26,789,367	4.87%
Zhongyin Health	–	–	–	–	8,036,810	1.46%
Total	123,827,459	152,484,600	183,646,804	8,873,587	81,707,570	100%

Note: As Dr. Li held 500 class A units and 200 profits interest units of Cloudbreak USA as trustee and nominee of Brillimedical pursuant to the Brillimedical Trust Arrangement prior to the Share Swap, 4,202,715 Class A Ordinary Shares, 8,180,866 Class B Ordinary Shares and 11,488,867 Class C Ordinary Shares continued to be held by Dr. Li on trust and for the benefit of Brillimedical upon completion of the Share Swap.

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(e) Series C Financing

Our Company underwent the Series C Financing. For details, see “– Pre-IPO Investments – Series C Financing” in this section.

(f) Surrender and Allotment of Shares pursuant to Equity Incentive Arrangements

Under the Series B Equity Incentive Arrangement, pursuant to surrender letters dated 23 March 2022, an aggregate of 9,732,246 Class A Ordinary Shares were surrendered by Water Lily Consultants, Ice Tree LLC, VD&TL and YDD Consulting, on 1 April 2022. On the same day, an aggregate of 7,788,237 Class A Ordinary Shares were allotted and issued to Water Lily Consultants, Ice Tree LLC and VD&TL, and RSUs representing 1,944,009 Class A Ordinary Shares were issued to YDD Consulting instead. Pursuant to the Series C Equity Incentive Arrangement, on 1 April 2022, an aggregate of 17,371,448 Class A Ordinary Shares were allotted and issued to certain individuals who are not Directors (of which 17,234,122 Class A Ordinary Shares were issued to Ms. Chan Ching Chu, chief financial officer of the Company, and 137,326 Class A Ordinary Shares were issued to a consultant of the Company who provided certain legal advisory services). These share awards are not subject to vesting conditions. For details, see “– Equity Incentive Arrangements” in this section and “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.

6. ADS Australia

ADS Australia was incorporated in New South Wales, Australia on 20 November 2020. Since its incorporation, it has been wholly-owned by ADS USA.

7. Cloudbreak Suzhou

Cloudbreak Suzhou was established under the laws of the PRC as a limited liability company (Taiwan, Hong Kong or Macau legal person sole proprietorship) (台港澳法人獨資) on 27 September 2021. Since the establishment of Cloudbreak Suzhou, it has been wholly-owned by Cloudbreak HK.

8. Cloudbreak Yixing

Cloudbreak Yixing was established under the laws of the PRC as a limited liability company (Taiwan, Hong Kong or Macau legal person sole proprietorship) (台港澳法人獨資) on 5 September 2023. Since the establishment of Cloudbreak Yixing, it has been wholly-owned by Cloudbreak HK. As of the Latest Practicable Date, Cloudbreak Yixing had not yet commenced operations.

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9. Cloudbreak Wenzhou

Cloudbreak Wenzhou was established under the laws of the PRC as a limited liability company on 11 June 2024. Since the establishment of Cloudbreak Wenzhou, it has been wholly-owned by Cloudbreak Suzhou. As of the Latest Practicable Date, Cloudbreak Wenzhou had not yet commenced operations.

PRE-IPO INVESTMENTS

Overview

Our Company obtained several rounds of investments from Pre-IPO Investors, namely the Series A Financing, Series B Financing and Series C Financing, details of which are set out below. There have also been certain transfers of existing Shares by our Shareholders. For more information on the background of the Pre-IPO Investors, see “– Pre-IPO Investments – Information about the Pre-IPO Investors” in this section.

Series A Financing

Yunxin Partnership and Cloudbreak Guangzhou entered into an investment agreement dated 29 October 2018 and a supplemental investment agreement dated 14 January 2019, pursuant to which Yunxin Partnership conducted a capital injection of RMB10 million in total into Cloudbreak Guangzhou, of which, RMB385,310 was credited to its registered capital, while the remaining amount of RMB9,614,690 was credited to its capital reserve. Such consideration was determined based on arm’s length negotiation. The aggregate investment amount of RMB10 million was fully settled by 21 May 2019. Upon completion of the capital injection, Cloudbreak Guangzhou was owned as to 60.23% by Dr. Ni, 36.13% by Cloudbreak USA and 3.64% by Yunxin Partnership. For details, see “– Major Shareholding Changes of our Group – 3. Cloudbreak Guangzhou – (b) Capital injection by Yunxin Partnership” in this section.

Subsequently in 2020, as part of the Group Restructuring, pursuant to a share purchase agreement dated 1 July 2020 entered into by, among others, Yunxin Holdings (which is controlled by Yunxin Partnership) and Cloudbreak HK, Yunxin Holdings subscribed for 8,873,587 series A preferred shares of Cloudbreak Cayman for a consideration of US\$21,589.39. Such consideration was determined based on arm’s length negotiation, and the aggregate consideration amount was fully settled on 1 June 2021. In August 2020, Yunxin Partnership transferred its 3.64% equity interest in Cloudbreak Guangzhou to Cloudbreak HK for a consideration of RMB662,261.6. Such consideration amount was fully settled by 7 December 2020. For details, see “– Major Shareholding Changes in our Group – 3. Cloudbreak Guangzhou – (b) Acquisition by Cloudbreak HK” in this section.

Between April 2020 to July 2020, Cloudbreak Cayman also underwent the Series B Financing. For details, see “– Pre-IPO Investments – Series B Financing” in this section. Upon completion of above Group Restructuring steps, the Series A Financing and the Series B Financing, Cloudbreak Guangzhou was indirectly wholly-owned by our Company through Cloudbreak HK, and Cloudbreak Cayman was held as to approximately 53.83% by

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Cloudbreak USA, 7.45% by Water Lily Consultants, 1.49% by Ice Tree Consultants, 3.65% by Yunxin Holdings, 11.01% by Grand Diamond, 19.27% by Yicun Holdings and 3.30% by Zhongyin Health.

From December 2020 to March 2021, the Share Exchange was carried out to establish our Company as the holding company of Cloudbreak Cayman. Pursuant to the Share Exchange Agreement, Yunxin Holdings sold its 8,873,587 series A preferred shares of Cloudbreak Cayman in consideration of our Company's issuance and allotment of 8,873,587 Series A Preferred Shares to it. Upon completion of the Share Exchange on 12 March 2021, Cloudbreak Cayman was wholly-owned by our Company and, in turn, our Company was owned as follows: (i) as to 55.42% by Cloudbreak USA, (ii) as to 14.26% by Water Lily Consultants, (iii) as to 1.31% by Ice Tree LLC, (iv) as to 1.31% by VD&TL, (v) as to 1.31% by YDD Consulting, (vi) as to 1.02% by Ice Tree Consultants, (vii) as to 2.49% by Yunxin Holdings, (viii) as to 13.13% by Yicun Holdings, (ix) as to 7.50% by Grand Diamond, and (x) as to 2.25% by Zhongyin Health. For details, see “– Major Shareholding Changes in our Group – 5. Our Company – (c) Share Exchange between Cloudbreak Cayman and our Company” in this section.

Series B Financing

Series B-1 Financing

Pursuant to a share purchase agreement dated 13 April 2020 by and between, among others, Cloudbreak Cayman and Grand Diamond, Grand Diamond subscribed for, and was issued and allotted with, 26,789,367 series B preferred shares of Cloudbreak Cayman for a consideration of US\$5,633,802.82. The relevant consideration was determined based on arm's length negotiation, and the aggregate consideration amount for the Series B-1 Financing was fully settled on 13 May 2020.

Series B-2 Financing

Pursuant to a share purchase agreement dated 1 July 2020 by, among others, Yicun Holdings, Zhongyin Health and Cloudbreak Cayman, Yicun Holdings and Zhongyin Health agreed to invest a total of approximately US\$11,549,295 by subscribing for 54,918,203 series B preferred shares of Cloudbreak Cayman. Each of Yicun Holdings and Zhongyin Health subscribed for, and was issued and allotted with 46,881,393 and 8,036,810 series B preferred shares of Cloudbreak Cayman, for a consideration of approximately US\$9,859,155 and US\$1,690,141, respectively. The relevant consideration was determined based on arm's length negotiation, and the aggregate consideration amount was fully settled by 12 November 2020.

Upon completion of the Series A Financing and the Series B Financing, Cloudbreak Cayman was held as to approximately 53.83% by Cloudbreak USA, 7.45% by Water Lily Consultants, 1.49% by Ice Tree Consultants, 3.65% by Yunxin Holdings, 11.01% by Grand Diamond, 19.27% by Yicun Holdings and 3.30% by Zhongyin Health.

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From December 2020 to March 2021, the Share Exchange was carried out to establish our Company as the holding company of Cloudbreak Cayman. Pursuant to the Share Exchange Agreement, Grand Diamond, Yicun Holdings and Zhongyin Health sold its 26,789,367, 46,881,393 and 8,036,810 series B preferred shares of Cloudbreak Cayman in consideration of our Company's issuance and allotment of 26,789,367, 46,881,393 and 8,036,810 Series B Preferred Shares to them, respectively. Upon completion of the Share Exchange on 12 March 2021, Cloudbreak Cayman was wholly-owned by our Company and, in turn, our Company was owned as to approximately (i) 55.42% by Cloudbreak USA, (ii) 14.26% by Water Lily Consultants, (iii) 1.31% by Ice Tree LLC, (iv) 1.31% by VD&TL, (v) 1.31% by YDD Consulting, (vi) 2.49% by Yunxin Holdings, (vii) 13.13% by Yicun Holdings, (viii) 7.50% by Grand Diamond, and (ix) 2.25% by Zhongyin Health. For details, see “– Major Shareholding Changes in our Group – 5. Our Company – (c) Share Exchange between Cloudbreak Cayman and our Company” in this section.

Series C Financing

Pursuant to a share and warrant purchase agreement dated 24 November 2021 (“**Series C Agreement**”) by and between, among others, our Company and the Series C Investors, the Series C Investors agreed to invest a total of US\$127 million (or its RMB equivalent) in our Company for an aggregate of 210,118,415 Series C Preferred Shares by subscription or by purchase pursuant to the exercise of the Series C Warrants. The relevant consideration was determined based on arm's length negotiations. As of the Latest Practicable Date, all the Series C Warrants have been fully exercised. Details of the Series C Financing which have completed are set out below:

No.	Name of Series C Investors ⁽⁷⁾	Number of Series C Preferred Shares subscribed for	Number of Series C Preferred Shares to be purchased pursuant to the Series C Warrants	Date on which shares were issued according to the register of members	Consideration	Date on which consideration was fully settled
1.	SKKETCH SHINE LIMITED (“Skketch Shine”)	49,634,271	–	24 November 2021	US\$30,000,000	24 April 2023 ⁽⁸⁾
2.	Design Time Limited (“Design Time”)	24,817,136	–	24 November 2021	US\$15,000,000	28 December 2021
3.	GAOTEJIA NEWCLOUD INVESTMENT CO., LTD. (“Gaotejia”)	37,225,703	–	24 November 2021	US\$22,500,000	17 December 2021
4.	CNCB Grand Healthcare Investment Fund LP (“CNCB”)	8,272,379	–	24 November 2021	US\$5,000,000	30 December 2021

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No.	Name of Series C Investors ⁽⁷⁾	Number of Series C Preferred Shares subscribed for	Number of Series C Preferred Shares to be purchased pursuant to the Series C Warrants	Date on which shares were issued according to the register of members	Consideration	Date on which consideration was fully settled
5.	Xiamen Dyee Evergreen Venture Capital Partnership (Limited Partnership) (廈門德屹長青創業投資合夥企業(有限合夥)) ("Dyee Evergreen") ⁽¹⁾	–	24,817,136	3 January 2023	RMB equivalent of US\$15,000,000	6 September 2022
6.	Hainan Efung-Junma Phase I Private Equity Fund Management Partnership (Limited Partnership) (海南倚鋒駿馬一期私募股權投資基金管理合夥企業(有限合夥)) ("Hainan Efung") ⁽²⁾	–	16,544,757	3 January 2023	RMB equivalent of US\$10,000,000	22 September 2022
7.	Cheng Guang Management Consulting (Li Shui) Partnership (Limited Partnership) (承光管理諮詢(麗水)合夥企業(有限合夥)) ("Cheng Guang") ⁽³⁾	–	12,408,567	3 January 2023	RMB equivalent of US\$7,500,000	4 August 2022
8.	Ying Ke Zhi De Pu Yun (Pingtan) Equity Investment Partnership (Limited Partnership) (盈科值得普雲(平潭)股權投資合夥企業(有限合夥)) ("Yingke Zhi De Pu Yun") ⁽⁴⁾	–	1,775,251	3 January 2023	RMB equivalent of US\$1,073,000	23 September 2022
9.	Ying Ke Rong Da Jingxuan (Pingtan) Equity Investment Partnership (Limited Partnership) (盈科融達精選(平潭)股權投資合夥企業(有限合夥)) ("Yingke Rong Da") ⁽⁴⁾	–	2,341,745	3 January 2023	RMB equivalent of US\$1,415,400	23 September 2022

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No.	Name of Series C Investors ⁽⁷⁾	Number of Series C Preferred Shares subscribed for	Number of Series C Preferred Shares to be purchased pursuant to the Series C Warrants	Date on which shares were issued according to the register of members	Consideration	Date on which consideration was fully settled
10.	Zibo Ying Ke Core Value I Venture Capital Investment Partnership (Limited Partnership) (淄博盈科核心价值一號創業投資合夥企業(有限合夥)) ("Zibo Yingke") (now known as Hangzhou Taifu Yingrui Venture Capital Partnership (Limited Partnership) (杭州泰富盈瑞創業投資合夥企業(有限合夥)) ⁽⁴⁾	–	1,654,476	3 January 2023	RMB equivalent of US\$1,000,000	23 September 2022
11.	Ying Ke Zhi De Pu Ze (Pingtan) Equity Investment Partnership (Limited Partnership) (盈科值得普澤(平潭)股權投資合夥企業(有限合夥)) ("Yingke Zhi De Pu Ze")	–	5,809,857	3 January 2023	RMB equivalent of US\$3,511,600	14 September 2022
12.	Hainan Tian Yi Rui Yao Enterprise Management Partnership (Limited Partnership) (海南天壹睿曜私募基金合夥企業(有限合夥)) ("Hainan Tianyi") ⁽⁵⁾	–	8,272,379	3 January 2023	RMB equivalent of US\$5,000,000	6 September 2022
13.	Shenzhen Chuang Dong Fang Chang Hui Investment Enterprise (Limited Partnership) (深圳市創東方長輝投資企業(有限合夥)) ("Chuangdongfang Changhui")	–	8,272,379	3 January 2023	RMB equivalent of US\$5,000,000	24 August 2022

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No.	Name of Series C Investors ⁽⁷⁾	Number of Series C Preferred Shares subscribed for	Number of Series C Preferred Shares to be purchased pursuant to the Series C Warrants	Date on which shares were issued according to the register of members	Consideration	Date on which consideration was fully settled
14.	Pingtang Xing Zheng Innovation Medical Venture Capital Partnership (Limited Partner) (平潭興證創新醫藥創業投資合夥企業(有限合夥)) (“ Pingtang Xing Zheng ”) ⁽⁶⁾	–	3,805,294	3 January 2023	RMB equivalent of US\$2,300,000	25 August 2022
15.	Jinhua Jin Kai Xing Zheng Medical Healthcare Industry Equity Investment Partnership (Limited Partnership) (金華金開興證醫藥健康產業股權投資合夥企業(有限合夥)) (“ Jinhua Jinkai ”)	–	4,467,085	3 January 2023	RMB equivalent of US\$2,700,000	26 August 2022

Notes:

- (1) Dyee Evergreen entered into an assignment and undertaking dated 24 November 2021 with Shanghai De Hong Xin Business Consulting Partnership (Limited Partnership) (上海德泓鑫商務諮詢合夥企業(有限合夥)) (“**De Hong Xin**”), which was formed by Dyee Evergreen as the special purpose vehicle, pursuant to which, Dyee Evergreen assigned and transferred to De Hong Xin, an affiliate of Dyee Evergreen, all of its rights, title and interest in and to the Series C Warrants. Upon full exercise of the Series C Warrants by De Hong Xin, it purchased 24,817,136 Series C Preferred Shares.
- (2) Hainan Efung’s investment was for 16,544,757 Series C Preferred Shares in aggregate at a consideration of RMB equivalent of US\$10,000,000 in total. Hainan Efung subsequently entered into an assignment and undertaking with Jiangmen Efung-Junma Phase II Venture Capital Partnership (Limited Partnership) (江門市倚鋒駿馬二期創業投資合夥企業(有限合夥)) (“**Jiangmen Efung**”), pursuant to which, Hainan Efung assigned and transferred to Jiangmen Efung all of its rights, title and interest in and to the Series C Warrants to purchase 5,090,694 Class C Preferred Shares. Upon full exercise of the Series C Warrants by each of Hainan Efung and Jiangmen Efung, they purchased 11,454,063 and 5,090,694 Class C Preferred Shares, respectively. Both Hainan Efung and Jiangmen Efung are managed by Hainan Efung Junma Private Equity Fund Management Co., Ltd. (海南倚鋒駿馬私募基金管理有限公司) (“**Efung Junma**”). For details, see “ – Pre-IPO Investments – Information regarding the Pre-IPO Investors” in this section.
- (3) Cheng Guang entered into an agreement on change of entity dated 23 December 2021 with Guan Zi Equity Investment (Li Shui) Partnership (Limited Partnership) (關子股權投資(麗水)合夥企業(有限合夥)) (“**Guan Zi Equity**”), which is an affiliate of Cheng Guang, Cloudbreak Guangzhou and our Company, pursuant to which Cheng Guang assigned and transferred to Guan Zi Equity all of its rights and obligations under its Series C Warrants. Upon full exercise of the Series C Warrants by Guan Zi Equity, it purchased 12,408,567 Series C Preferred Shares.

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- (4) Each of Zibo Yingke, Yingke Rong Da and Yingke Zhi De Pu Yun entered into an assignment and undertaking dated 4 March 2022 with Yunwen Capital Limited (“**Yunwen**”), which was used by Zibo Yingke, Yingke Rong Da and Yingke Zhi De Pu Yun as the vehicle for overseas investment, pursuant to which, each of them assigned and transferred to Yunwen, an affiliate of them, all of their rights, title and interest in and to the Series C Warrants. Upon full exercise of the Series C Warrants by Yunwen, it became the holder of 5,771,472 Series C Preferred Shares.
- (5) Hainan Tianyi subsequently entered into an assignment and undertaking with Shanghai Tian Yi Rui Yao Enterprise Management Partnership (Limited Partnership) (上海天壹睿曜企業管理合夥企業(有限合夥)) (“**Shanghai Tianyi**”), which was the entity formed by Hainan Tianyi and used as its vehicle for overseas investment, pursuant to which, Hainan Tianyi assigned and transferred to Shanghai Tianyi, an affiliate of Hainan Tianyi, all of its rights, title and interest in and to the Series C Warrants. Upon full exercise of the Series C Warrants by Shanghai Tianyi, it purchased 8,272,379 Series C Preferred Shares.
- (6) Pingtan Xing Zheng entered into an assignment and undertaking dated 4 January 2022 with Shanghai Yiyue Enterprise Management Partnership (Limited Partnership) (上海屹玥企業管理合夥企業(有限合夥)) (“**Shanghai Yiyue**”), which was used as Pingtan Xing Zheng’s investment vehicle, pursuant to which, Pingtan Xing Zheng assigned and transferred to Shanghai Yiyue, an affiliate of Pingtan Xing Zheng, all of its rights, title and interest in and to the Series C Warrants. Upon full exercise of the Series C Warrants by Shanghai Yiyue, it purchased 3,805,294 Series C Preferred Shares.
- (7) Under the Series C Agreement, Orient Champion Investment Limited (“**Orient**”) had subscribed for 4,963,427 Series C Preferred Shares for a consideration of US\$3 million. Such shares were issued by our Company to Orient on 24 November 2021 prior to Orient’s payment. Orient defaulted on its payment obligations and subsequently surrendered all the shares issued to it on 12 May 2023. For illustrative purpose, such shares would have represented approximately 0.59% of the total issued shares of our Company, assuming those Shares have not been surrendered, immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements). Orient is an Independent Third Party.
- (8) The settlement date was 24 April 2023 as the Company and Skketch Shine had separately agreed that consideration may be paid in two tranches in order to facilitate settlement. The first tranche of approximately US\$27.2 million, representing approximately 90.67% of the total investment amount by Skketch Shine, was settled in December 2021, and the second tranche of the remaining US\$2.8 million, representing approximately 9.33% of the total investment amount by Skketch Shine, was settled in April 2023.

Upon completion of the Series C Financing, details of our Company’s shareholding were as follows:

	Class A Ordinary Shares	Class B Ordinary Shares	Class C Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Series C Preferred Shares	Percentage interest
Directors							
Dr. Ni and his close associates							
Water Lily Consultants	55,592,019	54,781,542	51,519,363	–	–	–	20.86%
Ice Tree LLC	6,632,148	–	–	–	–	–	0.85%
Ice Tree Consultants	5,770	3,619,200	–	–	–	–	0.47%
Mr. Dinh							
VD&TL	15,559,916	17,378,497	24,405,636	–	–	–	7.39%
Dr. Yang							
YDD Consulting	6,273,163	3,085,355	4,332,944	–	–	–	1.76%
Dr. Li ⁽¹⁾	9,864,373	19,201,662	26,966,012	–	–	–	7.22%

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	Class A Ordinary Shares	Class B Ordinary Shares	Class C Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Series C Preferred Shares	Percentage interest
<i>Other shareholders</i>							
Bright Future	16,810,861	32,723,465	45,955,468	–	–	–	12.30%
Skketch Shine	–	–	–	–	–	49,634,271	6.39%
Yicun Holdings	–	–	–	–	46,881,393	–	6.04%
Gaotejia	–	–	–	–	–	37,225,703	4.80%
Whitcup Life	4,803,103	9,349,562	13,130,134	–	–	–	3.51%
Grand Diamond	–	–	–	–	26,789,367	–	3.45%
Design Time	–	–	–	–	–	24,817,136	3.20%
De Hong Xin	–	–	–	–	–	24,817,136	3.20%
Individuals who are not							
Directors holding shares							
issued pursuant to the Equity							
Incentive Arrangements ⁽²⁾	17,371,448	–	–	–	–	–	2.24%
Saier Holdings	3,001,940	5,843,476	8,206,334	–	–	–	2.20%
Guan Zi Equity	–	–	–	–	–	12,408,567	1.60%
Hainan Efung	–	–	–	–	–	11,454,063	1.48%
K. RUI	1,985,282	3,864,485	5,427,121	–	–	–	1.45%
Yunxin Holdings	–	–	–	8,873,587	–	–	1.14%
CNCB	–	–	–	–	–	8,272,379	1.07%
Shanghai Tianyi	–	–	–	–	–	8,272,379	1.07%
Chuangdongfang Changhui	–	–	–	–	–	8,272,379	1.07%
Zhongyin Health	–	–	–	–	8,036,810	–	1.03%
Renfu Zhou Ltd.	1,216,786	2,368,556	3,326,301	–	–	–	0.89%
Yingke Zhi De Pu Ze	–	–	–	–	–	5,809,857	0.75%
Yunwen	–	–	–	–	–	5,771,472	0.74%
Jiangmen Efung	–	–	–	–	–	5,090,694	0.66%
Jinhua Jinkai	–	–	–	–	–	4,467,085	0.58%
Shanghai Yiyue	–	–	–	–	–	3,805,294	0.49%
Dr. John Hovanesian	138,089	268,800	377,491	–	–	–	0.10%
Total	139,254,898	152,484,600	183,646,804	8,873,587	81,707,570	210,118,415	100.00%

Notes:

- (1) Dr. Li held 4,202,715 Class A Ordinary Shares, 8,180,866 Class B Ordinary Shares and 11,488,867 Class C Ordinary Shares on trust and for the benefit of Brillimedical pursuant to the Brillimedical Trust Arrangement.
- (2) Under the Series B Equity Incentive Arrangement and Series C Equity Incentive Arrangement which have been adopted upon completion of the Series C Financing, an aggregate of 105,816,483 Class A Ordinary Shares have been reserved for grant (in whatever form). Upon completion of the Series C Financing, 17,371,448 Class A Ordinary Shares have been granted and issued on 1 April 2022 to certain individuals who are not Directors (of which 17,234,122 Class A Ordinary Shares were issued to Ms. Chan Ching Chu, chief financial officer of the Company, and 137,326 Class A Ordinary Shares were issued to a consultant of the Company who provided certain legal advisory services). These share awards are not subject to vesting conditions. For details, see “– Equity Incentive Arrangements” in this section and “Statutory and General Information – D. Equity Incentive Arrangements – (2) Series C Equity Incentive Arrangement” set out in Appendix IV to this prospectus.

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Acquisition of Series C Preferred Shares by Mr. Mok Ka Ying from CNCB

On 22 December 2023, CNCB and Mr. Mok Ka Ying (“**Mr. Mok**”), an Independent Third Party, entered into a share purchase agreement, pursuant to which Mr. Mok acquired 8,272,379 Series C Preferred Shares (being CNCB’s entire holdings in the Company) from CNCB for a consideration of US\$5,000,000. The relevant consideration was determined between CNCB and Mr. Mok, based on arm’s length negotiations and was fully settled on 29 January 2024. The relevant Series C Preferred Shares were transferred from CNCB to Mr. Mok on 27 February 2024. CNCB’s share transfer to Mr. Mok was primarily because CNCB’s investment period stipulated under its relevant agreement of exempted limited partnership expired in June 2023, and therefore CNCB no longer has the mandate to continue to make capital contributions in respect of the portfolio investments under the partnership. At the same time, Mr. Mok was interested in investing in the biotech and healthcare industry, and considered the Company as a suitable investment opportunity. As confirmed by Mr. Mok, he is an independent third party to CNCB and its respective core connected persons and close associates.

Principal Terms of the Pre-IPO Investments

	Series A Financing	Series B-1 Financing	Series B-2 Financing	Series C Financing	Acquisition by Mok Ka Ying
Date of investment	29 October 2018	13 April 2020	1 July 2020	24 November 2021	22 December 2023
Date of full settlement	21 May 2019	13 May 2020	12 November 2020	24 April 2023	29 January 2024
Shares subscribed for or underlying Shares purchased	8,873,587 Series A Preferred Shares	26,789,367 Series B Preferred Shares	54,918,203 Series B Preferred Shares	210,118,425 Series C Preferred Shares ⁽¹⁾	8,272,379 Series C Preferred Shares
Cost per Share paid ⁽²⁾	RMB1.13 (equivalent to US\$0.16 or HK\$1.24)	US\$0.21 (equivalent to HK\$1.65)	US\$0.21 (equivalent to HK\$1.65)	US\$0.60 (equivalent to HK\$4.71)	US\$0.60 (equivalent to HK\$4.71)
Discount to Offer Price ⁽³⁾	87.8%	83.7%	83.7%	53.4%	53.4%
Funds raised by our Group (approximation)	RMB10.0 million (equivalent to US\$1.4 million or HK\$10.9 million)	US\$5.6 million (equivalent to HK\$44.0 million)	US\$11.5 million (equivalent to HK\$90.3 million)	US\$127.0 million (equivalent to HK\$996.9 million)	N/A – None of the proceeds were received by our Company as no new Shares were issued.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Series A Financing	Series B-1 Financing	Series B-2 Financing	Series C Financing	Acquisition by Mok Ka Ying
Implied valuation of our Group (approximation) ⁽⁸⁾	RMB877.2 million (equivalent to US\$122.2 million or HK\$957.5 million) ⁽⁴⁾	US\$163.0 million (equivalent to HK\$1,279.5 million) ⁽⁵⁾	US\$163.0 million (equivalent to HK\$1,279.5 million) ⁽⁵⁾	US\$469.0 million (equivalent to HK\$3,681.6 million) ⁽⁶⁾	US\$469.0 million (equivalent to HK\$3,681.6 million) ⁽⁷⁾
Use of proceeds	The proceeds from the Pre-IPO Investments have been used for research and development, funding manufacturing facilities and commercialisation activities and general working capital of our Group. In particular, US\$30,000,000 of the funds raised from the Series C Financing was used to repay the Promissory Note in connection with the Share Swap. As of the Latest Practicable Date, approximately 85.3% of the net proceeds from the Pre-IPO Investments have been utilised by our Group, where 100.00% of the net proceeds from the Series A Financing, Series B-1 Financing and Series B-2 Financing and approximately 83.1% of net proceeds from the Series C Investment had been utilised by our Group, primarily for research and development of drug candidates and pipeline of our products, as well as general working capital and administrative expenses. As of the Latest Practicable Date, approximately US\$21.4 million of the proceeds from the Pre-IPO Investments had not been utilised. We intend to utilise the remaining net proceeds from the Pre-IPO Investments primarily for our continuing research and development efforts, funding manufacturing equipment and facilities as well as payment of Listing expenses and general working capital of our Group.				N/A – None of the proceeds were received by our Company as no new Shares were issued.
Strategic benefits	At the time of the Pre-IPO Investments, it was considered that our Group could benefit from the additional capital that would be provided by the Pre-IPO Investors' investments.				N/A – This transfer was not initiated by our Company nor did it involve any issuance of new Shares.
Lock-up period	Yunxin Holdings, Yicun Holdings, Grand Diamond, Zhongyin Health, Skketch Shine, Gaotejia, Design Time, De Hong Xin, Hainan Efung, Shanghai Tianyi, Chuangdongfang Changhui, Yingke Zhi De Pu Ze, Yunwen, Jiangmen Efung, Jinhua Jinkai and Shanghai Yiyue are subject to a lock-up undertaking for a period commencing on the date of this prospectus and ending on the last day of six (6) months from the Listing Date.				

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

- (1) 90,168,926 Series C Preferred Shares were purchased by relevant Series C Investors or their assignees pursuant to the exercise of the Series C Warrants.
- (2) Cost per Share paid is calculated by dividing the total consideration paid by the total number of Shares held following the conversion of the relevant Preferred Shares to ordinary Shares on a 1:1 basis.
- (3) The discount to the Offer Price is calculated based on the Offer Price at HK\$10.10 per Share.
- (4) The implied valuation was determined based on arm's length negotiations among the relevant parties taking into account the then advancement in the research and development of our Company's drug candidates, in particular the completion of phase 2 clinical trial of CBT-001 in the United States.
- (5) The implied valuation of our Company increased during the period between the Series A Financing and the Series B Financing, primarily due to the FDA's no objection for us to proceed with phase 3 clinical trial of CBT-001.
- (6) The implied valuation of our Company increased during the period between the Series B Financing and the Series C Financing, primarily due to (i) the progress made in the clinical trial of CBT-001, including review of data from its phase 2 clinical trial in the United States and the pre-IND meeting with the NMPA in March 2020; and (ii) the IND approval obtained to proceed with phase 2 clinical trial of CBT-004 in the United States.
- (7) The implied valuation of our Company remained the same as that in Series C Financing, as the consideration for such acquisition of Series C Preferred Shares by Mr. Mok from CNCB was determined based on arm's length negotiations among the relevant parties (which did not include our Company). No new funds were raised by the Company.
- (8) The implied valuation of our Company upon Listing represents a substantial increase from the implied valuation for the Series C Financing, mainly due to (i) commencement of phase 3 MRCT in the United States and the PRC, as well as the licensing agreement with Santen, in respect of CBT-001; (ii) completion of phase 1/2 clinical trial in Australia and no objection from the FDA to proceed with phase 3 clinical trial in respect of CBT-009; and (iii) completion of phase 2 clinical trial in the United States in respect of CBT-006.

Special Rights of the Pre-IPO Investors

All Shareholders (including the Pre-IPO Investors) are bound by (i) the terms of the existing memorandum and articles of association (as amended from time to time) of our Company which will be replaced by the Memorandum and Articles of Association effective upon the Listing, and (ii) the Company's shareholders' agreement dated 3 December 2021 (the "**Shareholders Agreement**") entered into by (among others) our Company and the Pre-IPO Investors which superseded all previous agreements among the contracting parties in respect of the shareholders' rights in our Company.

Pursuant to the Shareholders Agreement and the existing memorandum and articles of association of our Company, the Pre-IPO Investors were granted certain special rights, including but not limited to inspection rights, pre-emptive rights, rights of first refusal, co-sale rights, redemption rights upon occurrence of certain events, certain rights to commercialisation of CBT-006, drag along rights, and director appointment rights to Yicun Holdings, Grand Diamond, Skketch Shine and Zhongyin Health. All the special rights have been or will be terminated immediately upon the Listing in accordance with chapter 4.2 of the Stock Exchange's Guide for New Listing Applicants.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Redemption rights

Upon occurrence of certain events and if the Group fails to fix the failures within thirty days after the Pre-IPO Investors' notice to fix such failures, at the written request of such Pre-IPO Investor and subject to applicable laws, our Company shall redeem all or a portion of the preferred shares held by such Pre-IPO Investor as requested at the redemption price. For details of the triggering events in relation to the redemption rights, see Note 25(a)(iii) to the Accountant's Report set out in Appendix I to this prospectus.

Termination of redemption rights

As the Listing is expected to take place after the deadline of a "Qualified IPO" (i.e. 31 December 2022), the relevant redemption events have occurred for the Series C Investors only. However, pursuant to the Shareholders Agreement, all of the above redemption rights have already been terminated effective from the date of our Company's listing application to the Stock Exchange, and shall only be restored before Listing if our Company fails to be listed in such listing application or decides to put on hold the Listing or withdraw such listing application. The Directors have confirmed that, on the basis that our Company intends to proceed with the Listing, it is currently expected that such redemption rights will remain terminated up to Listing, and on such basis, the delay in the listing of the Company beyond the deadline for a "Qualified IPO" (i.e. 31 December 2022) shall not have any material impact on the relevant pre-IPO investments or the Company.

Information regarding the Pre-IPO Investors

A number of our Pre-IPO Investors are Sophisticated Investors who made meaningful investment in our Company, namely Skketch Shine, Design Time, Gaotejia, Grand Diamond and Dyee Evergreen. Set out below is a description of our Pre-IPO Investors:

Pre-IPO Investor	Background
Skketch Shine	Skketch Shine, a Sophisticated Investor, is a company incorporated under the laws of BVI and is directly and held equally by two Cayman Islands incorporated private equity funds, both of which have the same general partner being CDH China HF Holdings Company Limited ("CDH China HF"), which is in turn wholly owned by CDH Wealth Management Company Limited ("CDH Wealth Management"). Each of Skketch Shine, CDH China HF and CDH Wealth Management is a member of the CDH Investments group (鼎暉投資), and each of them is an Independent Third Party. CDH Investment group was established in 2002 with over US\$20 billion of assets under management, and invests across the alternative asset classes in private equity, venture & growth, private credit, public equities and real assets through member companies, covering investments in industries such as biological technology, hard technology, consumer, new energy, industrial and business services. Skketch Shine is an entity dedicated to healthcare investments in our Company since 2021, and CDH Investment group's portfolio companies include but not limited to Grand Pharma Group, LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. (stock code: 2291) and I-Mab Biopharma Co., Ltd. (NASDAQ stock code: IMAB). The two private equity funds holding equal equity interests of Skketch Shine were incorporated in the Cayman Islands, have more than 70 limited partners in aggregate, and the limited partner with the largest equity in each fund is interested in approximately 18.4% and 68.5% of the equity interest, respectively. Skketch Shine has made meaningful investment in our Company at least six months before the Listing Date.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
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Design Time	Design Time, a Sophisticated Investor, is a limited liability business company incorporated in the BVI. It is an investment holding company indirectly wholly-owned by CCB International (Holdings) Limited (建銀國際(控股)有限公司) (“ CCB International ”), which is in turn an indirect wholly-owned subsidiary of China Construction Bank Corporation (中國建設銀行股份有限公司). China Construction Bank Corporation is a joint stock company incorporated in the PRC with limited liability and the shares of which are listed on the Main Board of the Stock Exchange (stock code: 00939) and Shanghai Stock Exchange (stock code: 601939). CCB International Capital Limited, one of the Joint Sponsors, is indirectly wholly owned by CCB International (Holdings) Limited. Design Time invested in our Company since 2021. CCB International, through its direct investment businesses and holding entities (including but not limited to Design Time), principally invests self-owned funds in the equity, debts and relevant securities of listed and non-listed companies in industries including technology, biopharmaceuticals and other sectors. CCB International’s investment’s portfolio companies in biopharmaceutical industry include but not limited to Shandong Boan Biotechnology Co., Ltd. (stock code: 6955) and Beijing Luzhu Biotechnology Co., Ltd. (stock code: 2480). It has made meaningful investment in our Company at least six months before the Listing Date.
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Gaotejia	Gaotejia, a Sophisticated Investor, is an exempted company with limited liability incorporated in the BVI. GAOTEJIA Investment Management Co., Limited (高特佳投資管理有限公司) holds the management shares (“ Management Shareholder ”) of Gaotejia, and the affairs of Gaotejia shall be conducted under the company name or such other name as the Management Shareholder may determine. The Management Shareholder is indirectly wholly-owned by Shenzhen GTJA Investment Group Co., Ltd. (深圳市高特佳投資集團有限公司) (“ Shenzhen GTJA ”), which is a company established in the PRC which primarily focuses on investment in the healthcare industry, with assets under management of over RMB20 billion as of 31 December 2023, and its portfolio companies include Akeso, Inc. (康方生物科技(開曼)有限公司) (stock code: 9926), Shanghai Henlius Biotech, Inc. (上海復宏漢霖生物技術股份有限公司) (stock code: 2696) and Viva Biotech Holdings (維亞生物科技控股集團) (stock code: 1873), each being listed on the Stock Exchange. Shenzhen GTJA is owned by four shareholders, with the largest shareholder being Suzhou Delai Electronics Co., Ltd* (蘇州德萊電器有限公司), holding approximately 84.0% of its equity interests, and is ultimately controlled by Bian Zhuang (卞庄). Gaotejia has a track record in the biopharmaceutical industry for over seven years. Each of Gaotejia and the abovementioned entities and/or individuals is an Independent Third Party. It has made meaningful investment in our Company at least six months before the Listing Date.
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HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
Grand Diamond	Grand Diamond, a Sophisticated Investor, is a company incorporated under the laws of the BVI. It is wholly-owned by Grand Pharma Group, the shares of which are listed on the Main Board of the Stock Exchange (stock code: 00512). Grand Pharma Group is an international and major pharmaceutical company which focuses on pharmaceutical technology, nuclear medicine anti-tumor diagnosis and treatment and cerebro-cardiovascular precision interventional diagnosis and treatment technology and biotechnology. Based on the public information, Grand Pharma Group's investments in research and development and various projects throughout 2022 amounted to approximately HK\$2.45 billion, and Grand Pharma Group's investments primarily involved acquiring private companies principally engaged in the development, and/or production of pharmaceutical technologies and devices as subsidiaries and associates of the Grand Pharma Group. Grand Diamond is an entity dedicated to healthcare investments in our Company since 2020. Each of Grand Diamond and the abovementioned entities is an Independent Third Party. It has made meaningful investment in our Company at least six months before the Listing Date.
Dyee Evergreen	Dyee Evergreen, a Sophisticated Investor, is a limited partnership established in the PRC, and is registered as a private equity fund with the Asset Management Association of China (中國證券投資基金業協會) ("AMAC"). Its investment manager is Xiamen Dyee Evergreen Equity Investment Management LP (廈門德屹長青股權投資管理合夥企業(有限合夥)) ("DYEE Capital"), a limited partnership established in the PRC with around RMB4 billion assets under management. As a fund under the DYEE Capital (德屹資本) group, Dyee Evergreen is mainly engaged in private equity investments, focusing on modern service industries, mainly invested in fields such as medical healthcare biopharmaceutical, information technology and services. DYEE Capital's portfolio companies include but not limited to Suzhou Zelgen Biopharmaceuticals Co., Ltd. (蘇州澤璟生物製藥股份有限公司) (Shanghai Stock Exchange stock code: 688266), Shanghai Allist Pharmaceuticals Co., Ltd. (上海艾力斯醫藥科技股份有限公司) (Shanghai Stock Exchange stock code: 688578) and InventisBio Co., Ltd. (益方生物科技(上海)股份有限公司) (Shanghai Stock Exchange stock code: 688382). Dyee Evergreen has a track record in the biopharmaceutical industry for four years. De Hong Xin was the special purpose vehicle formed by Dyee Evergreen. The general partner of Dyee Evergreen is Xiamen Derong Investment Partnership (Limited Partnership) (廈門德嶸投資合夥企業(有限合夥)), which is managed by DYEE Capital as its general partner and managing partner. The limited partners of Dyee Evergreen are (i) Xiamen Delihong Investment Partnership (Limited Partnership) (廈門德利泓投資合夥企業(有限合夥)) which is interested in approximately 50.00% of its equity interest, (ii) Xiamen Jinyuan Investment Group Co., Ltd (廈門金圓投資集團有限公司), which is interested in approximately 11.25% of its equity interest; (iii) Xiamen Siming District Industrial Investment Co., Ltd (廈門市思明區產業投資有限公司), which is interested in approximately 11.25% of its equity interest, (iv) Xiamen High-tech Innovation Angel Venture Capital Co., Ltd (廈門高新科創天使創業投資有限公司), which is interested in approximately 2.50% of its equity interest; (v) Zheng Ye (鄭燁), who is interested in approximately 19.38% of its equity interest; and (vi) two individuals each of whom is interested in no more than 10% of its equity interests. Each of Dyee Evergreen and the abovementioned entities and/or individuals is an Independent Third Party. Dyee Evergreen has made meaningful investment in our Company at least six months before the Listing Date.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
CNCB	CNCB is an exempted limited partnership established in the Cayman Islands. CNCB is an entity dedicated to healthcare investments in our Company as one of the Series-C Investors in 2021 and is primarily focused on investment opportunities in pharmaceutical companies and medical device manufacturers in the fields of biopharmaceutical, cardiovascular, ophthalmic and oncology therapeutics. CNCB ceased to be our Shareholder after the transfer of all its equity interests held in our Company to Mr. Mok Ka Ying in February 2024. Prior to such transfer, the general partner of CNCB is CNCB Grand Pham Healthcare Fund GP Limited, a company incorporated in the Cayman Islands, which is (i) indirectly held as to 50% by Shanghai Grand Financial Investment Co., Ltd (上海遠大產融投資管理有限公司) which is indirectly held as to 70% by Hu Kaijun (胡凱軍), a controlling shareholder of Grand Pharma Group, the shares of which are listed on the Main Board of the Stock Exchange (stock code: 00512), and (ii) indirectly held as to 50% by CNCB (Hong Kong) Investment Limited (“ CNCB Investment ”), which is in turn held as to 100% by China CITIC Bank Corporation Limited (“ CITIC Bank ”), the shares of which are listed on the Main Board of the Stock Exchange (stock code: 0998) and the Shanghai Stock Exchange (stock code: 601998). The limited partners of CNCB are (i) CNCB (Hong Kong) Investment Limited, which is interested in 44.44% of its equity interest and is in turn an indirect wholly-owned subsidiary of CITIC Bank, and (ii) Grand Strength Investment Limited, which is interested in 55.56% of its equity interest and is in turn a direct wholly-owned subsidiary of Grand Pharma Group. Each of CNCB, Hu Kaijun (胡凱軍) and the abovementioned entities is an Independent Third Party.
Mok Ka Ying	Mok Ka Ying is an Independent Third Party and an individual investor. He previously worked in established financial and banking institutions.
Yunxin Holdings	Yunxin Holdings is a company incorporated under the laws of the BVI. It is controlled by Yunxin Partnership, a limited partnership established in the PRC, which is a private equity fund focused on investment in companies engaged in the development of novel drugs and/or medical devices. The general partner of Yunxin Partnership is Shanghai Yunxin Enterprise Management Co., Ltd (上海雲鉉企業管理有限公司) (“ Yunxin Management ”). Yunxin Holdings, Yunxin Partnership and Yunxin Management are ultimately controlled by Liu Lingyun (劉凌雲), an Independent Third Party.
Yicun Holdings	Yicun Holdings is a company incorporated under the laws of the BVI. It is controlled by Shanghai Xucun Enterprise Management Consulting Partnership (Limited Partnership) (上海絮村企業管理諮詢合夥企業(有限合夥)) (“ Xucun Partnership ”), a limited partnership established in the PRC. The general partner of Xucun Partnership is Jiangyin Huaxicun Investment Co., Ltd. (江陰華西村投資有限公司) (“ Jiangyin Huaxicun ”), a company established in the PRC. Jiangyin Huaxicun is wholly-owned by Yicun Capital Co., Ltd. (一村資本有限公司), a company established in the PRC, which is ultimately controlled by various local branches of the State-owned Assets Supervision and Administration Commission of the PRC.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
Zhongyin Health	Zhongyin Health is a company incorporated under the laws of the BVI. It is wholly-owned by Suzhou Zhongyu Yingjia Health Investment Partnership (Limited Partnership) (蘇州中譽贏嘉健康投資合夥企業(有限合夥)) (“ Suzhou Zhongyu ”), a limited partnership established in the PRC, which is a private equity fund focused on investment in healthcare and biopharmaceutical companies. The general partner of Suzhou Zhongyu is BOC International Capital Limited (中銀國際投資有限責任公司) (“ BOC International Capital ”), a company established in the PRC and which is a subsidiary of BOC International (China) Co., Ltd. (中銀國際證券股份有限公司), the shares of which are listed on the Shanghai Stock Exchange (stock code: 601696). Each of Zhongyin Health, Suzhou Zhongyu and BOC International Capital is a member of the BOC International Group.
Zibo Yingke, Yingke Rong Da, and Yingke Zhi De Pu Yun	Zibo Yingke (now known as Hangzhou Taifu Yingrui Venture Capital Partnership (Limited Partnership) (杭州泰富盈瑞創業投資合夥企業(有限合夥))) is a limited partnership established in the PRC and registered as a venture capital fund with the AMAC. It focuses on investments in healthcare, technology, new materials, energy conservation and environmental protection, intelligent manufacturing, electronic equipment and clean technologies, with assets under management of RMB301 million. Its general partner is Guangxi Yingji Investment Co., Ltd. (廣西盈吉投資控股有限公司), which is owned (i) as to 49% by Lai Zhendong (賴振東), and (ii) as to 51% by Yingke Innovative Assets Management Co., Ltd. (盈科創新資產管理有限公司) (“ Yingke Innovative ”), a company established in the PRC an investment manager registered with the AMAC in the PRC and the largest shareholder of which is Qian Mingfei (錢明飛). The limited partners of Zibo Yingke are (i) Yingjia Keda Investment Co., Ltd (盈嘉科達投資有限公司), which is interested in approximately 60.13% of its equity interest and is in turn indirectly owned by 17 shareholders, with approximately 35.65% held by the largest shareholder Qian Mingfei (錢明飛), (ii) Hangzhou Taikun Capital Funds Limited Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)) which is interested in approximately 19.93% of its equity interest and its general partner is Hangzhou Tailong Venture Capital Partnership (Limited Partnership) (杭州泰龍創業投資合夥企業(有限合夥)), and (iii) Chen Chunsheng (陳春生), who is interested in approximately 16.61% of its equity interest. The governor of Zibo Yingke is Yingke Innovative.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO Investor

Background

Yingke Rong Da is a limited partnership established in the PRC and registered as a private equity fund with the AMAC. It focuses on investments in technological innovation industries such as high-tech, high-growth biomedicine, mass consumption, new energy, energy conservation and environmental protection and intelligent manufacturing, with assets under management of RMB50 million. Its general partner and governor is Shanghai Yingke Zhide Private Equity Fund Management Co., Ltd. (上海盈科值得私募基金管理有限公司) (“**Zhide Management**”), which is a company established in the PRC and an investment manager registered with the AMAC in the PRC. It is ultimately controlled by Qian Mingfei (錢明飛).

Yingke Zhi De Pu Yun is a limited partnership established in the PRC and registered as a private equity fund with the AMAC. It focuses on investments in biomedicine, new materials, energy conservation and environmental protection, intelligent manufacturing, electronic equipment and clean technologies, with assets under management of RMB34 million. Its general partner and governor is Zhide Management.

Zibo Yingke, Yingke Rong Da and Yingke Zhi De Pu Yun subsequently transferred all of their rights under the Series C Warrants to purchase Series C Preferred Shares to Yunwen, which was used as the vehicle for overseas investment, in accordance with instructions from their investors. Yunwen is a company incorporated under the laws of the BVI. It is wholly-owned by Shanghai Yunwen Enterprise Management Partnership (Limited Partnership) (上海雲溫企業管理合夥企業(有限合夥)) (“**Yunwen Partnership**”), a limited partnership established in the PRC. The general partner of Yunwen Partnership is Lai Zhendong (賴振東), an Independent Third Party. Yunwen Partnership is owned as to 40.56% by Yingke Rong Da, as to 30.75% by Yingke Zhi De Pu Yun, as to 28.65% by Zibo Yingke, and as to 0.04% by Lai Zhendong (賴振東). Zibo Yingke, Yingke Rong Da, Yingke Zhi De Pu Yun, and each of the abovementioned parties is an Independent Third Party.

Yingke Zhi De Pu Ze

Yingke Zhi De Pu Ze is a limited partnership established in the PRC, a private equity fund established specifically for investment into our Group. Its general partner is Zhide Management. There are nine limited partners of Yingke Zhi De Pu Ze and the limited partner with the largest equity in Yingke Zhi De Pu Ze is Guosen Capital Co., Ltd. (國信資本有限公司) (“**Guosen Capital**”) with approximately 19.61% of its equity interest. Guosen Capital is ultimately owned by 10 shareholders, with the largest shareholder being Shenzhen City Investment Holding Co., Ltd. (深圳市投資控股有限公司) holding approximately 33.46% of its equity interest, and is wholly owned by the local branch of the State-owned Assets Supervision and Administration Commission of the PRC. Each of the Yingke Zhi De Pu Ze and the abovementioned limited partners is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
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Hainan Efung	<p>Hainan Efung is a limited partnership established in the PRC and focuses primarily on venture capital and private equity investments in the biopharmaceuticals and high-end medical devices industries with asset under management of approximately RMB136.5 million. Its general partner is Efung Junma, a company established in the PRC, registered as a private equity fund with the AMAC, and which is ultimately controlled by Zhu Jinqiao (朱晉橋), an Independent Third Party. As of the Latest Practicable Date, Hainan Efung had 20 limited partners, the largest of which is Ma Weihua (馬蔚華) with approximately 10.99% of equity interest in Hainan Efung. Hainan Efung subsequently transferred its rights under the Series C Warrants to purchase 5,090,694 Series C Preferred Shares to Jiangmen Efung. Jiangmen Efung is a limited partnership established in the PRC which is also managed by Efung Junma. The limited partners of Jiangmen Efung are (i) Guosen Capital which is interested in approximately 46.73% of its equity interest, (ii) Shenzhen Qianhai Huirong Times Asset Management Co., Ltd. (深圳前海匯融時代資產管理有限公司) which is interested in approximately 23.36% of its equity interest and is in turn ultimately controlled by Xie Mulin (謝木林) and Zeng Simin (曾絲敏), (iii) Beijing Contemporary Economics Foundation (北京當代經濟學基金會) which is interested in approximately 4.67% of its equity interest, and is a public welfare organisation approved by the Beijing Civil Affairs Bureau (北京市民政局), (iv) Liao Chongqin (廖崇清) who is interested in approximately 14.02% of its equity interest, and (v) two individuals each of whom is interested in no more than 10% of its equity interests. Hainan Efung, Jiangmen Efung, and each of the abovementioned parties is an Independent Third Party.</p>
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Cheng Guang	<p>Cheng Guang is a limited partnership established in the PRC. It focuses on investments in biopharmaceuticals, consumer goods sectors and etc. Cheng Guang subsequently transferred all of its rights under the Series C Warrants to purchase Series C Preferred Shares to Guan Zi Equity, which is an affiliate of Cheng Guang. Guan Zi Equity is a venture capital fund registered with the AMAC. The managing partner of both Cheng Guang and Guan Zi Equity is Guanzi Management Consulting (Lishui) Partnership (Limited Partnership) ((關子管理諮詢(麗水)合夥企業(有限合夥))). The limited partners of Cheng Guang are (i) Zhejiang Jingning Guanzi Technology Development Co., Ltd. (浙江景寧關子科技發展有限公司), which holds approximately 74.44% of its equity interest, (ii) an individual who is an Independent Third Party, who holds approximately 24.81% of its equity interest, (iii) Guanzi Management Consulting (Lishui) Partnership (關子管理諮詢(麗水)合夥企業(有限合夥)), which holds approximately 0.50% of its equity interest, and (iv) Xinquan Consulting Management (Lishui) Partnership (新泉諮詢管理(麗水)合夥企業(有限合夥)), which holds approximately 0.25% of its equity interest. Each of Cheng Guang, Guan Zi Equity and abovementioned parties is an Independent Third Party.</p>
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HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pre-IPO

Investor	Background
Hainan Tianyi	Hainan Tianyi is a limited partnership established in the PRC. It is mainly engaged in equity investments in the pharmaceutical industry, new consumer goods and other strategic emerging industries. Hainan Tianyi subsequently transferred all of its rights under the Series C Warrants to purchase Series C Preferred Shares to Shanghai Tian Yi Rui Yao Enterprise Management Partnership (Limited Partnership) (上海天壹睿曜企業管理合夥企業(有限合夥)) (“ Shanghai Tianyi ”) which was the entity formed by Hainan Tianyi and used as its vehicle for overseas investment. Each of their general partner is Tianshi Chuangxin (Fujian) Venture Capital Co., Ltd. (天時創新(福建)創業投資有限公司), a company established in the PRC and which is ultimately controlled by Zhou Guiliang (周桂良). The limited partners of Hainan Tianyi are (i) Zheng Ye (鄭燁), who is interested in approximately 77.11% of its equity interest, (ii) He Xiaorui (何曉銳) who is interested in approximately 14.28% of its equity interest, and (iii) two other individuals each of whom is interested in no more than 10% of its equity interests. The limited partner of Shanghai Tianyi is Hainan Tianyi. Each of Hainan Tianyi, Shanghai Tianyi and abovementioned parties is an Independent Third Party.
Chuangdongfang Changhui	Chuangdongfang Changhui is a limited partnership established in the PRC. It is registered as a private equity fund with the AMAC, mainly focusing on venture capital investments in biotech projects. Its general partner is Shenzhen CDF Capital Co., Ltd. (深圳市創東方投資有限公司) (“ CDF Capital ”), a company established in the PRC which is ultimately controlled by Xiao Shuilong (肖水龍). Its limited partners are (i) Guosen Capital which is interested in approximately 48.71% of its equity interest, (ii) Yantai Guotai Chengfeng Asset Management Co., Ltd (煙台國泰誠豐資產管理有限公司) which is interested in approximately 28.65% of its equity interest and is in turn ultimately controlled by local branch of the State-owned Assets Supervision and Administration Commission of the PRC, and (iii) three individuals each of whom is interested in no more than 10% of its equity interests. CDF Capital had total assets under management of approximately RMB25 billion as of the Latest Practicable Date. Each of Chuangdongfang Changhui and the abovementioned parties is an Independent Third Party.
Pingtang Xing Zheng, and Jinhua Jinkai	Each of Pingtan Xing Zheng and Jinhua Jinkai is a limited partnership established in the PRC, mainly focusing on investments in companies engaged in high-growth innovative drugs, innovative medical devices and related businesses with assets under management of RMB268 million, and RMB0.2 billion, respectively. Each of their general partner is Industrial Securities Innovation Capital Management Co., Ltd. (興證創新資本管理有限公司) (“ Industrial Innovation ”), which is registered as a private equity fund with the AMAC, and a wholly-owned subsidiary of Industrial Securities Co., Ltd. (興業證券股份有限公司), a joint stock company incorporated in the PRC with limited liability and the shares of which are listed on the Shanghai Stock Exchange (601377.SH). The limited partner with the largest equity in Pingtan Xing Zheng is Zhou Xiao Chun (周曉春) with approximately 7.46% equity interest in Pingtan Xing Zheng. The limited partner of Jinhua Jinkai is Jinhua Jinkai Linkson Cornerstone Equity Investment Co., Ltd. (金華金開領信基石股權投資有限公司), which is wholly-owned by Jinhua Jinkai State-owned Capital Investment Co., Ltd. (金華金開國有資本投資有限公司), a state-owned company in the PRC. Pingtan Xing Zheng subsequently transferred all of its rights under the Series C Warrants to purchase Series C Preferred Shares to Shanghai Yiyue Enterprise Management Partnership (Limited Partnership) (上海屹玥企業管理合夥企業(有限合夥)) (“ Shanghai Yiyue ”), which was used as its investment vehicle. Shanghai Yiyue is a limited partnership established in the PRC, and of which 99% of its partnership interest is owned by Pingtan Xing Zheng. The general partner of Shanghai Yiyue is Xiang Jun (項軍). Each of Jinhua Jinkai, Pingtan Xing Zheng and the abovementioned entities is an Independent Third Party.

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Except for (1) Zibo Yingke, Yingke Rong Da, and Yingke Zhi De Pu Yun which are ultimately controlled by Qian Mingfei (錢明飛), (2) Pingtan Xing Zheng and Jinhua Jinkai which have the same general partner Industrial Securities Innovation Capital Management Co., Ltd. (興證創新資本管理有限公司), and (3) Hainan Efung and Jiangmen Efung which have the same manager Hainan Efung Junma Private Equity Fund Management Co., Ltd. (海南倚鋒駿馬私募基金管理有限公司), as disclosed in the table above, there are no other past or present relationship among the Pre-IPO Investors as of the Latest Practicable Date.

From 22 July 2021 to 24 June 2024, Mr. Zhou Chao was our Non-executive Director as designated by Grand Diamond, one of our Pre-IPO Investors and Sophisticated Investors. As of the Latest Practicable Date, he is a director of Cloudbreak Cayman and Cloudbreak Guangzhou, both of which are our wholly owned subsidiaries. He is also an executive director and the chief executive officer of Grand Pharma Group, which in turn wholly-owns Grand Diamond. Upon Mr. Zhou Chao's resignation as our Non-executive Director, since 26 June 2024, Mr. Xia Zhidong was appointed as our Non-executive Director designated by Grand Diamond, one of our Pre-IPO Investors and Sophisticated Investors. He also holds various positions with non-wholly-owned subsidiaries of the Grand Pharma Group, including legal representative and manager of Wuhan Grand Pharmaceutical Group Sales Co., Ltd.* (武漢遠大製藥集團銷售有限公司), general manager of Xi'an Beilin Pharmaceutical Co., Ltd.* (西安碑林藥業股份有限公司) and Grand Pharmaceutical Huangshi Feiyun Pharmaceutical Co., Ltd.* (遠大醫藥黃石飛雲製藥有限公司), and vice president of Grand Pharma (China) Co., Ltd.* (遠大醫藥(中國)有限公司). Mr. Cao Xu is our Non-executive Director designated by Skketch Shine, one of our Pre-IPO Investors and Sophisticated Investors. He is also a partner of CDH Investment Co., Ltd.* (上海鼎暉百孚投資管理有限公司), which is a member of the CDH Investments group (鼎暉投資) to which Skketch Shine belong as well. Mr. Zhao Jianghua was our director from 15 July 2021 to 1 November 2023, as designated by one of our Pre-IPO Investors, Yicun Holdings. Save as aforementioned, there are no other Pre-IPO Investors and/or Sophisticated Investors which have other past or present relationship (including, without limitation, family, business, financing, employment or otherwise) with the Company, its subsidiaries, their shareholders, directors, or senior management or any of their respective associates as of the Latest Practicable Date.

Confirmation from the Joint Sponsors

On the basis that (i) the consideration for the Pre-IPO Investments was irrevocably settled more than 28 clear days before the date of our first submission of the listing application to the Stock Exchange; and (ii) the special rights granted to the Pre-IPO Investors shall cease to be effective and be discontinued upon the Listing, the Joint Sponsors confirm that based on the documents provided by our Company relating to the Pre-IPO Investments, the Pre-IPO Investments are in compliance with chapter 4.2 of Guide for New Listing Applicants.

EQUITY INCENTIVE ARRANGEMENTS

To incentivise and recognise the contribution of certain employees, adviser and officers of our Company, our Company approved and adopted the Series B Equity Incentive Arrangement on 24 November 2021 (which was adopted by Cloudbreak Cayman on 27

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August 2020 prior to the Share Exchange), the Series C Equity Incentive Arrangement on 24 November 2021, and the 2023 Equity Incentive Scheme on 14 March 2025. As of the Latest Practicable Date,

- (a) under the Series B Equity Incentive Arrangement, an aggregate of 7,788,237 Class A Ordinary Shares have been granted and issued, and RSUs for an aggregate of 1,944,009 Class A Ordinary Shares have been granted (but the corresponding Shares have not yet been issued);
- (b) under the Series C Equity Incentive Arrangement, an aggregate of 96,084,237 Class A Ordinary Shares have been reserved for grant (in whatever form). 17,371,448 Class A Ordinary Shares have been granted and issued, RSUs and share options for an aggregate of 78,712,789 Class A Ordinary Shares have been granted (but the corresponding Shares have not been issued yet); and
- (c) under the 2023 Equity Incentive Scheme, RSUs for an aggregate of 85,674,265 Class A Ordinary Shares have been granted (but the corresponding Shares have not been issued yet),

to certain persons related to our Company. Such outstanding share options and RSUs will be vested to grantees after the completion of the Global Offering and according to their respective vesting schedules and conditions. Upon Listing, share options and RSUs representing an aggregate of 164,106,063 Shares remain subject to vesting conditions under the Equity Incentive Arrangements.

For details, see “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.

PUBLIC FLOAT

Upon the Listing, the 161,892,924 Shares held by Dr. Ni (through Water Lily Consultants and Ni Legacy Trust), 10,257,118 Shares held by Ms. Leng (through Ice Tree LLC, Ice Tree Consultants and Leng Legacy Trust), 57,344,049 Shares held by Mr. Dinh (through VD&TL and Dinh Legacy Trust), 13,691,462 Shares held by Dr. Yang (through YDD Consulting), 32,159,598 Shares held by Dr. Li, and 95,489,794 Shares held by Bright Future will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the Listing, accounting for an aggregate of approximately 44.21% of the total enlarged issued share capital of our Company immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements). Save as disclosed above, to the best of our Directors’ knowledge, all other Shareholders are not core connected persons of our Company and the 468,057,929 Shares held by them, accounting for approximately 55.79% of the total enlarged issued share capital of our Company immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), will be counted towards the public

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float for the purpose of Rule 8.08 of the Listing Rules after the Listing. As a result, over 25% of our Company's total issued Shares will be held by the public upon completion of the Global Offering, which will satisfy the minimum public float requirement and the minimum market capitalisation of at least HK\$375 million as required under Rule 8.08(1)(a) and Rule 18A.07 of the Listing Rules.

SHARE CONVERSION AND INCREASE IN AUTHORISED SHARE CAPITAL

Upon the Global Offering becoming unconditional, with effect immediately prior to the Listing, (i) each of the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares will be converted into one Share with a par value of US\$0.0001 each on a 1:1 basis by way of re-designation and re-classification; and (ii) our authorised share capital will be increased from US\$100,000 to US\$200,000 by the creation of additional 1,000,000,000 Shares, such that following such increase, the authorised share capital of our Company will be US\$200,000 divided into 2,000,000,000 Shares of US\$0.0001 each.

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THE CAPITALISATION TABLE

The following table illustrates the capitalisation of the Company as of the date of this prospectus and upon completion of the Global Offering (assuming that all the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares have been converted to ordinary Shares on a 1:1 basis, and no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements):

Shareholders	Class A Ordinary Shares	Class B Ordinary Shares	Class C Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Series C Preferred Shares	Aggregate number of shares as of the date of this prospectus	Aggregate shareholding percentage as of the date of this prospectus	Aggregate number of Shares immediately upon the completion of the Global Offering ⁽⁹⁾	Aggregate Shareholding percentage immediately upon the completion of the Global Offering ⁽⁹⁾
Directors										
Dr. Ni and his close associates ^{(1), (5), (6)}										
Water Lily Consultants ^{(1), (5)}	51,691,800	54,781,542	51,519,363	–	–	–	157,992,705	20.36%	157,992,705	18.83%
Ni Legacy Trust ⁽¹⁾	3,900,219	–	–	–	–	–	3,900,219	0.50%	3,900,219	0.46%
Ice Tree LLC ^{(1), (6)}	5,288,139	–	–	–	–	–	5,288,139	0.68%	5,288,139	0.63%
Ice Tree Consultants ⁽¹⁾	5,770	3,619,200	–	–	–	–	3,624,970	0.47%	3,624,970	0.43%
Leng Legacy Trust ⁽¹⁾	1,344,009	–	–	–	–	–	1,344,009	0.17%	1,344,009	0.16%
Mr. Dinh ^{(2), (7)}										
VD&TL ^{(2), (7)}	13,615,907	17,378,497	24,405,636	–	–	–	55,400,040	7.14%	55,400,040	6.60%
Dinh Legacy Trust ^{(2), (7)}	1,944,009	–	–	–	–	–	1,944,009	0.25%	1,944,009	0.23%
Dr. Yang ^{(3), (8)}										
YDD Consulting ^{(3), (8)}	6,273,163	3,085,355	4,332,944	–	–	–	13,691,462	1.76%	13,691,462	1.63%
Dr. Li ⁽¹⁰⁾										
	5,661,658	11,020,796	15,477,145	–	–	–	32,159,599	4.14%	32,159,599	3.83%
Other shareholders										
Bright Future	16,810,861	32,723,465	45,955,468	–	–	–	95,489,794	12.30%	95,489,794	11.38%
Individuals who are not Directors holding shares issued pursuant to the Equity Incentive Arrangements ⁽⁴⁾										
	17,371,448	–	–	–	–	–	17,371,448	2.24%	19,414,076	2.34%
Sketch Shine	–	–	–	–	–	49,634,271	49,634,271	6.39%	49,634,271	5.92%
Yicun Holdings	–	–	–	–	46,881,393	–	46,881,393	6.04%	46,881,393	5.59%
Gaotejia	–	–	–	–	–	37,225,703	37,225,703	4.80%	37,225,703	4.44%
Whitcup Life	4,803,103	9,349,562	13,130,134	–	–	–	27,282,799	3.51%	27,282,799	3.25%
Grand Diamond	–	–	–	–	26,789,367	–	26,789,367	3.45%	26,789,367	3.19%
Design Time	–	–	–	–	–	24,817,136	24,817,136	3.20%	24,817,136	2.96%
De Hong Xin	–	–	–	–	–	24,817,136	24,817,136	3.20%	24,817,136	2.96%
Brillimedical ⁽¹⁰⁾	4,202,715	8,180,866	11,488,867	–	–	–	23,872,448	3.08%	23,872,448	2.85%
Saier Holdings	3,001,940	5,843,476	8,206,334	–	–	–	17,051,750	2.20%	17,051,750	2.03%
Guan Zi Equity	–	–	–	–	–	12,408,567	12,408,567	1.60%	12,408,567	1.48%
Hainan Efung	–	–	–	–	–	11,454,063	11,454,063	1.48%	11,454,063	1.37%
K. RUI	1,985,282	3,864,485	5,427,121	–	–	–	11,276,888	1.45%	11,276,888	1.34%
Yunxin Holdings	–	–	–	8,873,587	–	–	8,873,587	1.14%	8,873,587	1.06%
Mok Ka Ying	–	–	–	–	–	8,272,379	8,272,379	1.07%	8,272,379	0.99%
Shanghai Tianyi	–	–	–	–	–	8,272,379	8,272,379	1.07%	8,272,379	0.99%
Chuangdongfang Changhui	–	–	–	–	–	8,272,379	8,272,379	1.07%	8,272,379	0.99%
Zhongyin Health	–	–	–	–	8,036,810	–	8,036,810	1.03%	8,036,810	0.96%
Renfu Zhou Ltd.	1,216,786	2,368,556	3,326,301	–	–	–	6,911,643	0.89%	6,911,643	0.82%
Yingke Zhi De Pu Ze	–	–	–	–	–	5,809,857	5,809,857	0.75%	5,809,857	0.69%
Yunwen	–	–	–	–	–	5,771,472	5,771,472	0.74%	5,771,472	0.69%

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Shareholders	Class A Ordinary Shares	Class B Ordinary Shares	Class C Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Series C Preferred Shares	Aggregate number of shares as of the date of this prospectus	Aggregate shareholding percentage as of the date of this prospectus	Aggregate number of Shares immediately upon the completion of the Global Offering ⁽⁹⁾	Aggregate Shareholding percentage immediately upon the completion of the Global Offering ⁽⁹⁾
Jiangmen Efung	-	-	-	-	-	5,090,694	5,090,694	0.66%	5,090,694	0.61%
Jinhua Jinkai	-	-	-	-	-	4,467,085	4,467,085	0.58%	4,467,085	0.53%
Shanghai Yiyue	-	-	-	-	-	3,805,294	3,805,294	0.49%	3,805,294	0.45%
Dr. John Hovanessian	138,089	268,800	377,491	-	-	-	784,380	0.10%	784,380	0.09%
<i>Public shareholders under the Global Offering</i>	-	-	-	-	-	-	-	-	60,582,000	7.22%
Total	139,254,898	152,484,600	183,646,804	8,873,587	81,707,570	210,118,415	776,085,874	100.00%	838,892,874	100.00%

Notes:

- (1) Ni Legacy Trust is a discretionary family trust established by Dr. Ni for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Dr. Ni's family members and charities independent of Dr. Ni. Each of Ice Tree LLC and Ice Tree Consultants is wholly-owned by Ms. Leng. Leng Legacy Trust is a discretionary family trust established by Ms. Leng for estate planning and controlled by her by virtue of being settlor and protector. The beneficiaries are Ms. Leng's family members and charities independent of Ms. Leng. Ms. Leng is the spouse of Dr. Ni. Therefore, Water Lily Consultants, Ni Legacy Trust, Ice Tree LLC, Ice Tree Consultants, Leng Legacy Trust and Ms. Leng are close associates of Dr. Ni.
- (2) Dinh Legacy Trust is a discretionary family trust established by Mr. Dinh for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Mr. Dinh's family members and charities independent of Mr. Dinh. Therefore, Dinh Legacy Trust is a close associate of Mr. Dinh.
- (3) YDD Consulting is wholly-owned by Dr. Yang.
- (4) Under the Equity Incentive Arrangements, an aggregate of 191,490,750 Class A Ordinary Shares have been reserved for grant (in whatever form). As of the Latest Practicable Date, 17,371,448 Class A Ordinary Shares have been granted and issued on 1 April 2022 to certain individuals who are not Directors (of which 17,234,122 Class A Ordinary Shares were issued to Ms. Chan Ching Chu, chief financial officer of the Company, and 137,326 Class A Ordinary Shares were issued to a consultant of the Company who provided certain legal advisory services), RSUs and share options for an aggregate of 71,443,181 Class A Ordinary Shares have been granted to certain individuals who are not Directors (but the corresponding Shares have not yet been issued). Upon Listing, RSUs representing 2,225,000 Class A Ordinary Shares shall become immediately vested and issued as Shares upon Listing, and the remaining RSUs representing 163,907,871 Shares and share options representing 198,192 Shares remain subject to vesting conditions under the Equity Incentive Arrangements. For details, see "– Equity Incentive Arrangements" in this section and "Statutory and General Information – D. Equity Incentive Arrangements – (2) Series C Equity Incentive Arrangement" set out in Appendix IV to this prospectus.
- (5) As of the Latest Practicable Date, pursuant to the Equity Incentive Arrangements, Water Lily Consultants has been issued with 3,900,219 Class A Ordinary Shares, and granted with RSUs representing an aggregate of 63,156,492 Class A Ordinary Shares. For details, see "– Equity Incentive Arrangements" in this section and "Statutory and General Information – D. Equity Incentive Arrangements" set out in Appendix IV to this prospectus.
- (6) As of the Latest Practicable Date, pursuant to the Equity Incentive Arrangements, Ice Tree LLC has been issued with 1,944,009 Class A Ordinary Shares, and granted with RSUs representing an aggregate of 9,929,127 Class A Ordinary Shares. For details, see "– Equity Incentive Arrangements" in this section and "Statutory and General Information – D. Equity Incentive Arrangements" set out in Appendix IV to this prospectus.

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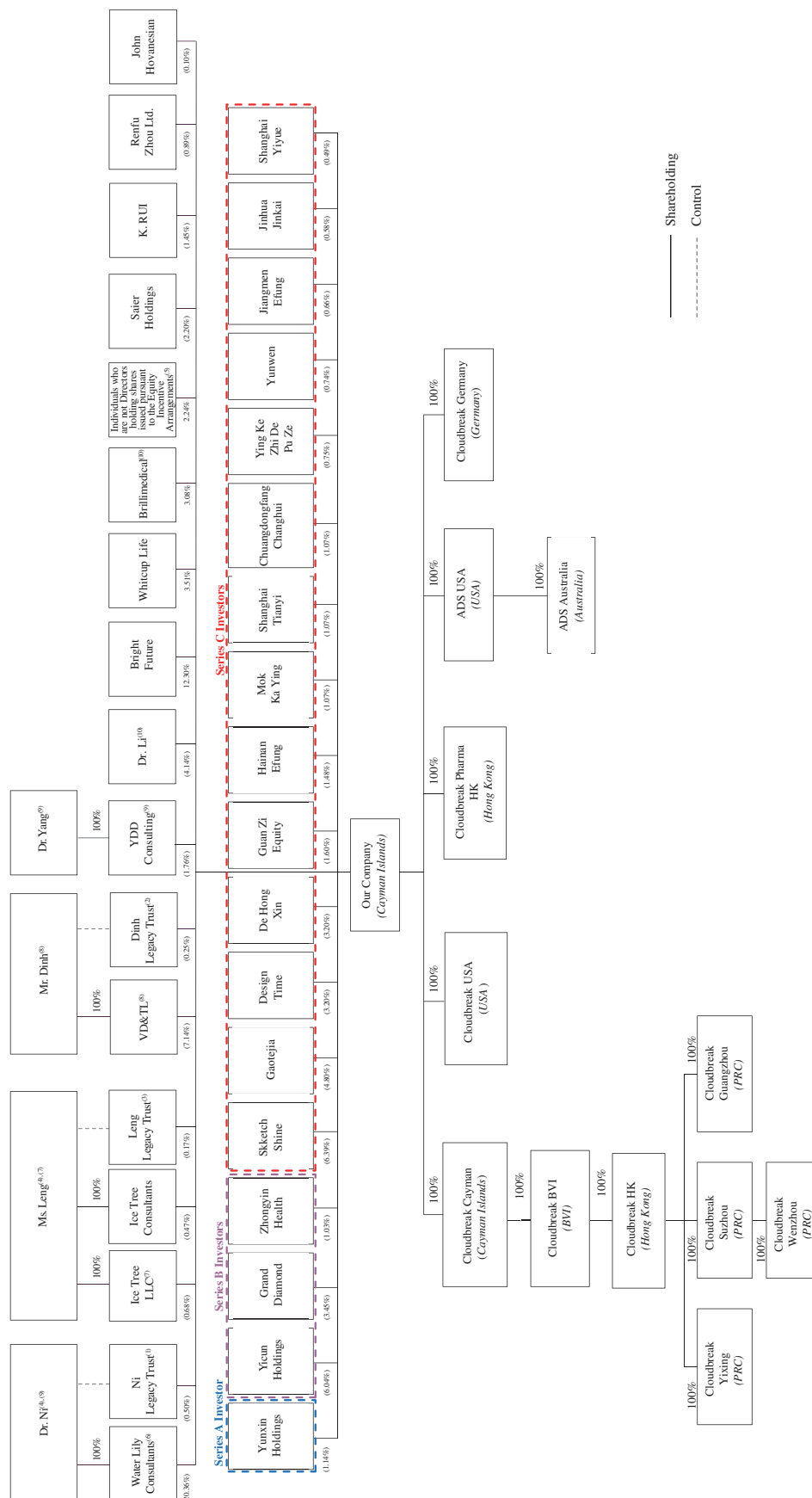
- (7) As of the Latest Practicable Date, pursuant to the Equity Incentive Arrangements, VD&TL has been issued with 1,944,009 Class A Ordinary Shares, and granted with RSUs representing an aggregate of 9,929,127 Class A Ordinary Shares. For details, see “– Equity Incentive Arrangements” in this section and “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.
- (8) As of the Latest Practicable Date, pursuant to the Equity Incentive Arrangements, YDD Consulting has been granted with RSUs representing an aggregate of 11,873,136 Class A Ordinary Shares. For details, see “– Equity Incentive Arrangements” in this section and “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.
- (9) Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).
- (10) On 28 November 2023, Dr. Li transferred 4,202,715 Class A Ordinary Shares, 8,180,866 Class B Ordinary Shares and 11,488,867 Class C Ordinary Shares to Brillimedical at nil consideration for the purpose of unwinding and terminating the Brillimedical Trust Arrangement.

CORPORATE AND SHAREHOLDING STRUCTURE

The following charts illustrate our corporate and shareholding structure (1) immediately prior to the vesting of RSUs under the Equity Incentive Arrangements and completion of the Global Offering and (2) immediately after the completion of the Global Offering (assuming all the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares have been converted to ordinary Shares on a 1:1 basis, and no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements):

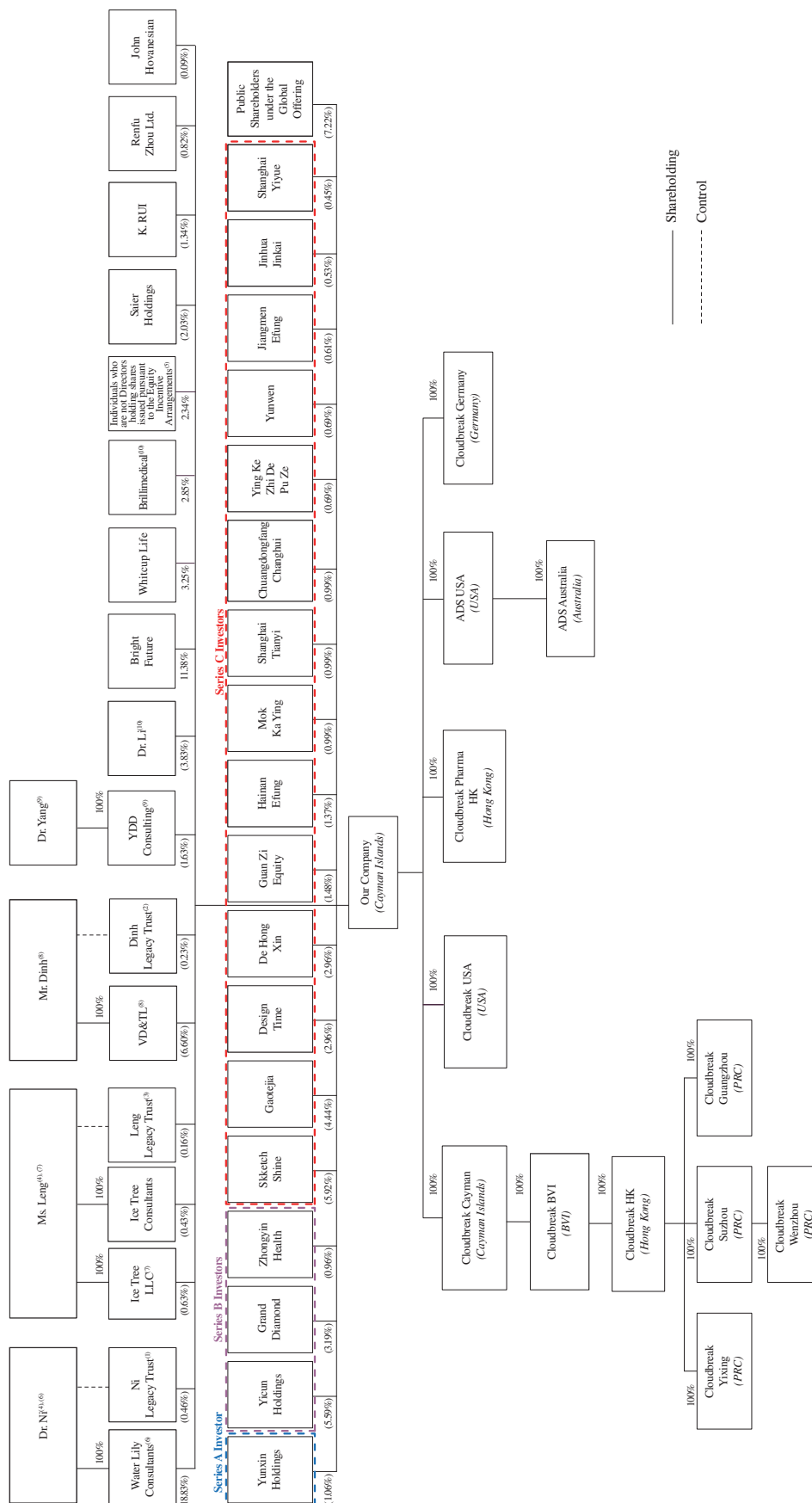
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(1) Immediately prior to the vesting of RSUs under the Equity Incentive Arrangements and completion of the Global Offering



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(2) Immediately after the completion of the Global Offering



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Notes:

- (1) Ni Legacy Trust is a discretionary family trust established by Dr. Ni for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Dr. Ni's family members and charities independent of Dr. Ni.
- (2) Dinh Legacy Trust is a discretionary family trust established by Mr. Dinh for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Mr. Dinh's family members and charities independent of Mr. Dinh.
- (3) Leng Legacy Trust is a discretionary family trust established by Ms. Leng for estate planning and controlled by her by virtue of being settlor and protector. The beneficiaries are Ms. Leng's family members and charities independent of Ms. Leng.
- (4) Ms. Leng is the spouse of Dr. Ni. Therefore, Water Lily Consultants, Ni Legacy Trust, Ice Tree LLC, Ice Tree Consultants, Leng Legacy Trust and Ms. Leng are close associates of Dr. Ni within the meaning of the Listing Rules.
- (5) See note 4 in “– The Capitalisation Table” in this section for details.
- (6) See note 5 in “– The Capitalisation Table” in this section for details.
- (7) See note 6 in “– The Capitalisation Table” in this section for details.
- (8) See note 7 in “– The Capitalisation Table” in this section for details.
- (9) See note 8 in “– The Capitalisation Table” in this section for details.
- (10) On 28 November 2023, Dr. Li transferred 4,202,715 Class A Ordinary Shares, 8,180,866 Class B Ordinary Shares and 11,488,867 Class C Ordinary Shares to Brillimedical at nil consideration for the purpose of unwinding and terminating the Brillimedical Trust Arrangement.

PRC REGULATORY REQUIREMENTS

Our PRC Legal Advisers have confirmed that the PRC subsidiaries in our Group have completed the requisite government filings and registrations in all material respects in respect of their relevant share transfers of equity interests as described in this section of the prospectus. The transfers of equity interests described above have been properly and legally completed.

M&A RULES

According to the Regulations on Merger with and Acquisition of Domestic Enterprises by Foreign Investors (《關於國外投資者併購境內企業的規定》) (the “**M&A Rules**”) jointly issued by the MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the SAT, the CSRC, SAIC and the SAFE on 8 August 2006, effective as of 8 September 2006 and amended on 22 June 2009, a foreign investor is required to obtain necessary approvals from MOFCOM or the department of commerce at the provincial level when it (i) acquires the equity of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (ii) subscribes the increased capital of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (iii) establishes a foreign-invested enterprise through which it

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purchases the assets of a domestic enterprise and operates these assets; or (iv) purchases the assets of a domestic enterprise, and then invests such assets to establish a foreign invested enterprise.

Cloudbreak Guangzhou was a sino-foreign equity joint venture enterprises upon its establishment, therefore, it does not need to be approved by the MOFCOM under the M&A Rules, where a domestic company or enterprise, or domestic natural person, through an overseas company legally established or controlled by it/him, acquires a domestic company which is related to or connected with it/him.

SAFE Circular 37

As disclosed in “Regulatory Overview – Any failure by the Shareholders or beneficial owners of our Shares to comply with certain PRC foreign exchange regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.” in this prospectus, the SAFE Circular 37, which replaced the former SAFE Circular 75, requires PRC residents to register with local branches of SAFE with regard to their establishment or indirect control of an offshore entity established for the purpose of overseas investment and financing. SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to, among others, the special purpose vehicle, the domestic individual resident shareholder, operating period, capital and merger or division events. As at the Latest Practicable Date, none of the direct Shareholders who are individuals, or ultimate beneficial owners of our Shareholders who are directly or indirectly owned or controlled by each of our founders and/or our senior management members and their respective affiliates is a PRC citizen subject to the registration requirement under SAFE Circular 37.

OVERVIEW

We are an innovation-driven clinical-stage ophthalmology biotechnology company dedicated to the development of novel and differentiated treatments. Ophthalmology is a branch of medical science dealing with the structure, function and diseases of the eyes. Since September 2015 when our first principal operating entity was incorporated in the United States, we have been committed to the in-house discovery, development and commercialisation of first-in-class and best-in-class ophthalmic therapies to address global unmet medical needs.

There is a large and growing ophthalmic patient population globally contributed by a variety of factors, including an increasing number of age-related ophthalmic diseases in an ageing society, as well as the prevalent use of smartphones and other digital devices. According to the F&S Report, the global market size of ophthalmic drugs increased from US\$33.7 billion in 2019 to US\$39.6 billion in 2023, with a CAGR of 4.1%. It is expected to reach US\$53.0 billion in 2028 and US\$70.3 billion in 2033, representing a CAGR of 6.0% from 2023 to 2028 and 5.8% from 2028 to 2033, respectively. A number of ophthalmic diseases, such as pterygium and vascularised pinguecula, lack targeted and accessible drug treatment options, which represent a substantial underserved market globally.

To capture the potential in this market, we have built strong R&D capabilities and a drug development model that adopts multiple R&D pathways enabling more predictable and sustainable discovery and development of novel and effective ophthalmic drugs. Our strong R&D capabilities also enable us to cover the entire lifecycle of drug translational science – from early-stage discovery through to large-scale multi-region clinical trials and global product registration process. We are currently developing CBT-001 and CBT-004 as potential first drug therapies globally for the treatment of pterygium (a benign proliferative ocular surface disease) and vascularised pinguecula (a disease where a tissue that develops on the conjunctiva becomes vascularised), respectively. According to the F&S Report, CBT-001 and CBT-004 have the potential to become pharmaceutical solutions to patients with pterygium and vascularised pinguecula, which is expected to reach 1,058.9 million and 1,262.1 million in 2033, respectively.

Our innovative drug development model and strong R&D capabilities are further strengthened by two proprietary technology platforms, multi-kinase inhibitor (“**MKI**”) and antibody-drug synergism (“**ADS**”). Our MKI platform is able to effectively identify, validate and develop novel MKI drug candidates targeting anterior ophthalmic diseases. These therapies have been proven to exert stronger inhibitory effects as compared to existing anti-VEGF antibodies therapies with topical application to achieve optimal efficacy and patient compliance. Our ADS platform is able to develop drug entities by combining an antibody with a small molecule drug via a proprietary linker that target posterior ophthalmic diseases. These conjugates overcome the limitations of single-modality treatment and produce synergistic effects on treatment efficacy by simultaneously targeting multiple pathogenic pathways. Each of our MKI and ADS platforms is an innovative platform for developing drug candidates targeting anterior and posterior ophthalmic diseases, respectively. We established these technology platforms by leveraging our deep understanding of ophthalmic disease pathogenesis and mechanism of actions for different treatment options, as well as scientific know-how we have accumulated through our drug discovery and development experience.

We have established an innovative pipeline of drug candidates covering major anterior and posterior ophthalmic diseases, with four clinical-stage drug candidates and four pre-clinical stage candidates. All of the drug candidates in our pipeline are proprietarily developed, and we believe they have the potential to become first-in-class or best-in-class therapies in the global ophthalmic drug market, including CBT-001 and CBT-004, which are potential first drug therapies globally for pterygium and vascularised pinguecula,

respectively. Our two Core Products CBT-001 and CBT-009 are in more advanced clinical development stage, while other drug candidates are in relatively earlier stage. The following chart summarises our pipeline of drug candidates as of the Latest Practicable Date:

Drug candidate	Mechanism	Indication	Commercial rights	Formulation	Pre-clinical	Phase 1	Phase 2	Phase 3	Relevant authority for clinical trial ⁽¹⁾	Competent authority and regulatory pathway ⁽¹⁾	Current status/ upcoming milestones
Clinical-stage Drug Candidates	CBT-001 ^(*)	MKI (VEGFRs, PDGFRs, FGFRs)	Prevention of pterygium progression and reduction of conjunctival hyperaemia	Global ⁽⁵⁾	Emulsion ⁽⁶⁾	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽⁷⁾			FDA	U.S.: FDA/ 505(b)(2) China: NMPA/ chemical drugs application (Class 2.2 and Class 2.4 ⁽⁵⁾)	- U.S.: commenced ph 3 MRCT in Jun 2022; expect to complete in June 2026 - China: commenced ph 3 MRCT in Sept 2023; expect to complete in June 2026 - New Zealand, Australia and India: commenced additional trials as part of global ph 3 MRCT
	CBT-009 ^(*)	Muscarinic receptor antagonist	Juvenile myopia	Global	Eye drop	Ph 1/2 combined and completed in Australia			TGA	U.S.: FDA/ 505(b)(2) China: NMPA/ chemical drugs application (Class 2.2 and Class 2.4 ⁽⁵⁾)	- U.S.: obtained the IND approval in Sept 2024; expect to commence ph 3 ⁽⁸⁾ - China: commenced toxicity study on juvenile animals in Feb 2025 and expect to submit IND application in third quarter of 2025
	CBT-006 ⁽⁹⁾	Cholesterol dissolving agent	MGD associated DED	Global	Eye drop	Ph 1 in U.S. expected to be directly commenced based on ph 1/2 results in Australia under the 505(b)(2) pathway ⁽⁹⁾			FDA	U.S.: FDA/ 505(b)(2) China: NMPA/ chemical drugs application (Class 1 ⁽⁵⁾)	- U.S.: completed ph 2 in May 2022 - HK: expect to commence additional clinical research by end of 2025
	CBT-004 ⁽¹⁰⁾	MKI (VEGFRs, PDGFRs)	Vascularised pinguecula	Global	Emulsion	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽⁷⁾			FDA	U.S.: FDA/ 505(b)(2) China: NMPA/ chemical drugs application (Class 2.2 ⁽⁵⁾)	- U.S.: intend to submit IND in third quarter of 2025
	CBT-007 ⁽¹¹⁾	MKI (PDGFRs, VEGFRs, FGFRs, PIGFRs, TGF-β)	Glaucoma	Global	Eye drop						- U.S.: intend to submit IND in third quarter of 2025
Pre-clinical Stage Drug Candidates	CBT-199 ⁽¹²⁾	Muscarinic cholinergic receptor agonist	Presbyopia	Global	Eye drop						- Australia: intend to submit IND in second quarter of 2025
	CBT-145 ⁽¹³⁾	Undisclosed	Presbyopia	Global	Eye drop						- As a back-up project for CBT-199; the IND application to be determined based on the progress of CBT-199
	CBT-011 ⁽¹⁴⁾	Antibody-drug synergism ("ADS")	Diabetic macular edema ("DME")/ age-related macular degeneration	Global	Eye drop						- U.S.: intend to submit IND by the end of 2025

* denotes our Core Products

■ represents the clinical trials we have conducted/ we are conducting

■ represents the development phase of a drug candidate that was exempted from clinical trials

Notes:

- (1) The jurisdiction of conducting clinical trials may differ from the jurisdiction where regulatory approval and commercialisation is pursued. We intend to obtain regulatory approval for and pursue commercialisation of our drug candidates primarily in the United States and China.
- (2) The clinical trials for a drug candidate before it is approved to be commercialised in the United States are generally conducted in three sequential phases, known as phase 1, phase 2 and phase 3. However, not all drug candidates are required to complete each of the three phases. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the “**FDCA**”) provides that FDA may rely on data not developed by the applicant for approval of a new drug application (“**NDA**”), even if this data was for a drug approved for a different indication. Under the 505(b)(2) pathway, we are able to utilise validated molecules or compounds with well-established safety and efficacy profiles currently applied in other therapeutic areas and develop them into novel ophthalmic drugs with new indications, dosage forms, routes of administration and formulation. All of our clinical-stage drug candidates have been approved by the FDA to adopt the 505(b)(2) pathway, and we were or will be able to skip the phase 1 clinical trial for them and directly proceed with the phase 2 clinical trial in the United States (for CBT-009, we will be able to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising the clinical trial results of phase 1/2 clinical trial in Australia).
- (3) The classification refers to the new drug classification under the Requirements for Registration Classification and Application Dossiers of Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA in 2020. “New drug” refers to new chemical entities or improved new forms of known chemical entities that have never been marketed anywhere in the world, namely Class 1, 2 and 5.1. Class 1 is classified as innovative new drugs which have never been marketed within or outside China. Class 2.2 is classified as new drugs the preparation of which uses new dosage form (including the new drug delivery system, new prescription process or administration route of known active ingredients), and which also have an obvious clinical advantage. Class 2.4 is classified as new drugs the preparation of which uses known active ingredients but with new indications. See “Industry Overview – Drug Application Pathways in the United States and China – Drug Application Pathways in China” for details.
- (4) For CBT-001, we submitted the IND application in the United States in December 2016, and the FDA did not raise any objection against proceeding with phase 2 clinical trial during the 30-day review period of the IND application. The phase 2 clinical trial was completed in April 2018. The FDA agreed that the CBT-001 could proceed to phase 3 MRCT in the EOP2 Meeting with the FDA in May 2019. Further, after reviewing the data from phase 2 clinical trial in the United States and conducting a pre-IND meeting with us in March 2020, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China in March 2023. We commenced phase 3 MRCT in the United States and China in June 2022 and September 2023, respectively. We expect to complete phase 3 MRCT in the United States and China in June 2026. We have also commenced additional clinical trials in New Zealand, Australia and India as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. In May 2025, we completed the patient recruitment across all five jurisdictions and recruited 660 patients in total. We plan to submit an NDA to the FDA and the NMPA upon the completion of global phase 3 MRCT. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Clinical Development Plan” in this section for details. The reference drug for CBT-001 under the 505(b)(2) pathway is Nintedanib (Ofev®).
- (5) We entered into a commercialisation licensing arrangement with Grand Pharma, pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in Greater China. Notwithstanding the above, we retain the right of applying for the NDA and expect to be the market authorisation holder of CBT-001. In addition, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand,

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Malaysia, Singapore, the Philippines and Indonesia (the “Territory”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan” in this section for details.

- (6) CBT-001 was designed in the form of eye drop (solution) in phase 2 clinical trial and was reformed into ophthalmic emulsion in phase 3 MRCT.
- (7) For CBT-009, the phase 1/2 clinical trial was completed in January 2023. On 21 September 2023, we received the FDA’s preliminary comments on our pre-IND application, approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular toxicity study to support phase 3 clinical trial, and received an approval letter from the FDA in September 2024 stating that it had no objection to us proceeding with phase 3 clinical trial. We have commenced the toxicity study on juvenile animals in China in February 2025 and expect to submit IND application to the NMPA in the third quarter of 2025. We plan to commence phase 3 clinical trial in the United States and China simultaneously, after the toxicity study in China is completed. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009 – Clinical Development Plan” in this section for details. The reference drug for CBT-009 under the 505(b)(2) pathway is atropine.
- (8) Notwithstanding the fact that we have made the pre-IND application to the FDA in July 2023 for CBT-009 and received its preliminary comments in September 2023, we made the IND application to the FDA in July 2024, one year after the pre-IND application, because it took around one year to prepare for and complete a GLP ocular toxicity study. The study was proposed by us and agreed by the FDA. It was conducted to support the phase 3 clinical trial of CBT-009 and has been completed in June 2024.
- (9) For CBT-006, we expect to commence additional clinical research in Hong Kong by the end of 2025. We may hold an EOP2 meeting with the FDA or a pre-IND meeting with the NMPA depending on the combined clinical results of the phase 2 clinical trial in the United States and additional clinical research in Hong Kong. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-006 – Clinical Development Plan” in this section for details. The reference drugs for CBT-006 under the 505(b)(2) pathway are Mitozytrex, Sporanox, Dexacort, Vibativ[®] and Perindopril Erbumin.
- (10) For CBT-004, we obtained the IND approval from the FDA in February 2021, and since then, our R&D team has developed an improved formulation to enable higher doses of CBT-004. Consequently, we decided to conduct additional formulation stability and GLP ocular toxicity studies in rabbits and dogs, which is the reason of the time gap between the IND approval and the IND amendment. The IND amendment was submitted in September 2023 to amend our previous IND submission and phase 2 clinical trial protocol. We completed phase 2 clinical trial in May 2025. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-004 – Clinical Development Plan” in this section for details. The reference drug for CBT-004 under the 505(b)(2) pathway is Inlyta (axitinib).
- (11) For CBT-007, we intend to submit the IND application to the FDA and/or other regulatory authorities in the third quarter of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-007 – Near-term Plans” in this section for details. CBT-007 will adopt the 505(b)(2) pathway and its reference drug is Stivarga (an oral prescription anticancer drug approved by the FDA for patients with metastatic colorectal cancer, gastrointestinal stromal tumor, and hepatocellular carcinoma).
- (12) For CBT-199, we intend to submit the IND application to the HREC in the second quarter of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-199 – Near-term Plans” in this section for details. CBT-199 is expected to adopt the 505(b)(1) pathway.

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- (13) For CBT-145, as a back-up project for CBT-199, the IND application is to be determined based on the progress of CBT-199. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-145 – Near-term Plans” for details. CBT-145 is expected to adopt the 505(b)(1) pathway.
- (14) For CBT-011, we intend to submit the IND application to the FDA and/or other regulatory authorities by the end of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-011 – Near-term Plans” in this section for details. CBT-011 is expected to adopt the 505(b)(1) pathway.

We have established an integrated global operation platform with a full suite of capabilities that we believe has positioned us to target the global market and achieve our goal of “global market, global lead”:

- **R&D centres in strategically selected regions worldwide.** We have three R&D centres located in both the United States and China, and are able to discover new drugs effectively and conduct clinical trials in strategically selected regions worldwide to maximise the long-term commercial potential of our future products across the global market. We are currently conducting clinical trials and MRCTs in the United States and China, and clinical trial locations with patient populations that best suit our target diseases are strategically selected.
- **Global regulatory affairs and product registration teams familiar with drug approval process in major markets.** We have extensive experience in regulatory affairs which provides us insight in regulatory requirements for new drug development in major markets. We have built an effective communication channel with the regulators and maintained a proven track record of engaging with regulatory authorities in major markets, including the FDA and the NMPA.
- **Collaboration arrangement achieving cost-effective commercialisation.** We have entered into a commercialisation licensing arrangement with Grand Pharma and a license agreement with Santen, which are international pharmaceutical companies with strong marketing and sales capability and complete industrial chains, pursuant to which we out licensed certain rights to develop, manufacture and/or commercialise CBT-001. We believe that our commercialisation partnerships are a testament to our R&D expertise, and we plan to leverage such partnership experience to secure strategic collaborations worldwide, in order to execute a cost-effective commercialisation strategy and establish our global sales channels.
- **Manufacturing capability meeting international standards.** We have a pilot production facility in Suzhou, Jiangsu, the PRC, which was designed and built with a view to complying with GMP standards in the United States, China and EU. We also plan to build an additional sizeable commercial production facility in Suzhou based on our clinical development progress and commercialisation needs that meets various quality standards set by relevant regulatory authorities globally, including GMPs to prepare for the anticipated commercialisation of our drug candidates.

- **Seasoned senior management team and R&D experts with international experience.** Our founder and CEO, Dr. Ni, has almost 30 years of industry experience in life sciences industry. He is an established scientist with extensive experience in leading ophthalmic drug development, and has served at Allergan, a leading global ophthalmic company, and a research institute. Most of our senior management and scientific advisory board team members have previous work experience at renowned global ophthalmology companies. We believe that our seasoned senior management team of experienced scientists and visionary market talents with solid knowledge and deep industry experience in pharmaceutical R&D, regulatory affairs and capital markets, together with our R&D experts with drug discovery and clinical development experience in major markets including the United States and the PRC, will lead us to navigate the competitive and complex ophthalmology biotechnology industry.

OUR STRENGTHS

An Innovation-driven Ophthalmology Biotechnology Company with Proprietary Technology Platforms

We are an innovation-driven clinical-stage ophthalmology biotechnology company with innovative technology platforms dedicated to the development of novel and differentiated treatments. We are committed to the in-house discovery, development and commercialisation of either first-in-class, or best-in-class ophthalmic therapies to address global unmet medical needs. Our innovative drug candidates target ophthalmic diseases for which the current standard of care is less optimal, or current treatment options are limited.

All of the drug candidates in our pipeline are proprietarily developed, and we believe they have the potential to become first-in-class or best-in-class therapies in the global ophthalmic drug market. According to the F&S Report, two of our clinical-stage products, namely, CBT-001 and CBT-004, are potential first-in-class drug therapies using breakthrough technology targeting pterygium and vascularised pinguecula, respectively, for which there is currently no available drug therapy globally. CBT-001, once approved, is expected to be the first approved drug targeting pterygium and may potentially reduce or postpone the need for excision surgery depending on the stage of pterygium progression. Likewise, CBT-004, once approved, is also expected to become the first drug available targeting vascularised pinguecula, the current standard of care for which can only temporarily alleviate symptoms. We believe these two drug candidates represent breakthrough innovations, which are testaments to our ability to overcome scientific challenges in exploring unknown fields, and enable us to enjoy significant first mover advantages.

Our potential first-in-class clinical-stage drug candidate CBT-006 is indicated for the treatment of MGD associated DED. MGD is a contributing factor in 70% to 86% of DED cases globally. DED is a common public health concern with a prevalence rate of approximately 10% out of total global population, and the number of patient population with MGD associated DED achieved 923.2 million in 2022 globally. DED could also result in severe consequences as it progresses, such as visual disruption or reduction in visual function.

Our clinical-stage drug candidate CBT-009 which has the potential to become a best-in-class product, indicated for the treatment of juvenile myopia, is expected to outperform its atropine-based competitors and the other current treatment methods in many aspects, including drug stability, safety, patient tolerability and length of shelf life.

To further drive innovation forward, we have built comprehensive R&D capabilities to progress our novel pipeline of drug candidates leading to future global commercialisation. According to the F&S Report, we are one of very few ophthalmology-focused biotech companies globally with R&D capabilities that cover the entire lifecycle of drug translational science – from early-stage discovery through to large-scale multi-region clinical trials and global product registration process. Our proprietary technology platforms, MKI and ADS platforms, are innovative platforms specifically built for drug discovery and development focusing on anterior and posterior ocular diseases, respectively.

Leveraging our regulatory communication and MRCT experiences, we have developed insight in regulatory requirements for new drug development, and have built an effective communication channel with regulators and maintained a proven track record of engaging with major regulatory authorities in major markets, including the FDA and the NMPA. Most of our senior management and scientific advisory board members have previous work experience at renowned global ophthalmology companies, and some of them are proficient in communicating with regulators.

As a recognition to our achievements in innovation, we were listed as a Top 10 Fastest Growing Small Molecule Innovative Drug Enterprises (最具成長性小分子創新藥企業) in 2022 by, among others, Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會). We believe that our potential first-in-class and best-in-class drug candidates, coupled with our solid R&D capabilities and deep regulatory insights, form the foundation for us to continue to capture market opportunities ahead of competition and fulfil unmet medical needs of ocular patients worldwide.

Proprietary-developed Pipeline Covering Major Ocular Diseases with Unmet Medical Needs and Significant Market Potential

We have established a proprietary-developed pipeline of drug candidates covering major anterior and posterior ocular diseases. Our drug candidates either offer potential first-in-class drug solutions using breakthrough technology, or are transformative to the current standard of care and therefore are expected to have a significant market potential.

Our Core Product CBT-001 is a potential first-in-class ocular drug therapy using multi-kinase inhibitor targeting platelet-derived growth factor receptors (“**PDGFRs**”), fibroblast growth factor receptors (“**FGFRs**”) and vascular endothelial growth factor receptors (“**VEGFRs**”), and is indicated for the prevention of pterygium progression and reduction of conjunctival hyperaemia. It is expected to be able to address a broad range of moderate to severe pterygium. According to the F&S Report, there is currently no approved drug therapy for the treatment of pterygium globally, and the current existing treatment option for pterygium is surgical excision. CBT-001 is expected to be the first drug therapy globally for the treatment of pterygium, and to potentially reduce or postpone the need for surgical excision via early non-invasive treatment to control pterygium progression, once

approved. The future use of CBT-001 by pterygium patients is also expected to bring substantial economic benefits compared to the more expensive treatment option using surgery.

We worked with the FDA to support the development of the treatment standard for pterygium based on data collected from our clinical trials of CBT-001. We had an EOP2 Meeting for CBT-001 with the FDA in May 2019. In the meeting, the FDA agreed that the CBT-001 could proceed to phase 3 MRCT. Further, in March 2023, we obtained the IND approval from the NMPA to proceed with phase 3 MRCT in China for CBT-001, after the NMPA reviewed the clinical trial results of CBT-001 in the United States and had a pre-IND meeting with us in March 2020. We commenced phase 3 MRCT for CBT-001 in the United States and China in June 2022 and September 2023, respectively. CBT-001 has demonstrated strong efficacy and a safety profile in its phase 2 clinical trial, and is expected to enjoy first-mover advantages in development and future commercialisation plans, as there are currently no existing drug therapy indicated for pterygium in the market due to high discovery, clinical and regulatory barriers, according to the F&S Report.

Our Core Product CBT-009 is a novel ophthalmic formulation of atropine indicated for the treatment of juvenile myopia (myopia in children and adolescents aged 5 to 19). We believe CBT-009 has the potential to become a best-in-class product and make improvements on the current standard of care for juvenile myopia by improving drug stability, safety, patient tolerability and shelf life. Even though low-dose atropine eye drops, which are currently the most commonly prescribed off-label drugs for juvenile myopia, have been validated as an effective treatment option, intrinsic concerns such as atropine's instability in aqueous solution leading to the short shelf life and tendency to cause irritation to patients, continue to present significant unmet clinical needs. Based on CBT-009's clinical trial and formulation stability results, despite the advantages of aqueous formulation eye drops including effective hydration and easier distribution evenly across the ocular surface, and good tolerance by patients and easy application without causing discomfort or stinging, CBT-009 is expected to improve patient tolerability, safety and product stability as compared with existing aqueous-based formulations based on pre-clinical and clinical studies conducted by us or our CROs. We believe that CBT-009, once approved, will become a best-in-class product to set a new standard of care for juvenile myopia. Following the anticipated launch of CBT-009, we believe it has the potential to reach a broad consumer population, which is expected to further diversify our product portfolio and will enable us to tap into vast market potential.

Our clinical-stage drug candidate CBT-006 is a potential first-in-class drug candidate indicated for the treatment of meibomian gland dysfunction associated dry eye disease ("**MGD associated DED**"; MGD is a chronic age-related macular of the meibomian glands and DED is an eye condition associated with inadequate tear production). None of the launched products or drug candidates indicated for MGD associated DED use the same active ingredient as CBT-006 does. CBT-006 uses cyclodextrin as the active ingredient while other drugs use perfluorohexyloctane, selenium disulfide, minocycline or lotilaner. CBT-006, once approved, is expected to become a first-in-class product for the treatment of MGD associated DED, by dissolving cholesterol and other lipids deposited at the orifice of

meibomian glands and thus improve meibum quality and the health of meibomian gland. Similarly as our expectation for CBT-009, we believe CBT-006 also has strong market potential following its anticipated launch.

Our clinical-stage drug candidate CBT-004 is a potential first-in-class ophthalmic drug using multi-kinase inhibitor targeting VEGFRs and PDGFRs, and is indicated for the treatment of vascularised pinguecula. According to the F&S Report, there is currently no approved drug therapy for the treatment of vascularised pinguecula globally, and the current existing treatment options, including lubricating eye drops and off-label use of non-steroidal anti-inflammatory drugs or steroid eye drops, are insufficient to fulfil the clinical needs due to safety concerns and lack of efficacy. CBT-004 is expected to have advantages over the current standard of care for which can only temporarily alleviate symptoms of pinguecula. We submitted an IND amendment in September 2023 to amend our previous IND submission and phase 1/2 clinical trial protocol. CBT-004 has the potential to become the first drug therapy indicated to treat pinguecula vascularity and to relieve its symptoms, once approved, and we are also working with the FDA with a view to setting global new standards for the treatment of vascularised pinguecula.

Unique Innovation Model Enabling Cost-effective Drug Development

We operate under a unique innovation model of strategically pursuing a variety of R&D pathways to develop novel drugs. Upon identifying unmet medical needs, we leverage our deep understanding and scientific know-how in ophthalmic disease pathology and pharmacology to explore compounds that we believe best serve the purpose of maximising the probability of our R&D success. We have developed our risk-balanced pipeline of drug candidates by adopting the optimal R&D pathway for each drug candidate, including using drug re-purposing to obtain an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (the “**505(b)(2) pathway**”), as well as using new chemical entities or new biologics.

The 505(b)(2) pathway allows the applicant for an NDA to rely, in part, on the previous findings of the FDA on safety and efficacy for a product with the same active pharmaceutical ingredient (“**API**”) or published literature. We adopt the 505(b)(2) pathway to reduce risks arising out of the drug development process when we determine it is most suitable for a particular drug candidate. It is a commonly adopted approach for drug development in the United States, and has been validated by successful launch and sale of many ophthalmic drugs with considerable sales revenue, according to the F&S Report. Under the risk-balanced, efficient and cost-effective R&D approach adopting the 505(b)(2) pathway, we are able to utilise validated molecules or compounds with well-established safety and efficacy profiles currently applied in other therapeutic areas and develop them into novel ophthalmic drugs with new indications, dosage forms, routes of administration and formulation. In the field of ophthalmology in particular, the appropriate drug candidate identification and effective reformulation of and changes to the reference drugs under the 505(b)(2) pathway requires a deep understanding of ophthalmic disease pathogenesis, extensive scientific know-how and strong R&D innovation capabilities. The innovation characteristics of our R&D work are demonstrated by the implementation of novel

mechanism of action adopted to address the unmet medical needs of ocular diseases, as well as the efforts taken to develop novel eye drop formulations. We have obtained various patents globally on disease treatment methods and/or formulations in this regard.

The 505(b)(2) pathway presents unique value for ophthalmic drug development in particular because ophthalmic drugs which are developed for topical use do not face any competition from their reference drugs which are in the form of oral medication (which is a form of systemic administration). Due to blood-ocular barrier, oral drugs would deliver insufficient amount of active ingredient to the ocular surface due to poor bioavailability, or cause adverse effects to liver or kidney by increasing systemic drug dosing, due to relatively low blood flow to various targets of receptors in human eyes. As a result, none of the oral drugs which were used as the reference drugs in the 505(b)(2) pathway are indicated for ophthalmic diseases. We also believe that off-label use of drug products adopting systemic administration (including oral drugs) poses minimal commercial threat to our ophthalmic drugs as they are rarely recommended in clinical practice due to safety concerns and lack of efficacy, according to the F&S Report.

We are pursuing 505(b)(2) pathway for all of our clinical-stage drug candidates. They have demonstrated a number of advantages, including:

- **Enhanced certainty in drug profile.** For example, by utilising validated mechanisms in angiogenesis and fibrosis inhibition for CBT-001 and CBT-004, we were able to apply our scientific know-how in ophthalmic diseases and focus on the development of new indications, dosage forms and regimens, routes of administration and formulations on the approved reference drugs under the 505(b)(2) pathway as an innovative treatment for pterygium and vascularised pinguecula.
- **Multiple intellectual property rights protection.** The 505(b)(2) pathway offers us the opportunities to develop and register new patents in a number of aspects, such as method of use, formulation and indication, without infringing on existing patents of the reference drugs, with a term of 20 years. These patents will work in tandem with regulatory hurdles to create barriers to entry that potential competitors would need to overcome to compete in our commercialisation space. We have established a strong intellectual properties protection system with multiple layers of patent protection covering various aspects of our clinical-stage drug candidates.
- **Expedited drug development process.** The 505(b)(2) pathway enables us to make full use of existing data on the clinical profiles of approved reference drugs and avoid certain lengthy duplicative clinical trial processes. For example, we were able to rely on certain existing human and animal safety data in the development of CBT-001 in the United States without the need to repeat these studies. Further, after reviewing the phase 2 clinical trial results in the United States for CBT-001 and conducting a pre-IND meeting with us, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China.

- **High technological barriers for competitors.** The appropriate drug candidate identification and effective reformulation of and changes to the reference drugs under the 505(b)(2) pathway requires a deep understanding of ophthalmic disease pathogenesis and extensive scientific know-how. Consequently, developing new drug therapies under the 505(b)(2) pathway creates high technological barriers for potential competitors to enter into the market, and we believe it is an effective approach for developing potential first-in-class drug therapies in the ophthalmic field.

In addition to adopting the 505(b)(2) pathway for some of our drug candidates, we have also leveraged our strong R&D capabilities to discover and develop new chemical entities or new biologics with a view to address unmet medical needs. For example, CBT-011, developed through our ADS platform, is designed to target two pathways via antibodies and small molecules, respectively, and potentially generates synergism and improves the treatment result for DME.

Our R&D work is led by senior scientists who have accumulated decades of pharmaceutical R&D and entrepreneurship experience in global ophthalmology giants and renowned research institutions, including our founder Dr. Ni and members of our scientific advisory board. We benefit from the leadership of our team of scientists, who have significant experience in the drug discovery and development processes with global pharmaceutical companies, which has enabled us to successfully develop our innovative portfolio of drug candidates. Seven of our R&D team members have over ten years of experience in ophthalmology.

Proprietary Technology Platforms Purposefully Built for Development of Ophthalmic Therapies

Our two proprietary technology platforms, MKI platform and ADS platform, are proprietary technology platforms specifically built for drug discovery and development focusing on anterior and posterior ophthalmic diseases, respectively. Each of MKI platform and ADS platform targets the development of small molecule drugs and conjugates between an antibody and a small molecule drug, respectively. The combination of our two technology platforms offers comprehensive solutions to cover a wide range of ophthalmic diseases.

Our MKI platform is able to effectively identify, validate and develop novel MKI candidates targeting a wide range of anterior ophthalmic diseases. We are developing clinical-stage drug candidates for the treatment of anterior ophthalmic diseases based on the MKI platform. MKIs have already been clinically proven to achieve better therapeutic effects compared to the more common single-kinase inhibitor therapies, as many diseases progress involving the action of multiple kinases rather than just one. Simultaneously targeting multiple kinases for anterior ophthalmic diseases achieves synergistic effects for better treatment outcome. Leveraging our know-how in small molecule MKI drugs and a deep understanding of pathogenesis of various anterior ophthalmic diseases, we have developed a unique set of techniques to select and combine multiple targets that form our MKI candidates on our MKI platform, with topical application to achieve optimal efficacy

and patient compliance. The platform has supported the development of three of our drug candidates, namely, CBT-001, CBT-004 and CBT-007. These drug candidates have so far demonstrated an optimisation of PK/PD characters and high potency in animal models.

Our ADS platform is able to develop drug entities formed by combining an antibody with a small molecule drug via a proprietary linker that target posterior ophthalmic diseases. These conjugates overcome the limitations of single-modality treatment and produce synergistic effects on treatment efficacy by simultaneously targeting multiple pathogenic pathways. Our ADS platform is an innovative ADS platform in the global ophthalmology field. There exists multiple biologics for the treatment of ophthalmic diseases. While large-sized biologics have shown higher specificity in treatment than small molecule drugs, they are limited in treating posterior ophthalmic diseases as it is difficult for biologics to penetrate through vitreous humour and might require high frequency of intraocular injection that significantly impacts patient compliance. Increased dosage could also lead to increased side effects. Our ADS platform is highly compatible with our technology in antibody and small molecule agent, in that its innovation involves conjugating an antibody drug to a small molecule drug, using a cleavable linker proprietarily designed to be enzymatically hydrolysed in the vitreous humour in a controlled manner. In an ADS compound, the role of antibody is no longer limited to acting solely as a carrier as the approach taken by traditional antibody-drug conjugate (“ADC”) technology. By enabling the antibody to exert therapeutic effect and to act as a sustained delivery vehicle for the small molecule which normally lasts for only a few hours if not linked to a large molecule, our ADS compound is able to generate synergistic effects between antibody and small molecule to magnify efficacy and response rate, and prolong the duration of effects. In developing our drug candidates on the ADS platform, we select different combinations of antibody and small molecule agents with favourable validated efficacy and safety profiles depending on the requirements of different ophthalmic diseases. We also tailor the design of the cleavable linker or small molecule and antibody ratio specifically for the treatment of posterior ophthalmic diseases.

We attach great importance to maintaining sufficient intellectual property protection for our proprietarily-developed MKI and ADS platforms. As of the Latest Practicable Date, we had 55 granted patents and 88 pending applications relating to individual compounds and drug candidates developed using our MKI and ADS platforms worldwide, and we will continue to enhance the intellectual property protection of drug candidates developed through our proprietary technology platforms to maintain our competitive edge.

Manufacturing Facilities and Commercialisation Channel Laying Foundation for Near-term Commercialisation Opportunities

We have a pilot production facility in Suzhou, Jiangsu, the PRC, which was designed and built in the view to complying with the GMP standards in the United States, China and EU. The facility is situated in Suzhou New District (蘇州高新技術產業開發區), a specially designated region for technological and industrial development. The facility is expected to have a designed annual production capacity of 3.5 million to 5.3 million bottles (0.2ml per bottle as the minimum filing capacity) to fulfil our future manufacturing needs for clinical trials in the PRC and early-stage commercialisation plans. We also plan to build a sizeable commercial production facility in Suzhou based on our clinical development progress and commercialisation needs that meets various quality standards set by relevant regulatory

authorities globally, including GMP, to prepare for the anticipated commercialisation of our drug candidates. We believe our established pilot production facility, together with our future commercial production facility, will lay foundation for us to meet manufacturing needs in clinical trials and after product launch.

We believe we are also prepared to achieve market penetration for product commercialisation. Led by our chief commercialisation officer Gregory Brooks, who has over 35 years of development and commercialisation experience worldwide, we plan to develop differentiated and tailored commercialisation strategies depending on the characteristics of each drug candidate and the commercialisation regions. For example, we entered into a commercialisation licensing arrangement with Grand Pharma for the purpose of, among others, commercialising one of our Core Products, CBT-001 and a license agreement with Santen. We believe that our commercialisation partnerships will also equip us with broader commercialisation access in Greater China and other key regions in Asia. It will enable us to leverage our partners' well-established network of distribution channels in those regions and optimise the market potential for CBT-001. It also enables us to generate predictable cash flows under the commercialisation licensing arrangement without having to make significant upfront investments in establishing a full sales team in the early stage of commercialisation. As we continue to progress clinical trials for other drug candidates in our pipeline, we expect to be able to leverage our partnership experience with Grand Pharma and Santen to secure strategic collaborations with other major market players to achieve a cost-effective commercialisation strategy and establish our global sales channels.

Our marketing efforts are supported by a widespread network of key opinion leaders (“**KOLs**”) and principal investigators (“**PIs**”). We have collaborated with PIs in the United States and China in our clinical trials, which paves the way for pre-launch market education. We believe these leading PIs who are also renowned KOLs worldwide will be able to help us increase the clinical acceptance of our drug candidates among doctors and accelerate their market penetration. We also actively participate in leading international academic conferences to raise awareness of our drug candidates to eye care professionals (“**ECPs**”) by presenting the clinical benefits of our drug candidates. Our chief medical officer, Abu Abraham, who has approximately 14 years of experience in developing strategies for clinical development programmes, is responsible for supervising and conducting general management of clinical trials for our pipeline of drug candidates. He also leads negotiations with governmental agencies, hospitals and insurance providers to discuss the potential future inclusion of our drug candidates in medical insurance coverage.

Visionary Leadership Team with Rich Industry Experience and Strong Scientific Expertise

We have a visionary leadership team with rich industry experience and strong scientific expertise in the ophthalmic drug industry.

We are led by our founder, chairman, Executive Director and CEO, Dr. Ni, an established scientist with extensive experience in leading ophthalmic drug development. Dr. Ni has almost 30 years of experience in life sciences industry in a research institute and a leading global ophthalmic company. Before establishing our Group in 2015, he served at

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Allergan from May 2000 to June 2015 as the scientific director in the drug safety department of drug safety. Dr. Ni was also a former research scientist and postdoctoral research fellow at the American Health Foundation and the University of Utah, respectively.

Other members of our senior leadership team focused on product development, intellectual property and innovation also have extensive work experience across the ophthalmology industry from leading international pharmaceutical companies, reputable research institutions and regulatory authorities, with complimentary expertise covering the entire drug development lifecycle, including drug discovery, preclinical and clinical trials, regulatory relations, intellectual property rights registration, manufacturing and commercialisation. For example:

- Van Son Dinh, our co-founder and chief operating officer, has over 26 years of experience in the pharmaceutical industry with a wide range of expertise from drug development to business management. He was a principal scientist in the department of drug safety evaluation and formerly a manager at Allergan. Mr. Dinh is familiar with requirements under GMP, GLP and GCP regulations.
- Elizabeth Capan, our chief patent officer and chief compliance officer, has over 16 years of experience in global intellectual property strategy development and execution, patent application and prosecutions. She served as the patent attorney for BASF, a patent attorney at Fish & Richardson, and a patent examiner and authorised PCT officer at the United States Patent and Trademark Office. Ms. Capan also founded Advancing Innovation ESC AB and served as its director and U.S. patent attorney.
- Dr. Rong Yang, our chief scientific officer, has approximately 24 years of experience in drug discovery and development affairs. He worked as an investigator research biology at Allergan from November 1999 to June 2015. Since joining our Group, Dr. Yang has successfully advanced a number of innovative drug candidates into non-clinical and clinical development.
- Dr. Wen Kui Fang, our chief innovation officer, has over 20 years of experience in drug discovery and development affairs with focuses on medicinal research for the design of new and innovative drugs. He served at Allergan from May 1998 to June 2015, and his last position was a scientist at Principle Chemistry responsible for drug generation and optimisation. Dr. Fang also has extensive experience in patent application matters with 64 patents covering his past research and innovation work.

We have assembled an experienced scientific advisory board composed of industry experts, Dr. Scott Whitcup and Dr. John Hovanesian, who have extensive experience in the field of ophthalmology. Dr. Whitcup is the chairman of the scientific advisory board. He has extensive experience in ophthalmology and is the owner of over 139 issued patents in the United States. He worked as an executive vice president, and a research and development and chief scientific officer at Allergan. He also serves on the board of certain pharmaceuticals companies. Dr. Hovanesian has long-standing experience in ophthalmology and in particular, the treatment for pterygium. He is the editor of the textbook “Pterygium

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Techniques and Technology for Surgical Success” and the lead author of the 2017 Pterygium “White Paper”. Dr. Hovanesian has been a PI in multiple ophthalmology clinical trials and he is a member of a number of scientific and medical advisory boards. Dr. Hovanesian currently serves as a clinician at Harvard Eye Associates.

Our capital markets team, facilitates existing and potential capital market activities and mergers and acquisitions (“M&A”) transactions, as well as our treasury management and cash flow maintenance. We believe that the visionary oversight of our capital markets team, combined with the scientific expertise of our senior scientists team and the scientific advisory board, will position us well to execute our long-term development plans.

OUR STRATEGIES

Accelerate Clinical Development of Our Pipeline of Drug Candidates in Global Markets

We plan to leverage our extensive experience and solid R&D capacities in clinical development of ophthalmic drugs to accelerate the clinical development of our drug candidates in global markets to achieve speed-to-market.

In respect of our most advanced drug candidate CBT-001, the FDA agreed that CBT-001 could proceed with phase 3 MRCT in the United States and agreed on phase 3 MRCT study design and efficacy endpoints in principle in the EOP2 Meeting in May 2019. The NMPA granted the IND approval for us to proceed with phase 3 MRCT in China in March 2023 after reviewing the clinical trial results for CBT-001 in the United States and conducting a pre-IND meeting with us in March 2020. We have commenced for phase 3 MRCT in the United States and China. We have also commenced additional clinical trials in New Zealand, Australia and India to continue to assess the efficacy of CBT-001 as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. In May 2025, we completed the patient recruitment across all five jurisdictions and recruited 660 patients in total. We aim to submit an NDA to the FDA and the NMPA upon the completion of global phase 3 MRCT.

In respect of our other clinical-stage drug candidates, we completed phase 1/2 clinical trial for CBT-009 in Australia in January 2023. In September 2023, we received the FDA’s preliminary comments on our pre-IND application approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular study to support phase 3 clinical trial, and received an approval letter from the FDA in September 2024 stating that it had no objection to us proceeding with phase 3 clinical trial. We have commenced the toxicity study on juvenile animals in China in February 2025 and expect to submit IND application to the NMPA in the third quarter of 2025. We are currently in preparation for additional clinical research for CBT-006 at Centre for Eye and Vision Research Limited, Hong Kong, a research collaboration between The Hong Kong Polytechnic University and the University of Waterloo under the InnoHK Initiative of the HKSAR Government, which is expected to commence by the end of 2025. We may hold an EOP2 meeting with the FDA or a pre-IND with the NMPA depending on the combined clinical results of the phase 2 clinical trial in the United States and additional clinical research in Hong Kong. In respect of CBT-004

which received clinical trial approval in February 2021, we submitted the IND amendment in September 2023 following our additional ocular toxicology studies at higher doses, and commenced phase 2 clinical trial in December 2023. The phase 2 clinical trial has been completed in May 2025.

In addition to accelerating clinical developments for our clinical-stage drug candidates, we plan to expedite the development of our preclinical-stage drug candidates which have proof of concept and to advance them to clinical trial stage. In respect of CBT-007, which is being developed to increase the rate of success of glaucoma surgery, we intend to submit the IND application to the FDA in third quarter of 2025. We also intend to submit the IND application to the HREC for CBT-199, which is indicated for presbyopia, in the second quarter of 2025. We intend to submit the IND application to the FDA for CBT-011, which is indicated for DME and age-related macular degeneration, by the end of 2025.

Continue to Enhance Our R&D Capabilities to Develop Technology Platforms and Modalities that Support Our Pipeline Expansion

We aim to further develop our strategically-determined pipeline of drug candidates to complement our existing portfolio, in particular potential first-in-class or best-in-class therapies, in order to maintain our competitiveness. To achieve this goal, we plan to continue to enhance our R&D capabilities to develop next-generation technology platform and modalities, which we believe will support the expansion of our pipeline of drug candidates.

We plan to take advantage of our MKI and ADS platforms to discover and develop additional drug candidates addressing anterior and posterior ophthalmic diseases, respectively. In addition to these two proprietary platforms, we intend to develop new technology platforms that are suitable for ophthalmic diseases, covering the whole process of drug discovery and development. We believe that the contemplated technology platforms will empower us to discover and develop drug candidates in a more efficient way, and further enrich our drug portfolio. For example, we intend to explore new drug candidates with a safer and more effective profile on our non-aqueous formulation platform.

We also intend to extend our R&D capabilities to additional innovative modalities that are able to treat both anterior and posterior ophthalmic diseases and potentially offer more solutions to ophthalmic patients worldwide. In addition to investing in our in-house drug discovery and development efforts, we may also seek collaboration with leading pharmaceutical companies, research institutions and hospitals to leverage their experience and expertise on drug discovery and development.

Pursue Diversified and Tailored Commercialisation Strategies for Our Drug Candidates

To bring our innovative ophthalmic drug candidates to the market, we will pursue diversified and tailor-made commercialisation strategies depending on the specific characteristics of our drug candidates and the intended commercialisation regions.

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In respect of our drug candidates at relatively late clinical development stage, we plan to organise pre-launch commercial activities prior to their anticipated NDA filings and regulatory approvals at an appropriate timing. For example, we have commenced pre-launch commercial activities for CBT-001, and plan to conduct similar market education activities in preparation for the commercialisation of CBT-009 once its phase 3 clinical trial commences. In preparing for the commercialisation of CBT-001 and CBT-009, we will focus our medical affairs function on educating ECPs on the clinical advantages of CBT-001 and CBT-009 and their market positioning as a potential first-in-class and best-in-class product, respectively. In particular, we seek to develop and maintain close relationship with PIs to provide scientific support and encourage patient recruitment for its clinical trials, and raise the awareness on pterygium and juvenile myopia, respectively, among ECPs by educating KOLs and clinicians at major eye care conferences in the United States. We also plan to gather insights through its ongoing marketing research assessments to understand the unmet medical needs of patients, ECPs and leading national insurance providers, in order to support the expected product launch of CBT-001 and CBT-009 and their future insurance coverage, as well as their life cycle management.

Once approved, we plan to commercialise our drug candidates in the United States through a hybrid sales and marketing approach working with a leading ophthalmic company as our business partner to deploy a field-based sales team, implement a direct-to-consumer marketing campaign, an ECP education campaign and a focused digital online marketing campaign. Believing in the importance of patient identification, we intend to increase awareness of relevant indications that our drug candidates are indicated for among patients with ophthalmic diseases through educational and marketing efforts directed towards the patient groups, and will arrange both in office on-site and digital promotional activities. In our campaign working with KOLs and various eye care medical associations, we will highlight the unmet medical needs of relevant indications, the need to increase earlier diagnosis, and the safety and efficacy of our drug candidates to build brand recognition for each of our new products.

To achieve a wide-spread market access, we plan to pursue third-party reimbursement from both government and private insurance providers for the cost of our drug candidates. We have commenced market access, pricing and reimbursement initiatives with national and local payers for our most advanced clinical-stage drug candidate, CBT-001, through market surveys to better present our studies on the cost effectiveness of using CBT-001 as an alternative to currently available treatment options to, and facilitate our future interaction with, insurance providers. We will also commence similar market surveys and discussions with relevant market players for our other drug candidates, when they progress to more advanced clinical development stages.

In the longer term, we will seek to establish and gradually expand our in-house sales and marketing team in the United States and China, and provide comprehensive training to our dedicated sales force in advance of product launches that enables them to educate the ophthalmic community on the benefits of our drug candidates. In addition, we may also seek a partnership with major eye care specialty companies to commercialise and promote our drug candidates in major markets, leveraging our experience in collaborating with Grand Pharma, which we believe will be a cost-effective way to expand our future sales into global markets. The partnership may take the form of out-licensing, or in a co-commercialisation or

co-promotion structure in which we provide resources and personnel while leveraging the potential partner's experience and expertise for the commercialisation of our drug candidates. We believe we are well-positioned to secure promising collaboration opportunities with reputable pharmaceutical companies for the commercialisation of our drug candidates in the near term.

Scale up Our Organisation to Build an International Platform

Since our inception, we have successfully established an innovative pipeline of drug candidates and a strong R&D infrastructure with a lean and highly capable team. Following the Listing, we plan to scale up our organisation to maximise the global value of our platform and drug candidates by building a global end-to-end integrated platform with strong capabilities in drug discovery, clinical development, manufacturing and sales and marketing.

We will expand our R&D team globally to support new drug discovery, development and innovation by recruiting additional seasoned scientists in the ophthalmic and pharmaceutical industry. We will also recruit talents with experience in regulatory affairs to expand our regulatory team, in order to develop further insights in the requirements of regulatory authorities and facilitate the communication with them. We will continue to strengthen our collaboration with leading and influential KOLs and PIs globally, who will likely provide scientific support and encourage patient recruitment for our clinical trials. They may also help raise the awareness on our drug candidates in the ophthalmic industry.

We also plan to further increase our manufacturing capabilities by optimising our in-house process technologies and improving quality control of our future commercialised drug products. In addition to our pilot production facility in Suzhou, we also plan to build a sizeable commercial production facility in Suzhou based on our clinical development progress and commercialisation needs that meets various quality standards set by relevant regulatory authorities globally including GMP to prepare for the anticipated commercialisation of our drug candidates.

We plan to strengthen our medical affairs team to promote our drug candidates to the global market and provide support when we strategically seek global commercialisation partnership opportunities, including potential out-license arrangements for our proprietary-developed drug candidates. We will explore collaboration opportunities in which we will be substantially involved in commercialisation activities to maximise the global commercial potential of our drug candidates. In the longer term, we will seek to establish and gradually expand our in-house sales and marketing team in the United States and China.

OUR PIPELINE OF DRUG CANDIDATES

Overview

We are committed to the in-house discovery, development and commercialisation of first-in-class and best-in-class ophthalmic therapies to address global unmet medical needs. We have established an innovative pipeline of eight drug candidates covering major anterior and posterior ophthalmic diseases, with four clinical-stage drug candidates (namely, CBT-001, CBT-009, CBT-006 and CBT-004) and four pre-clinical stage drug candidates (namely, CBT-007, CBT-199 and CBT-145 and CBT-011), each as described in more details below. Our two Core Products CBT-001 and CBT-009 are in more advanced clinical development stage, while other drug candidates are in relatively earlier stage. The following chart summarises our pipeline of drug candidates as of the Latest Practicable Date:

Drug candidate	Mechanism	Indication	Commercial rights	Formulation	Pre-clinical	Phase 1	Phase 2	Phase 3	Relevant authority for clinical trial ⁽¹⁾	Competent authority and regulatory pathway ⁽¹⁾	Current status/ upcoming milestones
Clinical-stage Drug Candidates	CBT-001 ^(*)	MKI (VEGFRs, PDGFRs, FGFRs)	Global ⁽⁵⁾	Emulsion ⁽⁶⁾	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽²⁾				FDA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 2.2 and Class 2.4 ⁽³⁾)	- U.S.: commenced ph 3 MRCT in Jun 2022; expect to complete in June 2026 - China: commenced ph 3 MRCT in Sept 2023; expect to complete in June 2026 - New Zealand, Australia and India: commenced additional trials as part of global ph 3 MRCT
	CBT-009 ^(*)	Muscarinic receptor antagonist	Global	Eye drop	Ph 1/2 combined and completed in Australia				TGA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 2.2 and Class 2.4 ⁽³⁾)	- Australia: completed ph 1/2 in Jan 2023 - U.S.: obtained the IND approval in Sept 2024; expect to commence ph 3 ⁽⁸⁾ - China: commenced toxicity study on juvenile animals in Feb 2025 and expect to submit IND application in third quarter of 2025
	CBT-006 ⁽⁹⁾	Cholesterol dissolving agent	Global	Eye drop	Ph 1 in U.S. skipped under 505(b)(2) pathway ⁽²⁾				FDA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 1 ⁽⁶⁾)	- U.S.: completed ph 2 in May 2022 - HK: expect to commence additional clinical research by end of 2025
	CBT-004 ⁽¹⁰⁾	MKI (VEGFRs, PDGFRs)	Global	Emulsion	Ph 2 in U.S. expected to be directly commenced under 505(b)(2) pathway ⁽²⁾				FDA	- U.S.: FDA/ 505(b)(2) - China: NMPA/chemical drugs application (Class 2.2 ⁽³⁾)	- U.S.: completed ph 2 in May 2025
Pre-clinical Stage Drug Candidates	CBT-007 ⁽¹¹⁾	MKI (VEGFRs, FGFRs, PDGFRs, TGF-β)	Global	Eye drop							- U.S.: intend to submit IND in third quarter of 2025
	CBT-199 ⁽¹²⁾	Muscarinic cholinergic receptor agonist	Global	Eye drop							- Australia: intend to submit IND in second quarter of 2025
	CBT-145 ⁽¹³⁾	Undisclosed	Global	Eye drop							- As a back-up project for CBT-199; the IND application to be determined based on the progress of CBT-199
	CBT-011 ⁽¹⁴⁾	Antibody-drug synergism ("ADS")	Global	Eye drop							- U.S.: intend to submit IND by the end of 2025

* denotes our Core Products

■ represents the clinical trials we have conducted/ we are conducting

■ represents the development phase of a drug candidate that was exempted from clinical trials

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Notes:

- (1) The jurisdiction of conducting clinical trials may differ from the jurisdiction where regulatory approval and commercialisation is pursued. We intend to obtain regulatory approval for and pursue commercialisation of our drug candidates primarily in the United States and China.
- (2) The clinical trials for a drug candidate before it is approved to be commercialised in the United States are generally conducted in three sequential phases, known as phase 1, phase 2 and phase 3. However, not all drug candidates are required to complete each of the three phases. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the “**FDCA**”) provides that FDA may rely on data not developed by the applicant for approval of a new drug application (“**NDA**”), even if this data was for a drug approved for a different indication. A 505(b)(2) NDA is an application for which one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Under the 505(b)(2) pathway, we are able to utilise validated molecules or compounds with well-established safety and efficacy profiles currently applied in other therapeutic areas and develop them into novel ophthalmic drugs with new indications, dosage forms, routes of administration and formulation. All of our clinical-stage drug candidates have been approved by the FDA to adopt the 505(b)(2) pathway, and we were or will be able to skip the phase 1 clinical trial for them and directly proceed with the phase 2 clinical trial in the United States (for CBT-009, we will be able to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising the clinical trial results of phase 1/2 clinical trial in Australia).
- (3) The classification refers to the new drug classification under the Requirements for Registration Classification and Application Dossiers of Chemical Drugs (《化學藥品註冊分類及申報資料要求》) issued by the NMPA in 2020. “New drug” refers to new chemical entities or improved new forms of known chemical entities that have never been marketed anywhere in the world, namely Class 1, 2 and 5.1. Class 1 is classified as innovative new drugs which have never been marketed within or outside China. Class 2.2 is classified as new drugs the preparation of which uses new dosage form (including the new drug delivery system, new prescription process or administration route of known active ingredients), and which also have an obvious clinical advantage. Class 2.4 is classified as new drugs the preparation of which uses known active ingredients but with new indications. See “Industry Overview – Drug Application Pathways in the United States and China – Drug Application Pathways in China” for details.
- (4) For CBT-001, we submitted the IND application in the United States in December 2016, and the FDA did not raise any objection against proceeding with phase 2 clinical trial during the 30-day review period of the IND application. The phase 2 clinical trial was completed in April 2018. The FDA agreed that the CBT-001 could proceed to phase 3 MRCT in the EOP2 Meeting with the FDA in May 2019. Further, after reviewing the data from phase 2 clinical trial in the United States and conducting a pre-IND meeting with us in March 2020, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China in March 2023. We commenced phase 3 MRCT in the United States and China in June 2022 and September 2023, respectively. We expect to complete phase 3 MRCT in the United States and China in June 2026. We have also commenced additional clinical trials in New Zealand, Australia and India as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. In May 2025, we completed the patient recruitment across all five jurisdictions and recruited 660 patients in total. We plan to submit an NDA to the FDA and the NMPA upon the completion of global phase 3 MRCT. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Clinical Development Plan” in this section for details. The reference drug for CBT-001 under the 505(b)(2) pathway is Nintedanib (Ofev®).
- (5) We entered into a commercialisation licensing arrangement with Grand Pharma, pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in Greater China. Notwithstanding the above, we retain the right of applying for the NDA and expect to be the market authorisation holder of CBT-001. In addition, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any

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pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan” in this section for details.

- (6) CBT-001 was designed in the form of eye drop (solution) in phase 2 clinical trial and was reformed into ophthalmic emulsion in phase 3 MRCT.
- (7) For CBT-009, the phase 1/2 clinical trial was completed in January 2023. On 21 September 2023, we received the FDA’s preliminary comments on our pre-IND application, approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular toxicity study to support phase 3 clinical trial, and received an approval letter from the FDA in September 2024 stating that it had no objection to us proceeding with phase 3 clinical trial. We has commenced the toxicity study on juvenile animals in China in February 2025 and expect to submit IND application to the NMPA in the third quarter of 2025. We plan to commence phase 3 clinical trial in the United States and China simultaneously, after the toxicity study in China is completed. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009 – Clinical Development Plan” in this section for details. The reference drug for CBT-009 under the 505(b)(2) pathway is atropine.
- (8) Notwithstanding the fact that we have made the pre-IND application to the FDA in July 2023 for CBT-009 and received its preliminary comments in September 2023, we made the IND application to the FDA in July 2024, one year after the pre-IND application, because it took around one year to prepare for and complete a GLP ocular toxicity study. The study was proposed by us and agreed by the FDA. It was conducted to support the phase 3 clinical trial of CBT-009 and has been completed in June 2024.
- (9) For CBT-006, we expect to commence additional clinical research in Hong Kong by the end of 2025. We may hold an EOP2 meeting with the FDA or a pre-IND meeting with the NMPA depending on the combined clinical results of the phase 2 clinical trial in the United States and additional clinical research in Hong Kong. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-006 – Clinical Development Plan” in this section for details. The reference drugs for CBT-006 under the 505(b)(2) pathway are Mitozytrex, Sporanox, Dexacort, Vibativ® and Perindopril Erbumin.
- (10) For CBT-004, we obtained the IND approval from the FDA in February 2021 and since then, our R&D team has developed an improved formulation to enable higher doses of CBT-004. Consequently, we decided to conduct additional formulation stability and GLP ocular toxicity studies in rabbits and dogs, which is the reason of the time gap between the IND approval and the IND amendment. The IND amendment was submitted in September 2023 to amend our previous IND submission and phase 2 clinical trial protocol. We completed phase 2 clinical trial in May 2025. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Clinical-stage Product – CBT-004 – Clinical Development Plan” in this section for details. The reference drug for CBT-004 under the 505(b)(2) pathway is Inlyta (axitinib).
- (11) For CBT-007, we intend to submit the IND application to the FDA and/or other regulatory authorities in the third quarter of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-007 – Near-term Plans” in this section for details. CBT-007 will adopt the 505(b)(2) pathway and its reference drug is Stivarga (an oral prescription anticancer drug approved by the FDA for patients with metastatic colorectal cancer, gastrointestinal stromal tumor, and hepatocellular carcinoma).

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- (12) For CBT-199, we intend to submit the IND application to the HREC in the second quarter of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-199 – Near-term Plans” in this section for details. CBT-199 is expected to adopt the 505(b)(1) pathway.
- (13) For CBT-145, the IND application is to be determined based on the progress of CBT-199. See “Business – Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-145 – Near-term Plans” for details. CBT-145 is expected to adopt the 505(b)(1) pathway.
- (14) For CBT-011, we intend to submit the IND application to the FDA and/or other regulatory authorities by the end of 2025 depending on the results of our ongoing pre-clinical research. See “– Our Pipeline of Drug Candidates – Pre-clinical Stage Drug Candidates – CBT-011 – Near-term Plans” in this section for details. CBT-011 is expected to adopt the 505(b)(1) pathway.

Clinical-stage Drug Candidates

Our Core Product – CBT-001

Overview

CBT-001 is our Core Product, and a potential first-in-class drug candidate, which is a multi-kinase inhibitor indicated for the prevention of pterygium progression and the reduction of conjunctival hyperaemia. We are currently conducting phase 3 MRCT for CBT-001 in the United States and China.

We developed CBT-001 through our proprietary MKI technology platform. We expect CBT-001 to be the first drug available targeting pterygium and to potentially reduce or postpone the need for excision surgery depending on the stage of pterygium progression, once approved.

CBT-001 was developed under the 505(b)(2) pathway in the United States. The 505(b)(2) pathway allows the applicant for an IND to rely, in part, on the previous findings of the FDA on safety and efficacy for a product with the same API or published literature. We commenced pre-clinical studies for CBT-001 in the United States since early 2016, and we submitted the IND application for CBT-001 in the United States in December 2016. We commenced phase 2 clinical trial for CBT-001 in April 2017, and completed phase 2 clinical trial in April 2018. We commenced phase 3 MRCT in the United States and China in June 2022 and September 2023, respectively. We have also commenced additional clinical trials in New Zealand, Australia and India as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. In May 2025, we completed the patient recruitment for phase 3 MRCT across all five jurisdictions and recruited 660 patients in total.

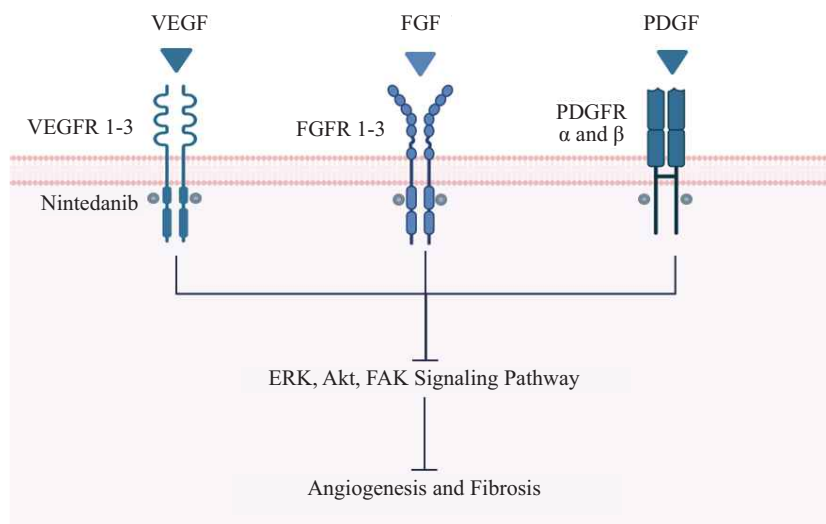
On 13 April 2020, we entered into an exclusive commercialisation licensing arrangement with Grand Pharma, pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in all human use of CBT-001 in mainland China, Hong Kong, Macau and Taiwan (together, the “**Greater China**”). On 6 August 2024, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of

ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. For details of these arrangements, see “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan” in this section.

Mechanism of Action and Advantages

CBT-001 is indicated for the prevention of pterygium progression and the reduction of conjunctival hyperaemia. Pterygium is a benign proliferative ocular surface disease characterised mainly by wing-shaped and fibrovascular growth of the limbal and conjunctival tissue over the adjacent cornea. It can lead to visual impairment due to its damage to the cornea. Pterygium is associated with ultraviolet light exposure (e.g. sunlight), and high risk groups of pterygium include populations with high exposure to sunlight. Some types of pterygium lesion progressively grow and affect vision, and other types grow slower. Both types of pterygium can cause severe symptoms, including foreign body sensation, hyperaemia, irritation, and visual impairment due to lesion obscuration of the visual axis. In particular, the abnormal tissue of pterygium can physically block the tear film from reaching the cornea, causing dryness and irritation which trigger the release of inflammatory mediators that cause blood vessels to dilate, leading to hyperaemia, which is also expected to be treated by CBT-001. In rare cases, pterygium could scar the cornea and lead to blindness if left untreated.

Pterygium is a multifactorial disease involving the upregulation of several growth factors and their receptors, including VEGFs, PDGFs and FGFs. CBT-001 is a small molecule potent MKI that targets VEGFRs, PDGFRs, and FGFRs, among other targets, and is able to inhibit angiogenesis and fibrosis. CBT-001, also known as Nintedanib free base, is formulated as a topical ocular eye drop (solution) for the treatment of pterygium which was reformed into ophthalmic emulsion in phase 3 MRCT. The following diagram illustrates the mechanism of action of Nintedanib:



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The mechanism of action of CBT-001 will potentially lead to disease modifying effects, including the reduction of pterygia-associated vascularity and hyperaemia, as well as inhibition of lesion growth. The mechanism of action of CBT-001 differs from that of traditional large molecule anti-VEGF proteins and thus anti-VEGF drugs are not considered as direct competitors with CBT-001, in that (i) traditional large molecule anti-VEGF proteins can only target VEGFs signalling specifically, but CBT-001 also targets FGF and PDGF signalling, making it more effective against pterygium, a disease with a fibrotic component; (ii) the protein drugs are injected into a liquid environment, the vitreous, where they can freely diffuse throughout the vitreous and soak up VEGF to deplete it from the retinal target tissues. When injected into a solid target tissue like pterygium, the protein drugs cannot diffuse freely and have limited area of effect. On the other hand, CBT-001 is a small molecule drug that can diffuse and distribute to the entire lesion diseased tissues more effectively to block the intended targets; and (iii) CBT-001 is designed in the form of eye drops with a non-invasive route of administration that is convenient for patients. Patients are able to self-dose CBT-001 emulsion, while the injection of protein drugs to the pterygium can only be performed by the physicians in the clinic setting.

We believe that CBT-001, by pharmacologically targeting the angiogenic and fibrotic pathogenesis of pterygium, has the potential to be the first drug available targeting pterygium and may potentially reduce or postpone the need for excision surgery depending on the stage of pterygium progression. Pursuant to the study design of phase 3 MRCT for CBT-001, subject to the conditions that primary and secondary endpoints are met, we anticipate that CBT-001 will be indicated for the “signs and symptoms associated with pterygium” and will be used for patients with mild, moderate and severe pterygium disease. In addition, we anticipate that CBT-001 product will be indicated for chronic administration with twice-daily dosing. Based on its clinical trial data, the pterygium lesion growth has slowed down, stopped or regressed upon continuous CBT-001 drug dosing for one month. The results support the hypothesis that CBT-001 has the potential of postponing the need for excision of pterygium surgery. However, an exact estimation on the duration for postponing the need for such surgery requires further clinical study and is not available yet.

The reference drug for CBT-001 under the 505(b)(2) pathway is Ofev[®]. The active pharmaceutical ingredient of Ofev[®] is nintedanib monoethanesulphonate salt. CBT-001 is a topical ocular formulation of nintedanib free base for the treatment of pterygium and therefore represents changes from Ofev[®] in formulation, delivery route and indication under the 505(b)(2) pathway. As we have obtained the patents for the use of nintedanib to treat pterygium disease, any attempt by others to develop nintedanib in any formulation to treat pterygium will infringe our method of use patent and therefore not allowed. We also own a patent on the development from nintedanib into the formulation of an emulsion eye drop. This process also required substantial time and expertise and thus difficult to be replicated by others. See information regarding the method family and formulation family of CBT-001’s patents in “ – Intellectual Property – Patent Family of CBT-001 – The U.S. Patent Family of CBT-001” for details.

Current Therapies and Limitations

There is currently no approved drug therapy for the treatment of pterygium globally. The most common treatment option for pterygium is surgical excision. Surgical excision offers a definitive solution by removing the abnormal tissue and has a long-standing history in clinical practice. While surgical intervention carries risks such as infection or recurrence, these are generally outweighed by its long-term effectiveness in restoring ocular health and appearance. Surgical excision is usually performed when the lesion encroaches on the visual axis, or when hyperaemia and other bothersome symptoms are persistent. Surgical removal at the early stage of pterygium may be performed on patients who experience vision-impairing astigmatism before pterygium extends to the central corneal, and several surgical techniques have been developed over the years. When the traditional bare sclera excision technique is adopted, post-surgery recurrence was relatively high, at a rate of approximately 30% to 80% in the past. The wide range of recurrence rate is resulted from various preoperative features, including the patient's age, ethnicity and gender, as well as the size of the pterygium and the surgeon's skill level and previous experience. Modern surgical techniques, including the use of various adjunct therapies such as mitomycin, beta irradiation, and subconjunctival bevacizumab injection, may lower the recurrence rate to approximately 10%. Conjunctival or conjunctiva-limbal autografting with intraoperative and postoperative mitomycin C ("MMC") remains the preferred method because it provides a lower recurrence rate and better cosmetic result. Surgical complications occur relatively rarely with these modern techniques, but the high costs of surgical excision and its recurrence rate remain big concerns for doctors and patients.

More conservative off-label treatment options are available but are mainly symptomatic and temporary, usually adopted in the early stages of the disease. The off-label drugs may be able to relieve some pterygium symptoms, but their long-term use may raise safety and effectiveness concerns. For instance, the use of topical corticosteroids is limited for long-term use due to the concern for ocular complications such as glaucoma and cataract. Moreover, it is difficult to detect pterygium at the early stage, especially for patients without proper awareness of disease prevention and control. Clinical examination by an ophthalmologist and anterior segment photographs are the main methods to detect pterygium. The condition of pterygium is often asymptomatic, especially early in its disease course. Additionally, the severity of pterygium is mainly based on the subjective evaluation of the ophthalmologists. However, due to the lack of ophthalmologists, screening for pterygium still faces a huge gap in remote or rural areas with relatively limited medical resources. Therefore, there are unmet clinical needs to develop a drug therapy to reduce pterygium associated hyperaemia and relieve relevant symptoms.

We believe CBT-001 has competitive advantages over the two major management methods for pterygium that are currently available, namely, pharmacological intervention and surgical intervention. Firstly, CBT-001 is indicated for the treatment of pterygium (i.e., the disease itself), and is expected to be more effective and has the potential to reduce or postpone the need for excision surgery; whereas current more conservative off-label treatment options under the category of pharmacological intervention (i) are mainly symptomatic and temporary, (ii) are usually only adopted in the early stages of the disease, (iii) are used to relieve symptoms instead of treating the disease, and (iv) the long-term use of which may raise safety and effectiveness concerns including ocular complications such as

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glaucoma and cataract. Secondly, when compared with surgery excision, CBT-001 is believed to be (i) more convenient for patients, as it is in the form of ophthalmic emulsion-based eye drop which is stable and has high commercial viability, and no significant limitation and disadvantage of ophthalmic emulsion has been identified yet; whereas it takes time and energy to undergo the surgery and surgery excision usually has a high post-surgery recurrence rate even when its associated adjunctive therapy is able to decrease such rate; and (ii) more cost-effective. For example, in the United States, the surgical excision costs approximately US\$5,000 to US\$10,000, but we plan to price CBT-001 at a net price of approximately US\$600.

Market Opportunity and Competition

Globally, the patient population of pterygium reached 974.1 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 1,017.8 million in 2028 and 1,058.9 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively. The patient population of pterygium in the United States reached 22.2 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 23.3 million in 2028 and 24.3 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively. The patient population of pterygium in China reached 150.9 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 155.3 million in 2028 and 160.6 million in 2033, respectively, representing a CAGR of 0.6% from 2023 to 2028 and 0.7% from 2028 to 2033, respectively.

There is currently no approved drug therapy for the treatment of pterygium globally. According to the F&S Report, the global market size of pterygium drug therapies is expected to reach US\$178.3 million in 2028 and US\$1,786.8 million in 2033, representing a CAGR of 58.6%. The market size of pterygium drug therapies in the United States is expected to reach US\$84.2 million in 2028 and US\$815.0 million in 2033, representing a CAGR of 57.5%. The market size of pterygium drug therapies in China is expected to reach US\$5.9 million in 2028 and US\$59.9 million in 2033, representing a CAGR of 59.1%.

The following table illustrates the competitive landscape of clinical-stage drug therapies indicated for pterygium and reduction of conjunctival hyperaemia globally as of the Latest Practicable Date:

Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Active ingredients	Mechanism	Indications	First posted date ⁽²⁾
CBT-001	Our Group	The United States	Phase 3	Nintedanib	Tyrosine kinase inhibitor	Prevention of pterygium progression and reduction of conjunctival hyperaemia	13 July 2022
		China					4 September 2023

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Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Active ingredients	Mechanism	Indications	First posted date ⁽²⁾
AG-86893	Allgenesis Biotherapeutics Inc	Australia	Phase 2	Nintedanib	Tyrosine kinase inhibitor	Prevention of pterygium progression and reduction of conjunctival hyperaemia	23 May 2018
RMP-A03	Suzhou Raymon Pharmaceuticals Company Ltd.	The United States	Phase 2	Not publicly disclosed	Not publicly disclosed	Prevention of pterygium progression and reduction of conjunctival hyperaemia	3 April 2023

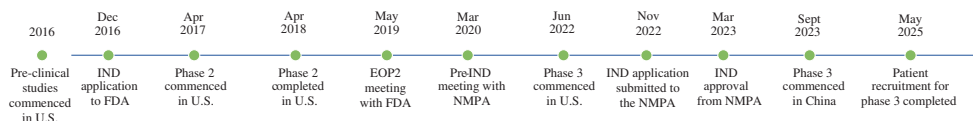
Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidates.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn.

Source: the CDE, ClinicalTrials.gov, F&S Report

Drug development timeline

The chart below summarises the development timeline of CBT-001:



Summary of Clinical Results

1. On-going phase 3 MRCT

In March 2019, we submitted a request to propose holding an EOP2 Meeting for CBT-001 with the FDA. Subsequently in April 2019, we submitted the EOP2 meeting briefing document that states the reformed formulation of CBT-001 from eye drop (solution) used in phase 2 clinical trial to ophthalmic emulsion. We proposed to test the reformed formulation in toxicity studies in animals conducting before phase 3 clinical trial. The reformation of formulation was not at the request of the FDA, nor related to the IPR Proceeding as discussed in details under “- *Inter Partes Review* of ‘820 Patent for CBT-001”. We used eye drop (solution) which was easier to develop so that phase 2 clinical trial, which focused on efficacy and safety profiles, could be commenced earlier. In between phase 2 and phase 3 trials, we developed CBT-001 into ophthalmic emulsion to improve its stability for commercial viability, which was demonstrated to be stable for four years when stored at certain level of temperature and humidity. Ophthalmic emulsion-based eye drop products have been approved for dry eye treatment through increasing tear production by the FDA and became well accepted by patients. Other than relatively high R&D entry barrier, no significant limitation and disadvantage of the ophthalmic emulsion has been identified.

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We had the EOP2 Meeting with the FDA for CBT-001 in May 2019. In the meeting, the FDA agreed that CBT-001 could proceed to phase 3 MRCT and also agreed on the phase 3 study design and efficacy endpoints in principle. The FDA also agreed with our proposal on testing the reformed formulation in toxicity studies in the EOP2 Meeting, and had no comment nor requested any additional information on the reformed formulation.

After the EOP2 Meeting, we spent approximately one and a half year to test the reformed formulation of CBT-001 in sequential GLP six-month ocular toxicity study in rabbits and the GLP nine-month ocular toxicity study in monkeys (both toxicity studies commenced in April 2019 and completed in September 2020, whereas “six” and “nine” months refer to the duration of dosing on rabbits and monkeys respectively) in order to fulfil the requirements for proceeding with phase 3 MRCT in the United States. We subsequently commenced phase 3 MRCT in the United States in June 2022.

The large time gap between the completion of the phase 2 clinical trial and the initiation of phase 3 MRCT was partly due to the COVID-19 pandemic, which halted operations at some clinical trial sites and impacted our clinical trial sites selection. We also had concerns regarding the potential difficulty in differentiating the occurrence of drug-related adverse events from COVID-19-related adverse events should phase 3 MRCT have commenced during the COVID-19 pandemic, which we believe would significantly impact the quality of our phase 3 MRCT. As such, we decided to delay the commencement of phase 3 MRCT in the United States until the COVID-19 pandemic was under control.

We conducted a pre-IND meeting with the NMPA in March 2020, and submitted the IND application in China in November 2022 after the toxicity studies in rabbits and monkeys were completed, so that there was sufficient data to facilitate our communication with the NMPA. Afterwards, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China in March 2023. We subsequently commenced phase 3 MRCT in China in September 2023. We have also commenced additional clinical trials in New Zealand, Australia and India as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively.

Study design. The phase 3 MRCT for CBT-001 is a multicentre, double-masked, randomised, vehicle-controlled 12-month (with a 12-month double-masked extension) parallel comparison study. The objective of phase 3 MRCT is to evaluate the safety and efficacy of 0.1% and 0.2% CBT-001 emulsion dosed twice daily for 24 months compared to vehicle in reducing conjunctival hyperaemia and preventing pterygium progression in patients with pterygia. The study treatment is a CBT-001 ophthalmic emulsion (which was reformed from the form of eye drop (solution) in phase 2 clinical trial) containing 0.1% or 0.2% of CBT-001, and the control treatment is an ophthalmic emulsion as the vehicle. The study measurements for primary endpoints include conjunctival hyperemia grade change, pterygium lesion length change and eye symptom score change using certain point scale. In addition to these measurements, those for secondary endpoints also include pterygium vascularity grade change and subjects' likelihood to seek surgery score change. There is substantially no deviation from the endpoints set out in the phase 2 clinical trial for CBT-001. The key inclusion criteria included: (i) male or female at least 12 years of age at the time of consent; and (ii) primary or recurrent pterygium subjects with at least one eye with (a) global conjunctival hyperemia grade is ≥ 3 on a 0-4-point scale at the screening

visit, and (b) a minimum of 1.2 mm and a maximum of 4.5 mm encroachment of the pterygium onto the cornea. The key exclusion criteria included: (i) clinically significant corneal abnormalities, other than pterygium or related to prior pterygium surgery that may affect the validity of the study findings; (ii) anticipated pterygium surgery within a year of enrolment in the study; and (iii) pterygium excision surgery within the six months prior to the enrolment in the study.

The inclusion criteria for phase 3 clinical trials provides a wide range of population with no restriction on lower limit of pterygium vascularity grade including both males and females, as well as juvenile at least 12 years of age. Notwithstanding that pterygium is rare in children and adolescents, the inclusion criteria is consistent with the intended patient group of CBT-001, which is patients with mild, moderate and severe pterygium disease, subject to regulatory authorities' approval. There is no specific exclusion criteria for patient enrolment in terms of ethnicity, so although the exact ethnicity composition percentage numbers are not available until the completion of phase 3 clinical trials, the participants are expected to have diverse demographic profiles in the regions where clinical trials are to be conducted. For the same reason, we believe that the patients recruited will be representative in terms of ethnicity composition.

Latest progress. In May 2025, we completed the patient recruitment in the United States, China, India, Australia and New Zealand for phase 3 MRCT and recruited 660 patients in total. As of the Latest Practicable Date, there was no interim data to analyse. We expect that phase 3 MRCT in the United States and China will complete in June 2026.

The dosage of CBT-001 is currently designed as “one drop of CBT-001 applied to eye(s) with pterygium twice daily for 24 months”. Based on the FDA's latest practice, it is also possible that the final label with dosage will not include the restriction on duration of use.

The clinical results of phase 3 MRCT had not become available as of the Latest Practicable Date.

2. Summary of phase 2 clinical trial in the United States

We submitted the IND application for CBT-001 in the United States in December 2016, and the FDA did not raise any objection against proceeding with phase 2 clinical trial under the 505(b)(2) pathway during the 30-day review period of the IND application. We commenced phase 2 clinical trial for CBT-001 in April 2017, and completed it in April 2018. The phase 2 clinical trial for CBT-001 was conducted in two stages from May 2017 to June 2017, and from June 2017 to April 2018, respectively. We designed the phase 2 clinical trial into two stages as there are different study goals to achieve with different enrolled patient numbers. The first stage of phase 2 clinical trial focused on safety, pharmacokinetics and dosage selection, and the second stage focused on safety and efficacy. The plan to design phase 2 clinical trial into two stages was reflected in the phase 2 clinical trial protocol which was included in the IND application submitted in December 2016, and the FDA did not have any comment on it.

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The following table sets forth an overview of study results of phase 2 clinical trial for CBT-001.

Stage	Number of subjects enrolled	Major enrolment criteria ⁽¹⁾	Key efficacy results	Key safety results	Patients' withdrawal
First stage	24 subjects divided into three cohorts (with 0.02%, 0.05% and 0.2% CBT-001 for cohort 1, cohort 2 and cohort 3, respectively)	Patients with a diagnosis of primary pterygium with moderate or severe vascularity	Only one efficacy measure. The efficacy has been proved ⁽²⁾	TEAEs of any causality (including mild eye irritation and mild foreign body sensation) were reported in 37.5% (3/8) of the patients in cohort 3, but no patients in the other cohorts. There were no reports of non-ocular TEAEs or high-grade (i.e. serious or severe) ocular TEAEs	No withdrawal due to AEs or any other reason
Second stage	51 patients with primary or recurrent pterygium, all of which exposed to drug (one subject lost contact after receiving the first treatment)	Patients with primary pterygium with 0.6–5.0 mm lesion length from the anterior edge of limbus to apex, associated with pterygium vascularity ≥grade 2; and patients with recurrent pterygium, with presence of corneal vessels with concomitant conjunctival vascularity of ≥grade 2 after excision surgery	One primary efficacy endpoint: met ⁽³⁾ One key secondary efficacy endpoint: met ⁽⁴⁾	TEAEs of any causality (including conjunctival discolouration, mild foreign body sensation and increased lacrimation) were reported in 65.4% (17/26) and 16.0% (4/25) in the study eyes of the drug and vehicle groups, respectively. Among them, there were two reports of treatment-related non-ocular TEAEs in the drug treatment group One serious non-ocular TEAE (transient ischemic attack) was reported in the vehicle treatment group but considered not treatment-related since it occurred during the follow-up period, and there was no treatment-related serious TEAEs	No withdrawal due to AEs and one withdrawal due to lost of patient's contact which generally had no impact on the clinical trial development

Notes:

- (1) The enrolled patient group in phase 2 clinical trial was consistent with the intended patient group of CBT-001, which is patients with mild, moderate and severe pterygium disease, subject to regulatory authorities' approval.
- (2) The only efficacy measure for stage 1 was pterygium vascularity intensity in the study eye graded using a 5-point pterygium hyperemia grading scale. Result: met. All patients in each of the three cohorts had moderate (grade 3) pterygium vascularity severity at pre-dose. No changes from pre-dose were observed in cohort 1. Decrease from moderate to mild using the grading scale was reported in both cohort 2 and cohort 3.

- (3) The primary efficacy endpoint for stage 2 is mean change from baseline (day 1) in the severity grade of pterygium vascularity at week 4. Result: met. At week 4, the mean vascularity score for CBT-001 0.2% treated patients had been reduced from baseline by 0.8 grade compared to no change in the vehicle treated patients. Statistical significance was also detected at all post-baseline visits through week 16.
- (4) The key secondary efficacy endpoints for stage 2 are (i) mean change from baseline in corneal pterygium lesion length at week 4. Result: met; and (ii) change in severity grade of conjunctival hyperemia from baseline. Result: met.

Details of the two stages of phase 2 clinical trial in the United States are set out below.

First stage of phase 2 clinical trial

Objective. The objective of the first stage of phase 2 clinical trial was to evaluate the safety, tolerability, pharmacokinetics and assessing signal of efficacy of CBT-001 ophthalmic solutions in reducing pterygium vascularity, following a single dose of CBT-001 ophthalmic solution with the increase of concentrations from 0.02%, 0.05% to 0.2%. This was the dose-escalating stage of the study.

Study design. The first stage was a single-centre, open-labelled, vehicle-controlled study in which 24 eyes of 24 patients received one drop of CBT-001 in a dose escalation fashion to determine the maximally tolerated dose. The patients were divided into three cohorts with eight patients in each cohort, and the eye with pterygium was dosed with a single drop of CBT-001 with concentration of 0.02%, 0.05% and 0.2% for patients in the first, second and third cohort, respectively.

Pharmacokinetics. Following single drop dose of 0.02%, 0.05%, and 0.2% of CBT-001 in cohort 1, 2 and 3, respectively, the systemic exposure of CBT-001 was minimal, meaning the amount of substance expected to enter into the bloodstream was minimal. The lower such amount is, the less possibility there is for a systemic side effect. Plasma concentration of CBT-001 was below the limit of quantitation (0.01 ng/mL, meaning the lowest limit of drug that could be measured systemically, and drug levels below such level of quantification are considered to be undetected in the systemic circulation) for all samples of cohort 1, for all but one sample of cohort 2, and for most samples of cohort 3. Pharmacokinetic parameters were not calculable for area under the curve and half-life. C_{\max} and T_{\max} were estimated for cohort 3 to be about 0.010 ± 0.009 ng/mL and 1.15 ± 1.60 hours, respectively. In comparison, the C_{\max} at steady state following oral dosing with 150 mg twice daily of Nintedanib was 34.8 ng/ml indicating that systemic exposure following ocular topical dosing is more than 3400-fold lower than with the marketed oral product, which means the amount of systemic exposure with ocular dosing of CBT-001 is 3,400 times less compared with oral dosing of the marketed oral product, showing the side effects seen with oral dosing are unlikely to be observed with ocular dosing.

Safety. In the first stage, the ocular treatment emergent adverse events (the “TEAEs”) of any causality were reported in 37.5% (3/8) of the patients in the third cohort (i.e. patients with CBT-001 of 0.2%) and no patients in the other cohorts. In the third cohort, there were three CBT-001 and two vehicle treated fellow eyes with TEAEs. Two of the three TEAEs in the study eye and two of two events in the vehicle-treated eyes were considered treatment-related. In this cohort, mild eye irritation was reported in both CBT-001 and

vehicle-treated eyes by two patients and only in the CBT-001-treated eye by one patient. Mild foreign body sensation in eyes was also reported only in the CBT-001-treated eye by one patient. There were no reports of non-ocular TEAES and no deaths or serious TEAES. There were no clinically significant changes in clinical laboratories (blood chemistry and haematology), vital signs, best corrected visual acuity (“**BCVA**”), ophthalmoscopy and intraocular pressure (“**IOP**”) when compared to the baseline, i.e. when compared to the metrics at the start of the study. The only post-treatment biomicroscopy finding was conjunctival follicles score change from baseline in one CBT-001-treated eye in cohort 1 which was considered not clinically significant by the investigator.

Efficacy. In the first stage, pterygium vascularity intensity of the study eye was the only efficacy measure. All patients in each of the three cohorts had moderate pterygium vascularity severity at pre-dose. No changes from pre-dose were observed in cohort 1. The only change observed for cohort 2 was a decrease from moderate to mild for one patient at two hours post-dose then returned to moderate at four and eight hours post-dose. In cohort 3, consistent changes from pre-dose occurred for three patients with two patients who showed decreases from moderate to mild starting at one hour post-dose and with an additional patient who showed a decrease from moderate to mild starting at two hours post-dose. Duration of effect for all three of these patients continued at four and eight hours post-dose.

Conclusion. The first stage demonstrated good ocular and systemic safety of all three doses of CBT-001. 0.2% of CBT-001 was determined to be the highest tolerable dose (i.e., the highest dose that does not cause unacceptable side effects) and it thus was selected for the second stage of the clinical trial. The systemic exposure of CBT-001 following single drop dose of 0.02%, 0.05% and 0.2% of CBT-001 was minimal and insignificant. A dose response was observed in the reduction of pterygium vascularity intensity from 0.02% to 0.2% of CBT-001.

Second stage of phase 2 clinical trial

Objective. The objective of the second stage was to evaluate the safety, tolerability and efficacy of CBT-001 ophthalmic solution in reducing pterygium or inhibiting pterygium growth following three times daily (“**TID**”) administration of 0.2% ophthalmic solution of CBT-001 for 28 days.

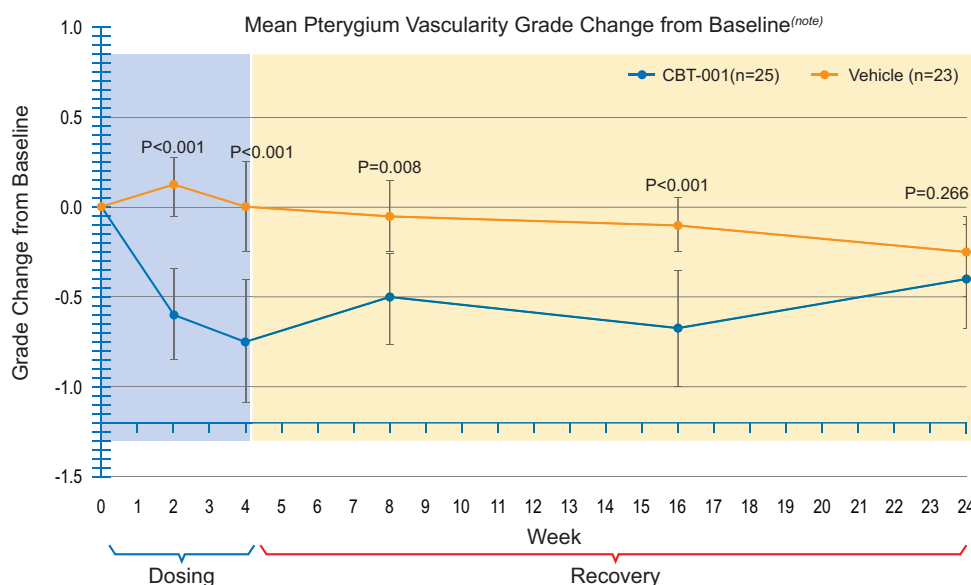
Study design. The second stage was a multicentre, randomised, double-masked, vehicle-controlled, parallel-group clinical trial in which 51 eyes of 51 patients with primary or recurrent pterygia were randomly assigned to receive the maximally tolerated dose of CBT-001 or vehicle dosed three times a day for four weeks with a 20-week follow up. The primary efficacy endpoint was mean change from baseline (day 1) in the severity grade of pterygium vascularity at week 4. The proportion of patients demonstrating improvements in pterygium vascularity intensity decreased from baseline of 1-grade and 2-grade is an additional study metric that demonstrates the significant differences between the drug and the vehicle groups and supports the statistical analysis on the primary efficacy endpoint. The secondary efficacy endpoint was lesion vascularity based on masked grading of colour

photographs on a validated scale (0: absent – 4: severe scale) by an independent reading centre. Other endpoints included dimensions of the cornea portion of the pterygium head (measured based on photographs analysed using an image software) and safety.

Safety. In the second stage, TEAEs of any causality were reported in 65.4% (17/26) and 16.0% (4/25) of the patients in the group of patients with CBT-001 of 0.2% and the vehicle groups, respectively. Non-ocular TEAEs were reported for seven patients in each treatment group. There were no study discontinuations (i.e. withdrawal of subjects) due to adverse events. No deaths were reported in the study. One serious adverse event, transient ischemic attack in the vehicle treatment group was reported but considered not treatment-related since it occurred during post treatment follow-up period. Conjunctival discolouration, reported by 14 (53.8%) patients, was the most commonly reported TEAE in patients with CBT-001 of 0.2%. All conjunctival discolouration (yellow conjunctiva) was mild in severity except for one case of moderate in severity. The yellow conjunctiva was because the colour of the drug is yellow. However, the yellow conjunctiva was not detected at any post treatment follow-up visits (which are either scheduled based on what was pre-specified in the clinical trial protocol or unscheduled timepoints during which the clinical trial data is collected and recorded). Two reports (7.7%) of mild foreign body sensation and two reports of increased lacrimation (one mild and one moderate in severity) were reported in patients with 0.2% of CBT-001. No other TEAE was reported in either eye for more than one patient with 0.2% of CBT-001. The only non-ocular TEAEs reported by more than one patient were dysgeusia which was reported by two (7.7%) patients in the patient group with 0.2% of CBT-001, and the Influenza A Virus Test reported by two (8.0%) patients in the vehicle group. There were no clinically significant changes from screening (a procedure to determine whether potential participants are eligible for the study) in clinical laboratories (blood chemistry and haematology), no notable changes from baseline in vital signs, no BCVA worsening in patients with 0.2% of CBT-001 as related to treatment, and no notable post-baseline intraocular pressure changes. The only significant biomicroscopy findings (i.e., findings that are observed with a microscope used for ophthalmic examinations) in patients with 0.2% of CBT-001 were for conjunctival hyperaemia for which 11.5% (3/26) patients had findings in the study eye and 15.4% (4/26) had findings in the non-study eye. By comparison, among vehicle – treated patients (excluding one patient who did not complete the clinical trial due to reasons not related to adverse events), 29.2% (7/24) and 8.3% (2/24) had significant conjunctival hyperaemia findings in the study eye and non-study eye, respectively.

Efficacy. In the second stage, at all post-baseline visits (i.e., the visits that take place after the start of the study), the patients with 0.2% of CBT-001 demonstrated greater reductions from baseline in pterygium vascularity scores compared to the vehicle treatment group. At the primary endpoint, at week 4, the mean vascularity score for the patients with 0.2% of CBT-001 had been reduced from baseline by 0.8 grade compared to no change in the vehicle treated patients. The mean difference (i.e., the difference between the average of 0.2% CBT-001 treated group and the vehicle group) of -0.76 at week 4 relative to baseline between the group with 0.2% of CBT-001 and vehicle treated groups was highly statistically significant ($p < 0.001$). Statistical significance was also detected at all post-baseline visits through week 16 ($p \leq 0.008$), meaning the result was likely due to a specific cause (i.e., the effect of CBT-001) instead of due to chance.

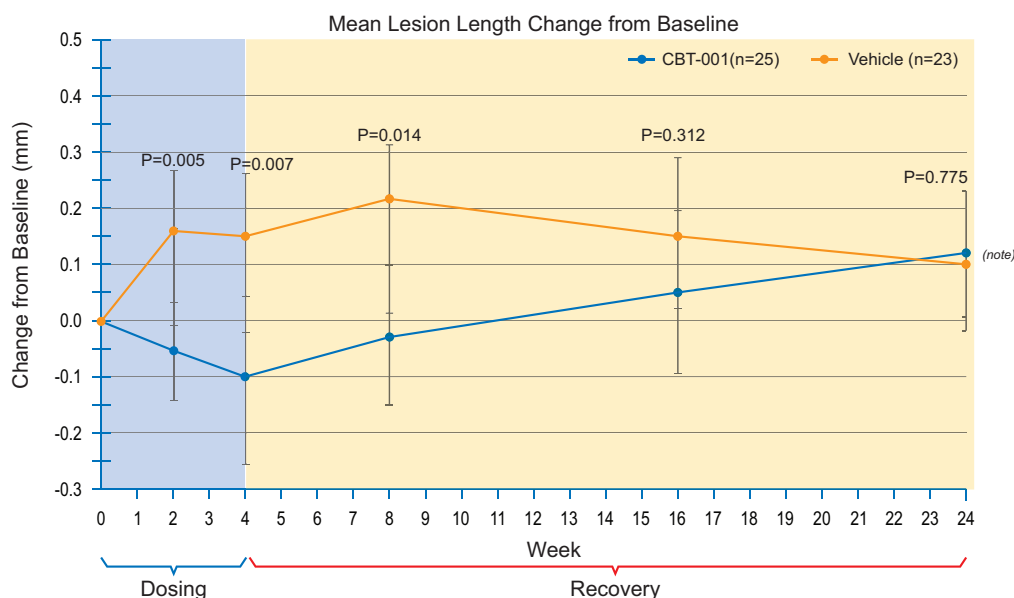
The proportion of patients achieving at least an one-grade improvement from baseline in pterygium vascularity was statistically significantly greater at all visits from week 2 through week 16 for the patients with 0.2% of CBT-001 than for the vehicle treatment group. The treatment differences in proportions of patients achieving at least one-grade improvement from baseline between the group with 0.2% of CBT-001 and vehicle groups were 60.0% at week 2, 55% at week 4 and 51% at week 16 ($p < 0.001$). Three patients (12%) in the group with 0.2% of CBT-001 demonstrated at least a two-grade improvement in pterygium vascularity at one or more visits compared to no patients in the vehicle group. By the end of the dosing period (week 4), 17 and three patients in CBT-001 treated group achieved at least one-grade and two-grade improvement in pterygium vascularity from baseline, respectively. At week 16, 15 patients in 0.2% CBT-001 group achieved at least one-grade improvement in pterygium vascularity from baseline, and two patients achieved at least two-grade improvement. By the end of the recovery period (week 24), ten and one patient in CBT-001 treated group achieved at least one-grade and two-grade improvement in pterygium vascularity from baseline, respectively. The chart below illustrates the mean vascularity score change (i.e., the average change from baseline of all treated subjects by cohort corresponding to the grades on the 5-point pterygium vascularity scale) from the baseline during the dosing period (till week 4) and the recovery period (till week 24):



Note: the p value is calculated based on the null distribution, which is a theatrical distribution of the study statistics when the null hypothesis (i.e., CBT-001 is not more effective than the vehicle on improving the condition of pterygium vascularity) is true. The p value was less than 0.001 at the end of week 2 (within the dosing period), week 4 (at the end of the dosing period), and week 16 (within the recovery period), which is “very strong evidence against the null hypothesis” (i.e., very strong evidence proving that CBT-001 is more effective than the vehicle on improving the condition of pterygium vascularity). The p value at week 24 (at the end of the recovery period) was more than 0.1, which means there was no evidence against the null hypothesis. It shows that CBT-001 used on the patients may have similar effect as compared to the vehicle 20 weeks after the last dosing, which potentially provides useful prescribing guidelines on duration of dosing when CBT-001 is put into clinical use in the future. The increase in p value towards the end of the recovery period was expected, because the patients had been discontinued from study treatment about five months prior to week 24. The FDA did not have any concerns or raise additional queries in this respect.

For the secondary endpoint of corneal pterygium lesion length mean changes from baseline, patients in treatment group with 0.2% of CBT-001 showed slight decreases relative to baseline values at week 2 through week 8 while patients in the vehicle treatment group showed increases from baseline at each visit. Statistical significance was detected for these treatment differences at weeks 2, 4 and 8 ($p = 0.014$). At week 4, on average, the patients with 0.2% of CBT-001 had a 3.3% reduction in corneal pterygium lesion length compared to an 8.0% increase in vehicle treated patients ($p = 0.006$). At week 16, the corneal lesion length of the patients with 0.2% of CBT-001 increased from the baseline slightly (0.05mm), compared to the patients with change in vehicle group (0.14mm), which indicated that the patients with 0.2% of CBT-001 had smaller growth of lesion length.

Results of analyses of secondary endpoint of pterygium lesion area mean changes from baseline were similar to those seen for corneal pterygium lesion length. At weeks two, four, and eight, on average, there was about 0.3 to 0.4 sq. mm reduction from baseline in lesion area treatment group of 0.2% of CBT-001 compared to about 0.2 to 0.3 sq. mm increase in the vehicle treatment group. Statistically significant differences were detected for lesion area change from baseline at weeks 2 and 8 ($p = 0.032$). The chart below illustrates the mean pterygium lesion length growth from the baseline during the dosing period (till week 4) and the recovery period (till week 24):



Note: No statistical significance ($p=0.775$) was detected between the lesion area treatment group and the vehicle treatment group, with the mean lesion length changes being 0.12 mm and 0.11 mm, respectively. The increase in p value towards the end of the recovery period was expected, because all the patients would cease to receive treatment at the end of the dosing period (i.e., the end of week 4) based on the study protocol. It potentially provides useful prescribing guidelines on duration of dosing when CBT-001 is put into clinical use in the future. The FDA did not have any concerns or raise additional queries in this respect.

Analyses of other secondary endpoints of lesion width and topographic astigmatism did not result in any notable treatment group differences.

Analyses of pterygium symptom and life quality (“**PSLQ**”) questionnaires showed no statistically significant differences between the group of patients with 0.2% of CBT-001 and vehicle treated groups for mean change from baseline for overall PSLQ, ocular symptom, vision-related functioning and impact on quality of life, except for impact on quality of life at week 8. However, there were trends that both the group of patients with 0.2% of CBT-001 and vehicle-treated groups showed improvements from baseline in PSLQ scores from week 2 through week 24.

Statistically significant changes from baseline (improvements) were detected in the group of 0.2% of CBT-001 during weeks 2, 4, 8, 16 and 24 for overall PSLQ scores and ocular symptom scores and during weeks 2, 4, 8, and 16 for impact on quality of life scores ($p < 0.024$). Statistically significant changes from baseline were also detected in the vehicle-treated group at weeks 2, 4 and 8 for overall PSLQ scores and ocular symptom scores, and only at week 2 for impact on quality of life scores ($p \leq 0.035$). No statistically significant changes from baseline were detected in the group with 0.2% of CBT-001 at any visit for the vision-related functioning score. Statistically significant changes from baseline were detected in the vehicle-treated group at weeks 4 and 8 for the vision-related functioning score ($p \leq 0.004$). For patients with baseline PSLQ red eye scores >1 (frequencies of red eye reported by patients from half of the time to all the time at the baseline day 1 visit), 13/14 (97%) patients in the group with 0.2% of CBT-001 responded red eye improvement at week 4 with mean PSLQ red eye score reduction of 2.7 point whereas 7/11 (64%) patients in the vehicle treated group responded red eye improvement with mean PSLQ red eye score reduction of 1.6 point.

Conclusion. In the second stage, baseline demographic characteristics were similar between patients receiving CBT-001 ($n=25$) and those receiving the vehicle ($n=23$). After four weeks of dosing, mean vascularity scores were significantly decreased in patients receiving CBT-001 (-0.8) compared to vehicle (0.0) ($p<0.001$). Vascularity remained significantly decreased at weeks 8 and 16, but not at week 24. CBT-001 also showed significantly greater mean reductions in lesion length at weeks 4 and 8 ($p<0.05$).

0.2% of CBT-001 showed efficacy in reduction of pterygium vascularity, conjunctival hyperaemia, lesion length and lesion area. Statistically significant differences between 0.2% of CBT-001 versus vehicle treated groups were demonstrated for pterygium vascularity and conjunctival hyperaemia reduction at week 2 through 16, and pterygium lesion length reduction at week 2 through 8, and pterygium lesion area reduction at weeks 2 and 8.

Overall conclusion. The most commonly reported adverse events associated with CBT-001 were ocular related, which were mild in severity, resolved after therapy, and did not result in discontinuation in study, meaning the adverse events did not lead to participants to withdraw from the study. The most frequent drug related adverse event observed was the mild conjunctival discolouration (yellow conjunctiva). It is considered drug related because the colour of the drug is yellow and the yellow conjunctiva was not detected at any post treatment follow-up visits. Other less frequent drug related adverse events observed were mild foreign body sensation in the eye, mild or moderate increased lacrimation and mild dysgeusia. In conclusion, CBT-001 lowered pterygia vascularity and lesion length after four weeks of dosing and was well tolerated with minimal systemic exposure.

3. *Summary of pre-clinical studies*

CBT-001, also known as Nintedanib free base, is formulated as a topical ocular solution for the treatment of pterygium. Nintedanib is the API of Ofev[®], approved by the FDA as an oral capsule for the treatment of idiopathic pulmonary fibrosis (“**IPF**”). We planned to take reference from non-clinical safety data of Nintedanib including systemic toxicity in two relevant toxicity species of rats and monkeys, safety pharmacology, genotoxicity, carcinogenicity, reproductive and developmental toxicity studies under the 505(b)(2) regulatory pathway. Therefore, our non-clinical testing strategy focused on conducting ocular safety evaluation of CBT-001 in two relevant toxicity species of rabbits and monkeys, evaluating efficacy in relevant animal disease models of *in vivo* cornea suture rabbit model and *in vivo* human pterygium mouse model, assessing pharmacokinetics and distribution via *in vitro* melanin binding and *in vivo* ocular pharmacokinetic studies.

Two ocular formulations have been developed to support non-clinical and clinical development. The first formulation is a topical ocular solution formulated with 2-hydroxypropyl-beta-cyclodextrin. This ophthalmic solution formulation was used to support GLP one-month ocular toxicity studies in rabbits and monkeys and phase 2 clinical trial. The second formulation is a topical ocular solution formulated with 2-hydroxypropyl-beta-cyclodextrin and other recipients. The second emulsion formulation was used in the GLP six-month ocular toxicity study in rabbits, the GLP nine-month ocular toxicity study in monkeys and will be used in phase 3 MRCT.

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Clinical Development Plan

The following table sets forth details of our clinical plans, trial design and registration plans of CBT-001 phase 3 MRCT in the planned jurisdictions.

<u>Initiation time</u>	<u>Expected completion time ^(note)</u>	<u>Trial design</u>	<u>Expected NDA submission time ^(note)</u>
U.S.: June 2022 China: September 2023 New Zealand: May 2024 Australia: May 2024 India: July 2024	In June 2026	<p>Overview: randomised, multicenter with treatment for 12 months followed by 12 months double-masked extension</p> <p>Patient size: approximately 600 subjects globally (planned, among which 200 subjects for trials in China (planned)) randomised in a 2:1:1 ratio to two concentrations of CBT-001 or vehicle: N= 300 (0.2%), N= 150 (0.1%) and N= 150 (vehicle)</p> <p>Subject selection criteria: conjunctival hyperemia grade ≥ 3 at baseline; pterygium length between 1.2 mm to 4.5 mm at baseline; and eye symptom score ≥ 2 at baseline</p> <p>Endpoints: Conjunctival hyperemia grade change from baseline at month 3; pterygium lesion length change from baseline at month 12; and subjects' eye symptom score change from baseline at month 12</p>	2026 (upon the completion of global phase 3 MRCT)

Note: the phase 3 MRCT for CBT-001 recruits patients and conducts studies simultaneously across multiple jurisdictions until the aggregate patient number reaches the planned number (approximately 600 subjects). The NDA submission in each of the United States and China will be made once the entire MRCT studies in all planned jurisdictions are completed.

We have completed a range of preparatory or early-stage work and are conducting additional ongoing work in support of our phase 3 MRCT for CBT-001 in the United States and China, including:

Literature review and formulation modification. We have conducted literature review to assess the prevalence rate of pterygium in different regions in the United States, to determine suitable locations for our clinical trial sites. We extracted data from public publications to support our preliminary findings on how the mechanism of action of CBT-001 aligns directly with the fibrovascular pathogenic features of pterygium. We have also decided to modify the formulation of CBT-001 to reduce the frequency of use from three times a day to two times a day and improve its efficacy, for the purpose of minimising patient compliance issues during phase 3 MRCT and progressing to the NDA submission.

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Engagement of the CRO and clinical trial sites. After assessing the capabilities of various CRO candidates, we have engaged a reputable CRO to manage our phase 3 MRCT, and we have assigned several senior scientists from our Group to closely supervise the CRO's work. We are in the process of selecting a number of clinical trial sites with experienced investigators that are most suitable for our phase 3 MRCT and the clinical trial sites selection in China has been completed. In addition, we plan to select and engage approximately 30 to 35 clinical trial sites in the United States to support phase 3 MRCT of CBT-001, which seek to, among others (i) target the specific disease (i.e. pterygium) adopting the standard International Classification of Diseases, Tenth Revision claims processing codes, and (ii) maintain a good track record of conducting clinical trials with satisfying historical performance, as well as experience with and easy access to the patient population.

Suppliers selection. We have selected quality suppliers of the materials and equipment necessary for our phase 3 MRCT. For details of the criteria we applied for selecting suppliers, see “– Suppliers and Raw Materials” in this section. We have also selected a central laboratory for specimen collection and analysis.

Preparation of trial-related plans and procedures. Our specialised clinical development team which is in charge of the clinical trials of CBT-001 has reviewed and approved a series of trial-related plans prepared by the CRO to manage phase 3 MRCT, including plans on site monitoring, data management, safety management and safety reporting. We have also prepared a set of documents and procedures to facilitate the execution of our study design, including laboratory manual and the working instructions to our reading centre. An electronic data capture system designed specifically for phase 3 MRCT as a joint effort between our clinical development team and our CRO's data management team has been designed and implemented, enabling our CRO and us to collect and conduct analysis on the data in a more effective and accurate way.

Investigators and site personnel training. All investigators who participate in phase 3 MRCT are trained during site initiation visits pursuant to the protocol prepared by our clinical development team, to ensure that the investigators have good knowledge about the clinical trial protocol, standard operating procedure, good clinical practice, and applicable regulatory requirements. Our CRO also provides training to the site personnel during site initiation visits on the topics of trial procedures and data collection. Prior to fully activating a certain clinical trial site for phase 3 MRCT, the central reading centre is in charge of ensuring certified photographers at each clinical trial site to be qualified for the study.

Review of clinical trial progress. We hold regular meetings with our CRO and our reading centre to review the clinical trial progress of phase 3 MRCT and make timely adjustments when necessary. Our R&D team holds internal meetings to review screening and enrolment figures, and evaluate actual metrics in phase 3 MRCT against projections on a monthly basis. The R&D personnel also routinely discuss reasons for screen failure and results of new measures to improve the performance of patient enrolment. In addition, regular meetings between our clinical development team and our CRO's study management team to track clinical trial progress, and monthly meetings among our trial medical monitor, our clinical development team and the safety review team of our CRO to review all data collected from phase 3 MRCT and raise queries to the clinical trial sites for follow-up, are

also conducted. Our clinical development team conducts regular masked review of trial images with our reading centre to facilitate the clarification between the clinical trial site and reading centre. This process enables us to ensure that trial images are evaluated within the protocol-defined screening window for each subject. Our R&D team oversees the timely shipment of cameras to the clinical trial sites and spot technical issues the clinical trial sites may encounter when taking photos for phase 3 MRCT.

We expect to complete phase 3 MRCT for CBT-001 in the United States and China in June 2026. We plan to submit an NDA to the FDA and the NMDA upon the completion of its global phase 3 MRCT. We have also commenced additional clinical trials in New Zealand, Australia and India to continue to assess the efficacy of CBT-001 as part of the global phase 3 MRCT, in May 2024, May 2024 and July 2024, respectively. We have decided to expand the ongoing phase 3 MRCT to New Zealand, Australia and India as they have substantial experience in maintaining clinical research sites that participate in large-scale clinical trials, and the practice patterns for treating pterygium in these jurisdictions are currently limited to surgical removal or symptomatic therapies, similar to that in the United States and China. In addition, Australia and India are also regions with higher prevalence of pterygium, so that patient enrolment in these regions might be easier.

We plan to outsource large-scale manufacturing of CBT-001 for phase 3 MRCT in each region, and commercial production, once approved.

Regulatory Communications

United States. In June 2016, we submitted a pre-investigational new drug application (the “**pre-IND**”) to the FDA, which included the proposed clinical, non-clinical and chemistry, manufacturing and controls (“**CMC**”) development plans (together, the “**Development Plans**”) for CBT-001. After reviewing the pre-IND application, the FDA had a pre-IND meeting with us on 9 August 2016, in which the FDA (i) recommended conducting an earlier trial to justify dose selection for phase 3 clinical trial for CBT-001, which indicated that we could not commence phase 3 clinical trial for CBT-001 directly without first completing the phase 2 clinical trial, (ii) provided other specific guidance on the Development Plans, (iii) agreed on the study design of phase 2 clinical trial for CBT-001, and (iv) agreed that we could rely on the FDA’s previous approval of Ofev® in a 505(b)(2) NDA for CBT-001.

Ofev®, the active pharmaceutical ingredient of which is nintedanib monoethanesulphonate salt, is an oral capsule approved by the FDA for the treatment of idiopathic pulmonary fibrosis. CBT-001 is a topical ocular formulation of nintedanib free base for the treatment of pterygium, and therefore represents changes from Ofev® in formulation from soft capsule to eye drop (i.e., the formulation adopted in phase 2 clinical trial, which was later reformed into ophthalmic emulsion in phase 3 MRCT), delivery route from oral to topical administration, and indication from idiopathic pulmonary fibrosis as a lung disease to pterygium as an ophthalmic disease, all of which are changes permitted under the 505(b)(2) pathway.

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Based on the guidance provided by the FDA, it is our understanding that it is necessary and essential to conduct phase 2 clinical trial for investigating the safety and efficacy data of CBT-001 before commencing phase 3 clinical trial, because (i) as compared with Ofev[®], CBT-001 changes the formulation from soft capsule to eye drop and the delivery route from oral dosing to ocular administration, and (ii) once approved, CBT-001 is expected to be the first drug therapy globally to treat pterygium progression, and such novelty on a new disease indication would require sufficient efficacy data from a phase 2 clinical trial to determine appropriate primary and secondary endpoints for the design of phase 3 clinical trial. We submitted the IND application for CBT-001 in the United States under the 505(b)(2) pathway on 27 December 2016, and the FDA did not raise any objection against proceeding with phase 2 clinical trial during the 30-day review period of the IND application.

Upon the completion of phase 2 clinical trial, we had an EOP2 Meeting with the FDA on 13 May 2019 and the FDA agreed in the meeting that CBT-001 could proceed with phase 3 MRCT in the United States. The FDA also agreed on the phase 3 study design and efficacy endpoint, as well as our proposed plan of change in CBT-001's formulation from eye drop (solution) to ophthalmic emulsion, in the EOP2 Meeting. Due to the change in formulation, the FDA requested to test more than a single dose of CBT-001 with different concentrations in the phase 3 MRCT in the United States. We submitted a special protocol assessment ("SPA") request to the FDA on 4 March 2022 which included both a high dose and a low dose of CBT-001 in the phase 3 MRCT design requesting the FDA to assess the protocol of phase 3 MRCT in the United States, and received the SPA approval from the FDA on 12 August 2022. The SPA approval documents the FDA's agreement on the design and planned analysis of phase 3 MRCT.

China. We had a pre-IND meeting with the NMPA on 19 March 2020, and submitted the IND application for CBT-001 in China on 1 November 2022. After reviewing the data from phase 2 clinical trial of CBT-001 in the United States, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China for CBT-001 on 6 March 2023. Based on the Notice of Approval for Clinical Trial of Drugs ("藥物臨床試驗批准通知書") issued by the NMPA, the NMPA approval to proceed with the phase 3 MRCT in China for CBT-001 is unconditional, and will not be affected by the results of the phase 3 MRCT in the United States. As advised by our PRC Legal Advisers, there are no applicable PRC laws or regulations that suggest that the IND approval would be conditional on the results of the phase 3 MRCT in the United States. We also plan to conduct additional clinical trials in other regions as part of the global phase 3 MRCT for CBT-001. The future NDA approval from the NMPA to commercialise CBT-001 in China will be based on, among others, the overall clinical trial results of the global Phase 3 MRCT in all selected regions.

Neither the FDA nor the NMPA raised any safety concern on the results of phase 2 clinical trial, or imposed any condition, or requested any adjustments to the endpoints or extension of the proposed trial plan of phase 3 MRCT trial protocol.

Other than the above, as of the Latest Practicable Date, we had not had any material regulatory communications with the FDA or the NMPA or other comparable regulatory authorities for CBT-001, and we were not aware of any material concerns or objections from any regulatory authorities in connection with CBT-001.

Commercialisation Plan

We plan to commence the commercialisation for CBT-001 in the United States and China upon obtaining the regulatory approvals from the competent authorities. Our commercialisation plan for CBT-001 in the United States and China is set out below, respectively.

1. Commercialisation plan in the United States

In connection with the commercialisation for CBT-001 in the United States, we will focus our medical affairs function on educating eye care professionals (“ECPs”) that CBT-001 is the first safe and effective pharmacotherapy for pterygium as its prelaunch efforts prior to the FDA filing and the expected approval of CBT-001. In particular, we seek to develop and maintain close relationship with PIs to provide scientific support and encourage patient recruitment for our phase 3 MRCT in the United States, and raise the awareness on pterygium among ECPs by educating KOLs and clinicians at major eye care conferences in the United States. We will build a medical scientific liaison (“MSL”) team pursuant to the progress of clinical trials, regulatory approval and launch of CBT-001, so that MSL team members will be able to engage national and regional KOLs at various stages as appropriate. In addition, starting from 2024, we are utilising public relations and social media communication strategies through our vendor to increase followers (with a focus on eye care professionals) on our Company’s profile page on the professional social networking platform, and increase the visibility and ranking of our official website on search engine results pages, so that we can further enhance public awareness of our drug pipelines, especially our most advanced drug candidate CBT-001, by increasing our public presence. We also plan to gather insights via our ongoing marketing research assessments to understand the unmet medical needs of patients, ECPs and leading national insurance providers, in order to support the expected product launch of CBT-001 and its future insurance coverage as well as life cycle management.

Once approved, we plan to commercialise CBT-001 in the United States via paralleled direct-to-consumer campaign and ECP education campaign. Believing in the importance of patent identification, we target to increase the awareness of pterygium among patients with ophthalmic diseases through educational and marketing efforts directed towards the patient groups, and will adopt a mixed approach of on-site and digital promotion activities. In its campaign facing KOLs and various medical associations, we will highlight the prevalence of pterygium, the need to increase earlier diagnosis of pterygium and the safety and efficacy of CBT-001 to build reputation for its brand name. For example, we may promote disease awareness among the public via our social media channels, to facilitate the patients to approach eye care specialists potentially offering CBT-001.

To achieve a wide-spread market access, we plan to pursue third party reimbursement from both government and private insurance providers for the cost of CBT-001. We have commenced market access, pricing and reimbursement initiatives with national and local payers through market surveys to better present our studies on cost effectiveness of using CBT-001 as an alternative to currently available treatment options to, and facilitate our

future interaction with, the insurance providers. We may engage dedicated market access personnels to cover various national insurance plans to conduct payer education and secure placement for CBT-001 in those insurance plans.

Sales managers and representatives are expected to be engaged by us six to nine months prior to the launch of CBT-001. In addition to gradually building and expanding our own sales and marketing team, we may also seek collaboration with leading pharmaceutical companies to commercialise CBT-001 in the United States, leveraging our experience in collaborating with Grand Pharma. The partnership may take the form of out-licensing, or in a co-commercialisation or co-promotion structure in which we provide resources and personnel while leveraging the potential partner's experience and expertise for the commercialisation of CBT-001 in the United States, as well as minimise the risks associated with costs of internal infrastructure and operational support requirements etc. We will carefully select the regions for our focused sales force. For example, we may focus our sales force efforts in warmer areas given warm weather with increased sunshine exposure contribute to the development of pterygium.

We support our existing commercialisation activities in the United States with our self-owned funds, and we plan to utilise part of the proceeds from the Global Offering to continue and expand such activities after the Listing.

2. Commercialisation plan in China, through Licensing Arrangement with Grand Pharma

We entered into a commercialisation licensing arrangement (the “**Licensing Agreement**”) with Grand Pharma (China) Co., Ltd. (“**Grand Pharma**”) on 13 April 2020, pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in all human use of CBT-001 (including prevention of pterygium progression and reduction of conjunctival hyperaemia) (the “**Field**”) in mainland China, Hong Kong, Macau and Taiwan (the “**Territory**”).

Salient Terms of the Licensing Agreement and Execution of Such Terms

Licensed Rights and Reversed Rights

Under the Licensing Agreement, we granted Grand Pharma an exclusive license under, among others, the know-how and patents, controlled by us that is reasonably necessary for the manufacture or commercialisation of CBT-001 in the Field and the Territory. Other than such licensed intellectual property rights (the “**Licensed IP Rights**”), each of the parties shall exclusively own all of its sole inventions and any patents that claim or disclose such sole inventions. For the avoidance of doubt, we reserved all rights not expressly licensed to Grand Pharma, including but not limited to (i) all rights with respect to CBT-001 outside the Field in the Territory, (ii) all rights with respect to the CBT-001 outside the Territory, whether in or outside the Field, and (iii) that any research and development on CBT-001 shall be conducted by us only, and Grand Pharma will not take part in or contribute to any research and development of CBT-001 without our prior written consent.

Our Obligations under the Licensing Agreement

We will be responsible for all development activities for CBT-001 within the Territory, and bear all costs arising from such activities, including conducting and completing all clinical trials. We will prepare, submit and maintain regulatory filings in our names and conducting communications with regulatory authorities, as well as obtain regulatory approvals in the Territory in our names. We shall also, at Grand Pharma's expenses, assist Grand Pharma to manufacture and commercialise CBT-001 in the Territory. We and our designee (a CDMO based in the United States named Woodstock Sterile Solutions, Inc) will supply to Grand Pharma or its affiliates the products of CBT-001 at actual, out-of-pocket cost plus related manufacturing costs. In the Licensing Agreement, parties agreed that Grand Pharma shall use commercially reasonable efforts to promote, market, sell and distribute CBT-001 in the Field in the Territory at its own costs.

Our Rights as the Market Authorisation Holder

We shall be responsible for all development activities for CBT-001 within the Territory, including obtaining regulatory approvals, in our names. We expect to be the market authorisation holder ("MAH") for CBT-001, unless, as stipulated in the Licensing Agreement, (i) we cannot satisfy the qualification requirement under applicable laws and regulations on MAH in mainland China (this may be triggered when there is serious violation against the PRC Drug Administration Law (《藥品管理法》) and its implementing regulations by us, such as manufacturing and sell illegal pharmaceutical products, failing to obtain regulatory approvals to commercialise our drug candidates, or non-compliance with GMP guidelines, against which we will make every efforts to avoid), or (ii) Grand Pharma cannot exercise the rights or obligations under the Licensing Agreement if we are the MAH in accordance with applicable laws and regulations. In such event, we and Grand Pharma shall have a discussion in good faith, and Grand Pharma may have the option to become the MAH for CBT-001. We believe that even in the unlikely event that our MAH is transferred to Grand Pharma, the impact of the transfer on our business operation will be very limited, as the Licensing Agreement has stipulated that the transfer of MAH shall be conducted in a way without causing harm to us. We shall assist Grand Pharma to complete the MAH transfer in this case. As at the Latest Practicable Date, we did not have any intention to transfer the MAH for CBT-001 to Grand Pharma and had identified no circumstance which would trigger item (ii) above, under which Grand Pharma cannot exercise its rights or obligations and we would need to transfer the MAH to Grand Pharma.

Payment Obligations of Grand Pharma

Subject to the terms and conditions of the Licensing Agreement, we are entitled to receive (i) a one-time upfront payment, (ii) a one-time right of first refusal payment, (iii) milestone payment upon regulatory approval from the NMPA for CBT-001 to commercialise in mainland China (such upfront payment, right of first refusal payment and milestone payment, in aggregate, amount up to RMB59.5 million), and if an independent phase 3 clinical trial is required by NMPA to be initiated in mainland China, certain additional payment upon approval from the NMPA to initiate the independent phase 3 clinical trial, and (iv) tiered royalty payments which is based on

total sales of CBT-001 in each year in the Territory during the Royalty Term (as defined below). In the event that Grand Pharma fails to achieve the annual minimum total sales target and fails to pay the royalties based on the annual minimum total sales for three consecutive years as set out in the Licence Agreement, we may terminate the Licence Agreement pursuant to the terms and conditions thereunder. The NMPA subsequently granted the IND approval for us to proceed with phase 3 MRCT in China, which is part of our MRCT study for CBT-001 across multiple regions or countries with the same study protocol, rather than an additional independent clinical trial which requires a separate study protocol and may use different study design and endpoints etc. As a result, the payment of RMB15 million under item (iii) above on the condition that an independent phase 3 clinical trial in mainland China is required by the NMPA, is not applicable. The one-time upfront payment and one-time right of first refusal payment had been made in full by Grand Pharma to us in the year of 2020.

Royalty Term under the Licensing Agreement

Under the Licensing Agreement, the “Royalty Term” is defined as the period commencing upon first commercial sale of CBT-001, and expiring upon the latest time of, (i) eight years from the date of the first commercial sale of CBT-001 in the Territory, (ii) expiration of the valid claim of the licensed patents (the last expiry date of which is in August 2039 as of the Latest Practicable Date) covering CBT-001 in the Territory, or (iii) expiration of the regulatory exclusivity of CBT-001 in the Territory (which is six years pursuant to the Regulations for the Implementation of the Drug Administration Law of the People’s Republic of China (中華人民共和國藥品管理法實施條例)). The term of the Licensing Agreement expires upon the expiration of the Royalty Term, unless certain early termination conditions stipulated in the Licensing Agreement takes effect.

Rights of First Refusal and related Rights

Grand Pharma has the right of manufacture and commercialisation of CBT-001 in the Field and the Territory. In addition to this, if Grand Pharma obtains our written consent, it also has the rights to development activities of CBT-001. For all other drug candidates in our existing and future portfolio, subject to the approval by the board of directors of Cloudbreak Cayman and Cloudbreak Guangzhou, Grand Pharma has a right of first refusal for developing, manufacturing or commercialisation of them within the term of the Licensing Agreement before others make competing offers in the Territory. Grand Pharma may exercise such right of first refusal when we do not intend to develop, manufacture or commercialise these products within the Territory by ourselves. We have granted Grand Pharma such right of first refusal in the Territory primarily considering its strong presence in the ophthalmology field in China. The ophthalmology division of Grand Pharma covers multiple ophthalmology subdivisions. It has established an international R&D centre in Wuhan, China for developing innovative products. It has also established a production facility and a production site for production of raw material pharmaceuticals and ophthalmic medicines with more than ten years of production experience. Grand Pharma also has a strong marketing and sales capacity, which includes nearly 3,300 sales personnel in the pharmaceutical area, covering over 20,000 hospitals in China in 2022. Grand Pharma would be our preferred collaboration partner should we decide not to conduct our own manufacturing,

marketing and sales of any pipeline products in China, as we believe with its strong production and commercialisation capacity, it will be in an appropriate position to manufacture, market and sell future products in China, which will be beneficial for our future business expansion and financial conditions and accordingly in the best interest of our Company and the shareholders as a whole. However, we may retain the right of development of CBT-001 without granting such right to Grand Pharma, and we may retain the right of development, manufacture or commercialisation of any other drug candidates in our existing and future portfolio, once commercialised, within the Territory by ourselves without granting any right of first refusal.

Functions of the Joint Steering Committee

Parties should establish a joint steering committee (“JSC”) for the overall coordination and discussion of the development and commercialisation activities under the Licensing Agreement. The JSC should consist of six members, with two representatives appointed by each of Grand Pharma, Cloudbreak Guangzhou and Cloudbreak USA. The roles of JSC include, among others, discuss and coordinate the clinical development plan and commercialisation plan and the overall progress for the manufacturing and commercialisation for CBT-001 in the Territory, and facilitate communications between the parties with respect to their obligations and responsibilities set out in the Licensing Agreement. We have established the JSC with Grand Pharma in 2020 shortly after the execution of the Licensing Agreement.

Termination Clause

Pursuant to the Licensing Agreement, Grand Pharma shall have the right to terminate the Licensing Agreement upon written notice to us, if we fail to successfully complete the first patient dosing of CBT-001 in mainland China by 13 April 2022 (or within a mutually agreed extended timeline), or fail to obtain the regulatory approval for CBT-001 in mainland China by 13 April 2025 (or within a mutually agreed extended timeline).

As discussed above, notwithstanding the commercial licensing arrangement with Grand Pharma, we have effective control over CBT-001 in all material aspects, in that either within or outside the Territory, (i) we are responsible for all development activities for CBT-001, including conducting pre-clinical studies, and engaging and supervising CROs and CDMOs to assist us with the clinical trials for CBT-001; and (ii) we prepare, submit and maintain regulatory filings, conduct communication with regulatory authorities and obtain regulatory approvals for CBT-001 in our names (such as the approvals we obtained from the FDA and the NMPA for us to proceed with phase 3 MRCT in the United States and China respectively); see “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Regulatory Communications” in this section for details. In addition, we are the sole owner of all CBT-001’s IP rights, and the rights to manufacture and commercialise CBT-001 outside the Territory (and such jurisdictions include the United States, which is one of the two jurisdictions we plan to launch CBT-001). Within the Territory, (i) we legally own or control all the Licensed IP Rights, and we have the first right, but not the obligation, to obtain, prosecute and maintain the licensed patents for CBT-001

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based on the Licensing Agreement. As of the Latest Practicable Date, all patents arising from the R&D activities of CBT-001 were applied for, obtained and maintained by us, not Grand Pharma; and (ii) Grand Pharma's rights on manufacture and commercialise CBT-001 are limited by the Licensing Agreement, and the relevant manufacturing and commercialisation plans and progress shall be reported to and discussed at the JSC, in which we have four out of six members seats.

Background of Grand Pharma and Benefit of Collaboration

Grand Pharmaceutical Group Limited (00512.HK) ("**Grand Pharma Group**") is an international pharmaceutical company listed on the Main Board of the Stock Exchange with a strong marketing and sales capability and a complete industrial chain. Aiming at technological innovation, the core businesses of Grand Pharma Group include pharmaceutical technology, nuclear medicine anti-tumour diagnosis and treatment and cerebro-cardiovascular precision interventional diagnosis and treatment technology. Grand Pharma is an indirectly non-wholly owned subsidiary of Grand Pharma Group. Grand Diamond (a wholly-owned subsidiary of Grand Pharma Group) and CNCB Grand Healthcare Investment Fund LP (a fund which is indirectly invested into and managed by an associate of the controlling shareholder of Grand Pharma Group) are our Series B Investor and our Series C Investor, respectively. See "History, Development and Corporate Structure – Major Shareholding Changes of our Group" and "History, Development and Corporate Structure – Pre-IPO Investment" for details.

We consider that Grand Pharma has significant experience in commercialisation, including manufacturing and sales, of pharmaceutical products, including in the ophthalmological space in the Territory. In particular, for mainland China (which is the area with highest population within the Territory), the number of patients with pterygium reached 150.9 million in 2023, and is expected to reach 160.6 million in 2033, according the F&S Report. We believe that the collaboration with Grand Pharma under the Licensing Agreement will equip us with broader commercialisation access in the Territory. It will enable us to leverage Grand Pharma's well-established network of distribution channels in the Territory and optimise the market potential for CBT-001, and generate predictable cash flows without having to make significant upfront investments in establishing a full sales team in the early stage of commercialisation of CBT-001. We also expect to be able to leverage our partnership experience with Grand Pharma to secure strategic collaborations with other major market players to implement a cost-effective commercialisation strategy and establish our global sales channels in the future. We consider that the terms of the Licensing Agreement are fair and reasonable and the transactions contemplated thereunder are in the interests of our Company and our Shareholders as a whole.

Delay in First Patient Dosing

The first patient dosing in mainland China occurred on 6 March 2024 which is after 13 April 2022, as the clinical trial progress was affected by COVID-19, which may give rise to Grand Pharma's right to terminate the Licensing Agreement with us absent a mutually agreed extended timeline or an amendment or waiver of the relevant terms. Grand Pharma has continued to actively cooperate with us in the project administration of CBT-001 clinical trials in Mainland China. As of the Latest Practicable Date, we had not received any notice

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from Grand Pharma of its intention to terminate the Licensing Agreement, and we were in the process of communicating with Grand Pharma on the matter. However, if we cannot reach agreement with Grand Pharma on this matter, or strictly comply with all other obligations triggering termination under the Licensing Agreement in a timely manner, Grand Pharma will have the right to terminate the Licensing Agreement, and we may need to identify and engage a new suitable collaboration partner for the commercialisation of CBT-001 in China, which may not be available to us on acceptable terms or at all. If we elect to undertake commercialisation activities on our own for CBT-001 in China, we will need to build up a capable in-house sales and marketing team which takes time and may require significant additional capital. Either approach may delay the commercialisation timeline and adversely affect the commercialisation prospects for CBT-001 in China. See “Risk Factors – Risks Relating to the Commercialisation of Our Drug Candidates – We have entered into a commercialisation licensing agreement with Grand Pharma and a license agreement with Santen in relation to the development, manufacture and commercialisation of one of our Core Products, CBT-001, in various regions, and may continue to seek strategic commercialisation partnerships or enter into additional licensing arrangements in the future, which is subject to risks” in this prospectus for further information.

3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen

We entered into an exclusive license agreement (the “**Santen Licensing Agreement**”) with Santen Pharmaceutical Co., Ltd. (“**Santen**”) on 6 August 2024.

Salient Terms of the Licensing Agreement

Licensed Rights and Reversed Rights

Under the Santen Licensing Agreement, we granted Santen and its affiliates an exclusive, fee-based, milestone and royalty-bearing license, with the right to sublicense, (a) to develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory.

The licence granted under item (a) above is exclusive in the Territory, even with respect to us, except that we reserve the non-exclusive right to conduct or have conducted any development and/or manufacturing activities in the Territory solely for commercialisation of the Product outside the Territory, subject to Santen’s consent. The license granted under item (b) above is non-exclusive.

Under the Santen Licensing Agreement, Santen will, at its sole expense (subject to our obligations as disclosed in “– Our Obligations under the Santen Licensing Agreement” below), use commercially reasonable efforts to develop Product through

drug approval in the Field in the Territory. Santen will use commercially reasonable efforts to have all development activities related to Product in the Territory be conducted through a written development plan submitted to the JSC (as defined below) for review and comment. On this basis, Santen has the exclusive right to conduct any clinical trials involving Product in the Field in the Territory, and we may conduct clinical trials involving Product in the Field in the Territory with Santen's prior written consent (not to be unreasonably withheld) but solely for commercialisation of Product in the Field outside the Territory. Santen shall also have the non-exclusive right to conduct clinical trials involving Product in the Field outside the Territory (but not within mainland China, Hong Kong, Macau and Taiwan) with our prior written consent (not to be unreasonably withheld), but solely for commercialisation of Product in the Field in the Territory.

Santen shall be solely responsible, at its expense, for the commercialisation of Product in the Territory, in accordance with the terms in the Santen Licensing Agreement and applicable laws. Santen shall, at its sole expense, develop the commercialisation strategy and perform all activities necessary for the commercialisation of Product in the Territory pursuant to a written commercialisation plan (and its updated versions(s)) submitted to the JSC (as defined below) for review and comment. Santen shall have the right to appoint its affiliates or other third parties to act as distributors of the Product in the Territory, and Santen shall remain responsible for distributor's compliance with applicable terms of the Santen Licensing Agreement.

Our Obligations under the Santen Licensing Agreement

Under the Santen Licensing Agreement, we shall provide Santen with access to all relevant know-how, regulatory materials and related information that is necessary or reasonably useful for the development, manufacture, or commercialisation of Nintedanib and/or Product in the Field in the Territory. We shall also procure CMOs and CROs to provide relevant regulatory materials to Santen. We shall also cooperate with Santen in dealing or communicating regulatory authorities.

In respect of commercialisation, we are obliged to use commercially reasonable efforts to prepare and submit to the JSC (as defined below) a high-level summary and its updated version(s) of our commercialisation activities identified by us in the United States.

Subject to all necessary authorisations and terms and conditions of the agreement, we will, if requested by Santen, provide Santen with sufficient clinical supplies of CBT-001 for its development activities related to Product in the Field in the Territory, and be reimbursed with relevant out-of-pocket costs. We have also agreed to contribute up to 50% of Santen's cost of clinical supply of CBT-001, subject to a maximum amount of our contribution being US\$0.5 million (the "**Contribution Amount**"). As an alternative, we have also authorized Santen to procure clinical supply of CBT-001 directly from our CMO. In the case of Santen purchasing clinical supply directly from

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our CMO, all pricing shall be negotiated between Santen and the CMO, and shall be payable by Santen directly to the CMO. We have also agreed to contribute the Contribution Amount in this case.

At Santen's request, we will discuss in good faith with Santen on entering into a commercial supply arrangement, under which we will supply CBT-001 to Santen for Santen's commercialisation efforts in the Field in the Territory. The details of such commercial supply arrangement will be set forth in a separate agreement.

The Expected Market Authorisation Holder

Santen shall lead all regulatory activities in the Territory with respect to the Product in the Field. During the term of the agreement, Santen will be responsible for handling all correspondence with relevant authorities related to Product in the Field in the Territory, including preparing and submitting regulatory materials at its sole cost. For regulatory developments relating to Product in the Field in the Territory, we shall be informed, and notified in writing by Santen on any action or decision by relevant regulatory authorities. All drug approval applications in the Territory shall be made in the name of Santen, its affiliates or sublicensees, or if necessary, distributors in certain countries as mutually agreed upon by Santen and us. As such, it is expected that Santen will be the market authorisation holder ("MAH") for Product in the Field in the Territory.

Payment Arrangement

Subject to the terms and conditions of the Santen Licensing Agreement, we are entitled to receive (i) a one-time upfront payment of US\$10.0 million; (ii) certain clinical development and regulatory milestone payments; and (iii) additional milestone payments in an aggregate amount of US\$52.0 million when annual net sales of Product first reach certain thresholds in the Territory, which together with the one-time upfront payment as well as the clinical development and regulatory milestone payments, in aggregate, equal to an amount not exceeding US\$91.0 million. We are also entitled to receive tiered royalty payments, which are based on total sales of the Product each year in all countries in the Territory within the term of the Santen Licensing Agreement, the incremental royalty percentage rates being two-digit numbers if the annual sales reach certain threshold. The one-time upfront payment of US\$10.0 million has been made in full by Santen to us in two batches in September 2024 and November 2024, respectively.

Term of the Santen Licensing Agreement

Unless terminated, the term of the Santen Licensing Agreement will continue in full force and effect, on a country-by-country basis until the later of (i) the expiration date of the last to expire valid claim covering the Product included in the patents controlled by us in such country, or (ii) 12 years from the Product launch in such country. Upon the natural expiration (i.e., not termination) of the Santen Licensing

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Agreement in any country in the Territory, Santen shall have a fully paid-up, non-exclusive, perpetual and irrevocable license to the rights licensed under the Santen Licensing Agreement for each country.

Rights of First Negotiation on CBT-004 Deals in the Territory

Pursuant to the Santen Licensing Agreement, we shall provide Santen written notice, if we desire to license, sell, supply or otherwise dispose in the Territory CBT-004 and/or equivalents containing same API as CBT-004, and/or the products (the “**Equivalent Products**”) manufactured therefrom for the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium and/or pinguecula (“**CBT-004 Deal(s)**”). Santen shall then notify us in writing whether it is interested in pursuing a CBT-004 Deal, and if so, parties shall negotiate in good faith the terms and conditions applicable for such deal. We will be free to enter into a CBT-004 deal with a third party if we cannot reach consensus with Santen within a certain period of time.

We have granted Santen such right of first refusal in the Territory primarily considering its strong presence in the ophthalmology field in the Territory. Santen would be our preferred collaboration partner should we decide not to conduct our own manufacturing, marketing and sales of CBT-004 and/or Equivalent Products in the Territory, as we believe Santen’s strong production and commercialisation capacity, it will be in an appropriate position to manufacture, market and sell CBT-004 and/or Equivalent Products in the Territory, which will be beneficial for our future business expansion and financial conditions and accordingly in the best interest of our Company and the shareholders as a whole. However, we may retain the rights to license, sell, supply or otherwise dispose CBT-004 and/or Equivalent Products in the Territory if we cannot reach an agreement with Santen on a CBT-004 Deal in good faith.

Functions of the Joint Steering Committee

Parties should establish a joint steering committee (“**JSC**”) to oversee, coordinate and review recommendations and approve decisions for development, manufacturing and commercialisation-related activities for Product under the Santen Licensing Agreement. The JSC should consist of up to three members from each of Santen and us. The functions of JSC include, among others, providing a forum for parties to exchange relevant information, and reviewing and discussing Santen’s implementation of the development and commercialisation plan of the Product.

The JSC shall operate by consensus, with our members having collectively one vote, and Santen’s members having collectively one vote, in all decisions. If there is dispute that cannot be solved by the JSC, the matter should be referred to the alliance managers (i.e., the two individuals acting as points of contact for communications on the matters under the Santen Licensing Agreement, designated by each of Santen and us), and further to our chief executive director and Santen’s president, or other executive-level personnel designated respectively by each party. In the event of disagreement that still cannot be resolved, such disagreement shall be resolved by Santen in the Territory in its sole and final discretion, and by us outside the Territory

in our sole and final discretion, provided that each party shall consider the other party's input in good faith, and that parties shall implement mitigation measures in the event the issue has material impacts in terms of regulation and finance.

Background of Santen and Benefit of Collaboration

Santen (4536.T) is a Japan-based global pharmaceutical company listed on the Tokyo Stock Exchange with a strong marketing and sales capability and a complete industrial chain. Santen is engaged in global research and development, manufacturing, and sales and marketing of pharmaceutical products in the field of eye care in more than 60 countries and regions, with a large patient population across the globe. Santen possesses three manufacturing sites specialising in ophthalmology, including the Shiga product supply center based in Shiga, Japan, focusing on establishing production systems for new products, the Noto plant based in Noto, Japan, specialising in high-volume and cost-effective mass production, and the Suzhou plant based in Suzhou, China, providing production capacity for the Chinese market, respectively. Based on the above, we consider that Santen has significant experience in clinical development and commercialisation, including manufacturing and sales, of pharmaceutical products indicated for ophthalmological diseases. We believe that the collaboration with Santen under the Santen Licensing Agreement will equip us with broader commercialisation access in the Territory. It will enable us to leverage Santen's well-established network of distribution channels in the Territory and optimise the market potential for CBT-001 and its Equivalent Products, and generate predictable cash flows without having to make significant upfront investments in establishing a full sales team in the Territory. We also expect to be able to leverage our partnership experience with Santen to secure strategic collaborations with other major market players to implement a cost-effective commercialisation strategy and establish our global sales channels in the future. We consider that the terms of the Santen Licensing Agreement are fair and reasonable and the transactions contemplated thereunder are in the interests of our Company and our Shareholders as a whole.

4. Pricing Strategies

Currently, there is no approved drug therapy for the treatment of pterygium globally, and the existing treatment option for pterygium is surgical excision, which costs between chagemaster (a comprehensive list of hospitals' products, procedures and services) price of US\$5,000 and US\$10,000 per procedure in the United States, excluding post-surgical follow-up visits, and approximately RMB3,000 in China. Whilst there are therapies currently used off-label to alleviate certain symptoms of pterygium, these therapies do not directly address the disease pathogenesis and cost approximately US\$600 for monthly supply. Once approved, CBT-001 is expected to be the first drug therapy globally for the treatment of pterygium.

We plan to price CBT-001 competitively with existing therapies which are used off-label to alleviate certain symptoms of pterygium. In the United States, the off-label use of artificial tears, topical corticosteroids and premium priced branded RX prescription dry eye medications (such as Restasis and Xiidra) are commonly used as a standard of care for pterygium. As per recent payer marketing research results, the current off-label pterygium treatment options are minimally managed by payers providing patients with full access under

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commercial and Medicare part D (a medical insurance plan for seniors) plan. As such, we believe CBT-001 will warrant a net price of approximately US\$600, at the dosage of one drop twice daily, subject to regulatory approvals (amounting to an annual cost of US\$7,200). After discounts and rebates, we assume that the pricing for CBT-001 will be competitive comparing with the pricing per month of each of the following products: Restasis (priced at US\$638 or more), and Xiidra (priced at US\$693 or more). In China, we expect to price CBT-001 at approximately RMB6,000, as comparable with the listed price of Eylea intravitreal solution (40 mg/mL) at RMB6,000 in China for a supply of 0.05ml. At this pricing level, we believe CBT-001 will offer a better alternative than the current off-label therapies and surgical excision, and will be a more cost-effective option for the treatment of pterygium.

Drug candidates under development indicated for pterygium contribute to a competitive landscape for CBT-001. As our potential competitors commercialise their drug candidates after obtaining regulatory approvals, we anticipate facing substantial pricing pressure and increased competition. Such situation may impact our market position and pricing power, potentially affecting the adoption rate of CBT-001. See “Risk Factors – Risks Relating to the Development, Clinical Trials and Regulatory Approval of Our Drug Candidates – The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised”.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CBT-001 SUCCESSFULLY.

Our Core Product - CBT-009

Overview

CBT-009 is our Core Product, which is a novel ophthalmic formulation of atropine indicated for the treatment of juvenile myopia. It has the potential to become a best-in-class product. We commenced pre-clinical studies for CBT-009 in China in 2021, and in the United States in 2022. The phase 1 and 2 clinical trials for CBT-009 were combined into a single trial, and we have completed phase 1/2 clinical trial for CBT-009 in Australia in January 2023. We have completed data analysis and clinical study report on the phase 1/2 clinical trial results of CBT-009. The FDA has approved us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising the phase 1/2 clinical results in Australia in September 2023. We expect CBT-009 to outperform its atropine-based competitors and the other current treatment methods in many aspects, including drug stability, safety, patient tolerability and length of shelf life and become a best-in-class product, once approved.

Mechanism of Action and Advantage

CBT-009 is a unique topical formulation of atropine indicated for the treatment of juvenile myopia. Myopia, also known as near-sightedness, develops and progresses in children and adolescents. Myopia is believed to be caused by an increase in eye length or change in corneal curvature which directs light from distant objects to focus in front of the

retina, and leads to blurred long-distance vision. Myopia generally characterised by a refractive error of 0.50 to -6.00 dioptres is considered as in low to moderate form, and it is considered as high myopia when exceeding -6.00 dioptres. Different from refractive myopia caused by ciliary muscle fatigue and ciliary contraction, juvenile myopia is characterised by rapid increase of the axial length (“AL”) and progressive elongation of the eyeball. Even if the ciliary muscle is healthy, it cannot accurately focus. Juvenile myopia can lead to high myopia and to pathologic degenerative changes of the eyeball, and patients may suffer retinal choroidal atrophy, choroidal neovascularisation, macular hole and retinal detachment, which can cause severe and permanent damage to vision. Myopia is the leading cause of blindness. Therefore, children and adolescents with moderate to high myopia are in urgent need to effectively control the rapid increase of AL and prevent complications.

As children aged between five and 19 are at a critical stage of visual development, myopia develops rapidly at this stage. If left uncorrected, myopia has been shown to have major consequences on children’s level of education, quality of life, and personal and psychological well-being, and may even cause global potential productivity loss. High risk groups of myopia are children living in developed urban areas.

Atropine has been shown by studies to slow down the progression of myopia, which is measured by cycloplegic autorefraction and axial length change over long periods. As a result, atropine sulphate ophthalmic solution has been used in some countries to treat patients with myopia. However, the mechanism of how myopia develops is not clear, and none of the speculations on how atropine exerts effect on myopia progress has been proven by scientific studies. For example, inhibition of accommodation was previously thought to be involved, however, there is evidence against this hypothesis.

In addition, even though low-dose atropine eye drops, which are currently the most commonly prescribed off-label drugs for juvenile myopia, have been validated as an effective treatment option, intrinsic concerns such as atropine’s instability in aqueous solution leading to the short shelf life and tendency to cause irritation to patients, continue to present significant unmet clinical needs. Except for CBT-009, current atropine drug candidates in the clinical trial stages are all water-based and prone to degradation during storage condition. Previous studies show that atropine tends to be hydrolysed at neutral pH of 6.6 to 7.8 and low pH of 3.5 to 6.0 could increase the stability of atropine in solution. However, the low level of pH may cause irritation in the eyes which may affect treatment compliance among juvenile patients.

CBT-009 is formulated in organic media that cause minimum hydrolysis of atropine. It is expected to maintain stable for long-term storage, and increase comfort level for eye as proven. We believe that the novel ophthalmic formulation CBT-009 eye drop adopts will improve the stability of atropine in the formulation and prolong the drug shelf life.

The reference drug for CBT-009 under the 505(b)(2) pathway is atropine. Atropine is the active pharmaceutical ingredient of several previously approved drugs for ocular indications, all of which were in aqueous-based formulations. We have formulated atropine into a special non-aqueous formulation that is very difficult to replicate without substantial expertise and research. In addition, this formulation as well as formulations using the key ingredients of CBT-009 are under our patent protection.

Current Therapies and Limitations

Juvenile myopia tends to progress rapidly in patients aged between five and 19. This disease has a considerable public health impact, and thus the field of juvenile myopia control has been developed rapidly. Current treatment options for preventing or reducing the progression of myopia mainly include optical correction and anticholinergics therapy, most of which have certain limitations and thus present unmet medical needs worldwide.

According to the F&S Report, optical correction with spectacle lenses and contact lens, and atropine eye drops as an anticholinergics therapy option are the major options for the treatment of myopia in children. However, the efficacy of optical correction in delaying the progression of myopia is limited, and it has certain limitations. For example, spectacle lenses might exacerbate myopia because the peripheral vision will fall behind the retina and the axial length will increase. Wearing heavy spectacle lenses might also cause discomfort on patients, especially children. Contact lenses require regular maintenance to avoid eye infections and complications. Wearing contact lenses for a long time everyday might also cause corneal hypoxia. Additionally, contact lenses, especially daily disposable lenses and specialised lenses for certain eye conditions, can be costly.

According to the F&S Report, atropine is the only treatment option that has been demonstrated to be consistently effective in slowing myopic progression and is the only anticholinergic that is recommended in the Guidelines for Appropriate Techniques for the Prevention and Control of Myopia in Children and Adolescents (《兒童青少年近視防控適宜技術指南》) in China. Higher concentrations of atropine such as 1% or 0.5% have been shown to be effective, but the high rate of photophobia as a side effect has been associated with high dropout rate. Patients may have various adverse reactions to atropine, even at low concentration, including photophobia, changes in intraocular pressure, rebound effect, local allergy and systemic adverse reactions, which may also lead to poor patient compliance. Photophobia is the most common adverse reaction in the use of atropine. The typical duration of treatment with atropine eye drops (including aqueous atropine eye drops and CBT-009) for juvenile myopia is at least two years, on the basis that after the treatment duration, the progression of myopia will be effectively controlled, and no significant rebound effect would be observed one year after the cessation of the treatment.

Currently, aqueous atropine eye drops are used in some countries to treat patients with myopia, and they have certain advantages including effective hydration to the eyes and easier distribution evenly across the ocular surface as they are formulated to mimic the natural composition of tears, and easy application and good tolerance by most individual patients as they can be applied easily without causing discomfort or stinging by the application procedure. However, the limited shelf life due to atropine's instability in the aqueous formulation has prevented aqueous atropine eye drops from being widely recognised as a treatment option.

Non-aqueous atropine eye drop differs from aqueous atropine eye drops in nature, in that:

- **Stability.** Non-aqueous atropine eye drops have higher stability than aqueous ones, as the non-aqueous solutions do not contain free hydroxide ions, which can (i) significantly reduce the degradation of atropine and thus result in a decrease in the production of impurities, and (ii) prevent the growth of bacteria, so no preservatives or single dose-packaging will be needed. On the other hand, aqueous atropine eye drops are unstable and easily decomposed, which could potentially affect the efficacy and safety of eye drops. As a result, preservatives are commonly used to solve the issue of microbial growth in aqueous atropine eye drops. Preservative-free formulations, single-use packaging or filtering systems might be alternatives, which will incur more costs. Accordingly, disadvantages in aqueous atropine eye drops such as rapid drug degradation and short shelf life, arising from its relatively low stability, may make patients turn to non-aqueous solution;
- **Bioavailability.** A significant challenge of topical delivery is the rapid clearance of drugs from the ocular surface by the dynamic precorneal clearance mechanisms. In this regard, non-aqueous atropine eye drops have higher bioavailability, as the low volume drop which leads to low surface tension between the drug and the eye surface will increase the drug's residence time. The longer duration on the ocular surface by non-aqueous atropine eye drops are likely due to their immiscibility with the tear fluid, affinity for the hydrophobic corneal surface and tendency to be incorporated into the tear film lipid layer. Moreover, since non-aqueous eye drops do not require pH and osmolarity adjustments, it will minimise compensatory reflex tearing and thus remain longer on the precorneal. Patients are believed to tend to choose non-aqueous solution which will prolong the time to remain on the ocular surface; and
- **Safety and comfort level.** Aqueous eye drops typically require additional excipients, including buffers and salts, viscosity builders and surfactants, which may increase local adverse events, such as stinging, burning and excessive tearing. The reason is that the possibility of tissue toxicity in connection with aqueous eye drops is especially high for colloidal drug delivery systems, which contain significantly higher levels of surfactants and co-surfactants. High surfactant concentrations are particularly detrimental for topical ocular application. Non-aqueous vehicles, in comparison, eliminate the need for pH and osmolarity adjustment, as hydrophobic drugs can often be dissolved directly in non-aqueous vehicles at therapeutically relevant concentrations without any additional surfactants. As such, the risks of occurring excipient related adverse events for patients applying drugs non-aqueous vehicles are relatively low.

We have developed a proprietary non-aqueous formulation of CBT-009, which is believed to have the potential to be a best-in-class product, mainly for the following reasons:

- **Stability.** Atropine is not stable in aqueous formulation at neutral pH (i.e. when pH is 6.6 to 7.8), the pH in current FDA-approved aqueous-based atropine eye drops has to be reduced to 3.5 to 6.0, which may cause discomfort to the eyes and the side effects may include eye irritations. CBT-009 employs a non-aqueous formulation, avoiding hydrolysis issues associated with aqueous solutions because it contains no water. This methodology itself creates R&D barriers for competitors. Thus, CBT-009 ensures better stability without the need for a low pH, and thus improve patient's compliance. As mentioned above, non-aqueous atropine eye drops are without free hydroxide ions, which can prevent the growth of bacteria, so CBT-009 will be packaged as multi-dose and preservatives-free product, as no preservatives or single dose-packaging will be needed;
- **Safety and comfort level.** In addition to the advantages of non-aqueous formulation of CBT-009 as mentioned above, CBT-009 also employs an excipient that not only stabilises the formulation but also treats dry eye, enhancing patient comfort and addressing the therapeutic needs at the same time. We have also conducted extensive pre-clinical research and R&D initiatives which demonstrate the safety and tolerability of CBT-009 in animals and humans as a non-aqueous formulation atropine eye drop, including a finding that certain concentration of CBT-009's non aqueous formulation dosed at approximately 15µL had similar efficacy in pupil dilation as the aqueous atropine formulation dosed at 30µL. In addition, the aqueous formulation drop size is about 30µL, which tends to drain into nasolacrimal duct and get to the systemic circulation and thus leading to higher risk of adverse systemic effects. In comparison, the non-aqueous CBT-009 formulation drop size is about 15µL which tends to retain in ocular surface tissue and thus only has low systemic exposure; and
- **Shelf life.** CBT-009, when formulated with these non-aqueous excipients, maintains good compound solubility and formulation stability. The non-aqueous formulation of CBT-009 has demonstrated in the clinical trials to be well-tolerated and safe, and to be stable for at least two years when stored at room temperature. This duration of shelf life is a current estimation subject to ongoing stability studies, based on data derived from stability tests initiated in April 2022. CBT-009 could achieve a longer shelf life as the clinical trials advance. The shelf life of Eikance approved in Australia in March 2021 is three years and that of Xingqi Meioupin approved in China in March 2024 is 18 months, and the expiry time for Ryjusea approved in Japan in December 2024 and in the EU in June 2025 is three months after opening, all of which are approved aqueous-based atropine eye drops. However, aqueous eye drops typically require additional excipients which may increase local adverse events, such as stinging, burning and excessive tearing. CBT-009 with its non-aqueous formulation is believed to have addressed these issues effectively.

In further clinical trials for CBT-009, we will enroll juvenile patients with myopia in various degree of severity with or without family history. Subject to the results of such study, the frequency and duration of dosing CBT-009 is likely to be once a day before bedtime for three to four years. CBT-009 is not intended for off-label use. Atropine delivered orally at higher doses has demonstrated reproductive toxicity in animals. Therefore, unauthorised off-label use of CBT-009 would carry the same risk as a class effect. However, due to the low concentration of the highest dose of CBT-009, reproductive safety concerns are less likely.

Refractive surgery mainly consists of non-laser surgery and laser surgery, and laser surgery includes excimer laser and femtosecond laser. Laser-assisted in situ keratomileusis (“**LASIK**”) is the most commonly performed refractive surgery. Eligibility for refractive surgery is determined by several factors, including age, corneal thickness, pupil diameter and ophthalmic disease history. Only some of the patients who meet the criteria are eligible for surgery. Refractive surgery can generally be performed once and the surgery effect might be offset by the progression of myopia over time or future presbyopia. In addition, the costs of refractive surgery can be high and not all health insurance plans in the United States and China cover such costs. For example, the average cost of LASIK eye surgery for both eyes is US\$4,400 in the United States, and ranges from RMB4,000 to RMB6,000 in China.

We believe CBT-009 has competitive advantages over the three major treatment options for myopia that are currently available, namely, optical correction, aqueous-based atropine eye drops and refractive surgery. Firstly, optical correction has certain limitations such as (i) the potential risks of exacerbating myopia, (ii) discomfort and inconvenience while wearing spectacle lenses and contact lens, and (iii) relatively high expenses of contact lens. Compared with optical correction, CBT-009 as a topical formulation of atropine is more convenient to use, and has proved to be well-tolerated and safe for eyes. Secondly, CBT-009 is formulated as a non-aqueous atropine eye drop, which has higher stability and accordingly has a shelf life which is two years or more and does not need preservatives or single does-packaging. Current aqueous atropine eye drops, which are often prescribed in off-label uses, on the other hand, may have limited shelf life due to atropine’s instability in the aqueous formulation, and cause side effects such as eye irritations because the pH in current FDA-approved aqueous-based atropine eye drops has to be reduced from neutral (at 6.6 to 7.8) to 3.5 to 6.0. CBT-009 will provide higher comfort level for the eyes and improve the patient tolerability and compliance among juvenile users. Thirdly, compared with refractive surgery, CBT-009 is (i) more convenient for patients, as it takes time and energy to undergo the surgery, and refractive surgery can only be performed in cases where there is potential of recurrence of myopia; (ii) has a broader targeted patient group, as although refractive surgery is one of the treatment options in industry guidelines for juvenile myopia, it is normally not suggested to be performed on patients less than 18 years of old when their eye visions have not been stabilised, whereas CBT-009 does not have such limiting factor; and (iii) more cost-effective. For example, the average cost of LASIK eye surgery for both eyes is US\$4,400 in the United States and ranges from RMB4,000 to RMB6,000 in China, whereas CBT-009 could be priced at a US\$75.0 to US\$100 (average wholesale price per month) direct to the pharmacies and eye doctor offices for distribution, which will be accepted by parents for their children to prevent the progression of myopia.

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Market Opportunity and Competition

Globally, the patient population of juvenile myopia (i.e. myopia on the patient population aged between five and 19) reached 586.2 million in 2023, with a CAGR of 2.8% from 2019 to 2023. It is estimated to reach 653.6 million in 2028 and 688.2 million in 2033, respectively, representing a CAGR of 2.2% from 2023 to 2028 and 1.0% from 2028 to 2033, respectively. The patient population of juvenile myopia in the United States reached 28.9 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 29.7 million in 2028 and 30.5 million in 2033, respectively, representing a CAGR of 0.5% from 2023 to 2028 and 0.6% from 2028 to 2033, respectively. The patient population of juvenile myopia in China reached 130.8 million in 2023, and is estimated to reach 121.0 million in 2028 and 111.4 million in 2033, respectively, primarily resulting from the Implementation Plan for Comprehensive Prevention and Control of Myopia among Children and Adolescents (“綜合防控兒童青少年近視實施方案”).

According to the F&S Report, the global market size of juvenile myopia drug therapies increased from US\$72.8 million in 2019 to US\$90.2 million in 2023, with a CAGR of 5.5%. It is expected to reach US\$858.3 million in 2028 and US\$3,697.0 million in 2033, representing a CAGR of 56.9% from 2023 to 2028 and 33.9% from 2028 to 2033, respectively. There is currently no approved atropine drug therapy for the treatment of juvenile myopia in the United States. Also, low-dose atropine eye drops are commonly prescribed in off-label uses. The market size of juvenile myopia drug therapies in the United States is expected to reach US\$308.4 million in 2028 and US\$1,370.0 million in 2033, representing a CAGR of 34.7%. The market size of juvenile myopia drug therapies in China is expected to reach US\$347.9 million in 2028 and US\$1,299.0 million in 2033, representing a CAGR of 30.1%.

Eikance 0.01% eye drop approved by the Australia Therapeutic Goods Administration (“TGA”) is the first available prescription for children aged between four and 14 years old as a treatment option to slow down the progression of myopia. In addition to Eikance, Xingqi Meioupin 0.01% eye drop was approved by the NMPA in China in March 2024 for children aged between six and 12 years old as a treatment option to slow down the progression of myopia. In December 2024 and June 2025, Ryjusea 0.025% eye drop was approved in Japan and in the EU for children aged between five and 15 years old as a treatment option to slow down the progression of myopia. The following table illustrates the competitive landscape of clinical-stage drug therapies indicated for myopia globally as of the Latest Practicable Date, divided by those in non-aqueous formulation and aqueous formulation:

Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Dosage ⁽⁴⁾	Indications	First posted date/ Approved date ⁽²⁾
<i>In non-aqueous formulation</i>						
CBT-009	Our Group	Australia	Phase 1/2 (completed)	Not publicly disclosed	Juvenile myopia	13 May 2022
<i>In aqueous formulation ⁽³⁾</i>						
Eikance	Aspen Pharmacare Australia Pty Ltd	Australia	Approved	0.01%	Juvenile myopia	19 March 2021

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Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Dosage ⁽⁴⁾	Indications	First posted date/ Approved date ⁽²⁾
Xingqi Meioupin	Shenyang Xinqi Pharmaceutical Co Ltd	China	Approved	0.01%	Juvenile myopia	12 March 2024
Ryjusea	Santen Pharmaceutical Co., Ltd.	Japan/EU	Approved	0.025%	Juvenile myopia	27 December 2024
NVK-002	Vyluma, Inc., Syneos Health, and Nevakar, Inc.	the United States	NDA	0.01%	Juvenile myopia	N/A
HR19034	Chengdu Suncadia Pharmaceuticals Co., Ltd.	China	NDA	Not publicly disclosed	Juvenile myopia	N/A
NVK-002	Zhaoke Ophthalmology Ltd	China	NDA	Not publicly disclosed	Juvenile myopia	N/A
SYD-101	Sydnexis, Inc.	the United States	Phase 3	0.01%/0.03%	Juvenile myopia	18 April 2019
Atropine	Bausch & Lomb Incorporated	the United States	Phase 3	0.01%	Juvenile myopia	8 May 2019
OT-101	Ocumension (Hong Kong) Limited/ ORA, Inc./ Statistics & Data Corporation	the United States	Phase 3	0.01%	Juvenile myopia	25 February 2021
Not publicly disclosed	Shenyang Xinqi Pharmaceutical Co., Ltd.	China	Phase 3	0.02%/0.04%	Juvenile myopia	27 September 2021
OT101	Ocumension Therapeutics, and Lyophilization Technology, Inc	China	Phase 3	0.01%	Juvenile myopia	17 December 2021
Atropine Sulfate	LitePharmTech Co., Ltd.	Korea	Phase 3	Not publicly disclosed	Juvenile myopia	6 September 2022
ARVN002	Arctic Vision Shanghai Biotechnology Co Ltd., and Alcami Corporation	China	Phase 3	0.01%	Juvenile myopia	14 September 2022
QLM3004	Qilu Pharmaceutical Co Ltd	China	Phase 3	0.01%/0.02%/0.04%	Juvenile myopia	2 August 2023
Not publicly disclosed	Zhejiang Shapuaisi Pharmaceutical Co., Ltd.	China	Phase 3	0.02%	Juvenile myopia	27 November 2023
Not publicly disclosed	BrightGene Pharmaceutical Co., Ltd	China	Phase 3	0.01%/0.02%	Juvenile myopia	15 March 2024
Not publicly disclosed	Seefunge Pharmaceutical Technology Co., Ltd.	China	Phase 3	0.01%/0.02%	Juvenile myopia	27 November 2024
Alliance®	Laboratorios Sophia S.A de C.V.	Not publicly disclosed	Phase 3	0.01%	Juvenile myopia	29 April 2024
DE-127	Santen Pharmaceutical Co Ltd	China	Phase 2/3	0.025%	Juvenile myopia	28 March 2022
Not publicly disclosed	Hangzhou Hels Technology	China	Phase 2/3	Not publicly disclosed	Juvenile myopia	23 April 2023
SHJ002	Sunhawk Vision Biotech, Inc.	Taiwan	Phase 2	Not publicly disclosed	Junveile myopia	30 August 2024
BHVI	Hai Yen Eye Care, and Brien Holden Vision Institute	Vietnam	Phase 1/2	0.02%	Juvenile myopia	10 March 2020
IVMED-85	iVeena Delivery Systems, Inc.	Not publicly disclosed	Phase 1/2	Not publicly disclosed	Juvenile myopia	9 March 2023
Not publicly disclosed	Aier Health Ophthalmology (Liaoning) Co., Ltd	China	Phase 1	Not publicly disclosed	Juvenile myopia	27 October 2022
STN1013400	Santen Pharmaceutical Co.,Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	27 March 2023
DA001	Wuhan Docan Pharmaceutical Co., Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	22 November 2023
GPN00884	Ebe Pharmaceutical Co., Ltd./ Grand Pharmaceutical Co., Ltd.	China	Phase 1	Not publicly disclosed	Juvenile myopia	23 April 2024
Not publicly disclosed	Lepu Medical	China	Phase 1	0.01%/0.03%	Juvenile myopia	10 May 2024

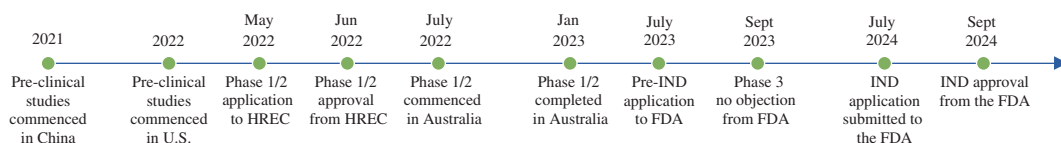
Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidate.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn. Approved date denotes the date on which the relevant drug products (i.e., Eikance, Xingqi Meioupin and Ryjusea) were approved by the regulatory authorities in the relevant authorities.
- (3) Drug candidates in aqueous formulation are included for information. CBT-009 adopts non-aqueous formulation, which is expected to improve patient tolerability, safety and product stability as compared with existing aqueous-based formulations based on pre-clinical and clinical studies conducted by us or our CROs.
- (4) The active pharmaceutical ingredient of all drug candidates in this table is atropine sulphate, with different level of dosages. The dosage of approved drug therapies (i.e., Eikance, Xingqi Meioupin and Ryjusea) refers to the dosage approved by the relevant regulatory authority, and the dosage of drug candidates at clinical trial stages refers to the dosage amount tested in the respective clinical trial.

Source: the CDE, ClinicalTrials.gov, F&S Report

Drug development timeline

The chart below summarises the development timeline of CBT-009:



Summary of Clinical Results

1. Summary of phase 1/2 clinical trial in Australia

The phase 1 and phase 2 clinical trials for CBT-009 were combined into a single trial. We commenced phase 1/2 clinical trial for CBT-009 in Australia in July 2022, and completed it in January 2023.

We chose to conduct phase 1/2 clinical trial for CBT-009 in Australia primarily for the following reasons: (i) the major excipient in the proprietary formulation we developed for CBT-009 is available in Australia as an over-the-counter artificial tear product. As such, the regulatory authority in Australia is familiar with this excipient and understands the safety of this excipient, which would facilitate the clinical development of CBT-009; (ii) there is a streamlined and efficient regulatory pathway for clinical trials in Australia, which made it easier for us to commence the first-in-human phase 1/2 clinical trials; and (iii) clinical trials conducted in Australia need to comply with GLP standards as well, and high-quality clinical data collected from clinical trials conducted in Australia are well recognised in key jurisdictions globally. The clinical development and approval process in Australia is

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comparable with those in the United States and China in terms of evaluating the drug candidates, and accordingly, the clinical trial results in Australia can be used to support CBT-009's contemplated commercialisation in the United States and China.

The following table sets forth an overview of study results of phase 1/2 clinical trial for CBT-009.

<u>Stage</u>	<u>Number of subjects enrolled</u>	<u>Major enrolment criteria⁽¹⁾</u>	<u>Key safety and pharmacodynamics results⁽²⁾</u>	<u>Key safety results</u>	<u>Patients' withdrawal</u>
First stage	32 subjects divided into four cohorts (with comparator, low, mid and high dose of CBT-009 for cohort 1, cohort 2, cohort 3, and cohort 4 respectively)	Healthy volunteers without any active ocular diseases with 18 to 36 years of age	One primary safety endpoint: met ⁽³⁾ Two secondary pharmacodynamics endpoints: met ⁽⁴⁾	Ocular TEAEs (including vision blurred, conjunctival hyperaemia, and glare) were reported for 59.4% of participants with CBT-009 or comparator in the treated eye, and 31.3% of participants with the vehicle ⁽⁶⁾⁽⁷⁾	No withdrawal due to AEs or any other reason
Second stage	52 subjects divided in two cohorts, and 49 of them were exposed to drug (3 subjects lost contact and did not receive treatment)	Healthy volunteers without any active ocular diseases with 18 to 36 years of age	One primary safety endpoint: met ⁽⁵⁾ One secondary pharmacodynamics endpoints: met ⁽⁶⁾	Ocular TEAEs (including vision blurred, photophobia, and administration site pain) were reported for 92.6% of participants with CBT-009 or comparator in the treated eye, and 63.6% of participants with the vehicle ⁽⁷⁾	Two subjects in cohort 2 had TEAEs leading to study withdrawal. This had no impact on study results, as the planned subject number was approximately 50, and the 47 subjects who completed the study have provided sufficient data Three withdrawals due to lost of patients' contact which generally had no impact on the clinical trial development

Notes:

- (1) The enrolled patient group in phase 2 clinical trial was all adults, because the phase 2 clinical trial was designed to demonstrate safety and pharmacodynamics profiles of different doses of CBT-009, which could be attained from a healthy adult population. From the perspective of safety profiles of atropine eye drops, ocular use of atropine in doses as high as 1% are commonly used in paediatric ophthalmology as a dilating drop for eye examinations and for the treatment of amblyopia, so it was considered not necessary to test the safety of low-dose atropine in a paediatric population. This drug development methodology was agreed by the FDA and it did not raise any concern in the preliminary comments on CBT-009's pre-IND application.
- (2) The primary endpoints for both stages of the phase 1/2 clinical trial for CBT-009 are safety endpoints. The secondary endpoints for both stages are pharmacodynamics endpoints. There was no efficacy endpoint in the clinical trial protocol.

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- (3) The only primary safety endpoint for stage 1 is ocular and non-ocular adverse events (AEs). Result: met.
- (4) The secondary pharmacodynamics endpoints for stage 1 are as follows:
 - (a) Change from baseline in the pupil diameter dilation area under the curve (AUC) from time 0 to 8 hours post-dose (AUC_{0-8}) after a single dose. Result: met.
 - (b) Change from baseline in the pupil diameter dilation peak (C_{max}). Result: met.
- (5) The only primary safety endpoint for stage 2 is ocular and non-ocular adverse events (AEs). Result: met.
- (6) The only secondary pharmacodynamics endpoint for stage 2 is change from baseline in the pupil diameter dilation. Result: met.
- (7) Most of these ocular adverse events (such as vision blurred and photophobia) were consistent with the intended effect of CBT-009 and other atropine formulated drugs, and do not impact the safety results.

Details of the phase 1/2 clinical trial in Australia are set out below.

Objective. The objective of phase 1/2 clinical trial for CBT-009 was to evaluate the safety, tolerability, and pharmacodynamics of CBT-009 in healthy adult volunteers aged between 18 and 36.

Study design. The phase 1/2 clinical trial was conducted in two stages from July 2022 to January 2023. The first stage of phase 1/2 clinical trial was a single centre, open-labelled, vehicle-controlled, single ascending dose study in which 32 healthy volunteers with eight subjects per cohort for a total of four cohorts were enrolled. Cohort 1 received single dose with 0.025% of atropine sulphate monohydrate in normal saline prepared by diluting 1% of atropine sulphate solution with physiologic saline, proprietary sterile ophthalmic solution as the vehicle formulation, and cohort 2 to 4 received low dose, mid dose and high dose of CBT-009 drug substance, respectively.

The second stage of phase 1/2 clinical trial was a parallel, double-masked, randomised, vehicle controlled study with dosing once daily in one eye with 52 participants (and 49 of them were in the group of safety population exposed to the drug; the other three subjects originally enrolled lost the contact) in two cohorts in a 28-day trial period, with no follow-up observations. The primary outcome measures of the second stage include (i) safety on near visual acuity, assessed using best-corrected distance spectacle correction with a reduced logarithm of the minimum angle of resolution reading chart (the “**logMAR chart**”, a chart to estimate visual acuity) placed at 40cm under well-lit conditions, (ii) safety on accommodation, measured using a near point rule with best-corrected distance spectacle correction, and (iii) safety on mesopic and photopic pupil, measured with a pupillometer, all three of which assessed or measured on the last day of the stage two trial.

Pharmacodynamic. In the first stage, photopic pupil diameter was to be measured over a period of eight hours after dosing on day 1. The pupil was to be measured at five to 15 minutes before dosing and at the certain time points after the dosing. In the second stage, photopic pupil diameter and mesopic pupil diameter were to be measured pre-dose on day 1 and on day 28 or in the early exit visit. For all pupil size measurements, at least five pupil

size readings (with a range of 0.5 mm) were to be recorded and averaged. Acceptable range in a bright environment was between 2 mm and 4 mm, and in a dark environment was between 4 mm and 8 mm.

In the first stage, a dose-related trend in mean photopic pupil dilation was observed in the CBT-009 treated eye but not in the vehicle-treated eye. AUC_{0-8} (i.e. area under the concentration-time curve from time 0 to 8 hours post-dose) and C_{max} (i.e. maximum diameter) for photopic pupil dilation increased with increasing CBT-009 dose across the cohorts. The mean photopic pupil dilation in all three CBT-009 cohorts demonstrated an expected dose response correlating to the amount of pupil dilation achieved with the 0.025% atropine comparator group. There were no statistically significant differences between the CBT-009 cohorts and comparator for AUC_{0-8} or C_{max} .

The CBT-009 ophthalmic emulsion concentration that demonstrated the optimal benefit to risk profile in the first stage was selected for further investigation in the second stage. The photopic pupil diameter in the right eye (i.e., the study eye) showed a mean increase from baseline to day 28 or early exit of 1.519 mm in cohort 2 (CBT-009) and 0.027 mm in cohort 1 (vehicle) ($p < 0.0001$). The amount of change from baseline in photopic pupil dilation over four weeks of dosing was within the published range observed in previous study of atropine for the treatment of childhood myopia where, after two weeks of dosing, 1.1 mm of photopic pupil diameter change from baseline was observed in the 0.01% dose of atropine sulfate solution, and approximately 2.8 mm and 3.3 mm of change from baseline was observed in the 0.1% and 0.5% doses of atropine sulfate solution, respectively.

The mesopic pupil diameter in the right eye (i.e., the study eye) showed a mean increase from baseline to day 28 or early exit of 1.292 mm in (CBT-009) and 0.313 mm in cohort 1 (vehicle) ($p < 0.0001$). The amount of mesopic pupil change from baseline after four weeks of dosing was within the published range observed in the previous study of atropine for the treatment of childhood myopia where, after two weeks of dosing, 1.3 mm of mesopic pupil diameter change from baseline was observed in the 0.01% dose of atropine, and approximately 3.3 mm and 3.8 mm of change from baseline was observed in the 0.1% and 0.5% doses of atropine, respectively.

Safety. In the first stage of the phase 1/2 clinical trial, ocular TEAEs were reported for 59.4% of participants with CBT-009 or comparator in the right eye, and 31.3% of participants with the vehicle in the left eye. The majority of ocular TEAEs in the CBT-009 treated-eyes were considered to be treatment-related. The most-commonly reported TEAEs were vision blurred, conjunctival hyperaemia, and glare. There was no report of severe ocular TEAEs or SAEs leading to withdrawal or study discontinuation, and all participants rated CBT-009 in the treated eye as “very comfortable” or “comfortable”, at 50.0% to 62.5%, and 37.5% to 50.0%, respectively, across the cohorts of patients treated with CBT-009. There was no participant rated CBT-009 in the treated eye as “slightly uncomfortable” or worse. In contrast, across the cohorts, 25% to 75%, 25% to 50%, and 25% of patients rated the vehicle in the other eye “very comfortable”, “comfortable”, and “slightly uncomfortable”, respectively.

In the second stage, ocular TEAEs were reported for 92.6% of participants with CBT-009 and 63.6% of participants with the vehicle. The majority of ocular TEAEs in the CBT-009 treated-eyes were considered to be treatment-related. The most-commonly reported TEAEs were vision blurred, photophobia, and administration site pain. The vision blurred and photophobia may be attributed to the monocular dosing design leading to perceived vision differences between the two eyes of an individual, and the lack of an option for subjects to use study-provided photochromatic lenses (which have been reported in literature to be used to minimise the effect of photophobia with atropine sulfate) may have contributed to the photophobia rate. There was no report of severe ocular TEAEs or SAEs, but two participants had ocular TEAEs leading to study withdrawal (conjunctival hyperaemia and foreign body sensation in eyes in one participant, and vision blurred and glare in another participant). There were no ophthalmoscopy findings, minimal changes in mean intraocular pressure, and no clinically relevant changes in vital signs results in either cohort. The majority of participants rated CBT-009 in the treated eye as “very comfortable” or “comfortable”, at 18.5%, and 51.9%, respectively, and there was no participant rated CBT-009 in the treated eye as “uncomfortable” or worse.

Conclusion. CBT-009 administered as both single doses and as multiple doses were well tolerated in healthy volunteers. A particular dosing regimen of CBT-009 demonstrated the optimal benefit among the three dosing regimen tested in the first stage. As further tested in the second stage, multiple doses of CBT-009 under a particular dosing regime significantly increased photopic and mesopic pupil dilation from baseline to day 28 or early exit compared with the vehicle and measured within the range of what has been reported in the literature of atropine for the treatment of juvenile myopia. Overall, the clinical trial results of phase 1/2 clinical trial support further investigation of CBT-009 for the treatment of juvenile myopia.

2. Summary of pre-clinical studies

CBT-009, also known as free base atropine, is a novel non-aqueous ophthalmic formulation of atropine. Three topical ocular formulations have been developed to support clinical and non-clinical studies. To facilitate the clinical development of the formulations of CBT-009, several non-clinical studies have been conducted, which include an one-month GLP rabbit toxicological study, a 14-day non-GLP ocular tolerability studies in rabbits and dogs, a 15-day *in vivo* pharmacology study in rabbits, and a seven-day ocular tolerability study in rabbits had demonstrated the safety and tolerability of the then-proposed CBT-009 ophthalmic solutions for its phase 1/2 clinical trial. The formulations of CBT-009 for its phase 1/2 clinical trial were projected to be safe in human ocular use based on above-mentioned studies in animals.

Clinical Development Plan

We are currently planning phase 3 clinical trials for CBT-009 in both the United States and China.

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The following table sets forth details of our clinical plans, trial design and registration plans of CBT-009 phase 3 clinical trials in the United States.

Planned jurisdiction	U.S.
Initiation time	To be commenced simultaneously with the phase 3 clinical trial in China, after the toxicity study on juvenile animals in China is completed
Expected completion time	2029 (estimated, based on the condition that the NDA to be filed in 2028 with 36-month data)
Study design	<p>Overview: randomised, double-masked, parallel study with treatment for 36 months followed by 12 months randomised withdrawal ^(Note)</p> <p>Patient size: approximately 600 subjects (planned) randomised in a 2:1 ratio to certain concentration of CBT-009 or vehicle</p> <p>Endpoints: proportion of participants with $\leq 0.5D$ myopic progression in the study eye at month 36</p> <p>Key inclusion criteria: (i) male or female between the age of four and 16 years of age; (ii) myopia of 0.50 D to 6.00 D refractive error by cycloplegic refraction at baseline; (iii) astigmatism of ≤ 1.5 D refractive error by cycloplegic refraction at baseline; (iv) anisometropia ≤ 1.00 D refractive error by cycloplegic refraction at baseline; and (v) a history of myopia progression of 0.50 D in the previous <12 months for those with baseline myopia <0.75 D. It is consistent with the intended patient group of CBT-009, which is children and adolescents with myopia.</p> <p>Key exclusion criteria: (i) history of abnormal refractive conditions; (ii) use of any anti-muscarinic agent for the treatment of myopia (e.g., atropine); (iii) use of rigid gas-permeable contact lenses, bi-focal or multi-focal lenses, orthokeratology; (iv) any ocular surgery history or planned ocular surgery; and (v) any ocular disease that may confound the assessment of visual acuity or refraction</p>

Note: in the United States, a single adequate and well-controlled study of 36 months treatment duration with a 12-month randomised withdrawal period is acceptable for the FDA, and the NDA can be filed after the completion of the 36-month treatment period.

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The dosage of CBT-009 is currently designed as “one drop of CBT-009 on each eye at night just before bedtime for 48 months”. Based on the FDA’s latest practice, it is also possible that the final label with dosage will not include the restriction on duration of use.

We have received the FDA’s preliminary comments on our pre-IND application in September 2023, approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed a six-month ocular toxicity study to support phase 3 clinical trial. The toxicity study was commenced in April 2023, and was completed in June 2024. We spotted nothing in the toxicity study that would suggest against proceeding with phase 3 clinical trial, nor negative findings on efficacy or safety of CBT-009. The FDA did not specifically ask us to conduct such toxicity study. We proposed to conduct the study in our pre-IND application as part of the preparation work before phase 3 clinical trial, and the FDA concurred with our toxicity study plan in its preliminary comments. In September 2024, we received an approval letter from the FDA stating that it had no objection to us proceeding with phase 3 clinical trial for CBT-009.

We have commenced the toxicity study on juvenile animals in China in February 2025 and expect to submit IND application to the NMPA in the third quarter of 2025. The phase 3 clinical trial in China for CBT-009 is expected to commence by the end of 2025, and complete in 2029 if the NDA is filed in 2028 with 24-month clinical trial data, and the 12-month withdrawal period is acceptable to the NMPA.

We plan to outsource large-scale manufacturing of CBT-009 for phase 3 MRCT and commercial production, once approved.

Regulatory Communications

We submitted the application for conducting phase 1/2 clinical trial in Australia under the National Mutual Acceptance scheme in May 2022 and received the approval from the Australia human research ethics committee (the “**HREC**”) in early June 2022. We subsequently submitted an amendment to phase 1/2 clinical trial protocol on, among others, additional safety measures, and received the HREC’s approval on the amendment at the end of June 2022. The plan to conduct phase 1/2 clinical trial in Australia was not previously communicated with the FDA, as trial data from early phase clinical trials in Australia would be generally accepted by the FDA provided that the trials meet certain criteria as set out by the FDA, and the Australian regulatory authorities did not require the FDA’s approval for an applicant to commence clinical trials in Australia. Our phase 1/2 clinical trial in Australia has met the FDA’s criteria, including that it was conducted in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice (the “**ICH GCP Guidelines**”), which have been incorporated by reference in the Therapeutic Goods Regulations 1990 in Australia, and the FDA is able to validate the data from the phase 1/2 clinical trial in Australia through an on-site inspection, if necessary.

In the United States, we submitted a pre-IND application for CBT-009 to the FDA in July 2023. In September 2023, we received the FDA’s preliminary comments on our pre-IND application, approving us to proceed with phase 3 clinical trial under the 505(b)(2) pathway

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in the United States. The preliminary comments documented, among others, the FDA's affirmative responses to our proposed specifications for CBT-009 based on the data that was submitted in the pre-IND application, consisting of the clinical trial data collected from phase 1/2 clinical trial in Australia, which demonstrates that phase 1/2 clinical trial for CBT-009 conducted in Australia has been accepted by and regarded as comparable to the completion of a phase 1/2 clinical trial in the United States by the FDA. The FDA did not require us to conduct any additional clinical trial or impose any condition before the commencement of phase 3 clinical trial in the United States based on the preliminary comments it issued. Further, the FDA did not raise any safety concern on the results of phase 1/2 clinical trial conducted in Australia, or requested any adjustments to the endpoints or extension of the proposed trial plan. We do not plan to provide responses to the FDA's preliminary comments on our pre-IND application as they are mainly (i) agreement and guidance on our CMC, non-clinical and phase 3 clinical designs and plans (including our proposed six-month supportive toxicity study), and (ii) answers to our questions regarding our various clinical study plans, which we have no follow-up queries at the current stage and will strictly follow. Instead, we will prepare our IND application based on the preliminary comments. We have fully communicated with the FDA on these CMC, non-clinical and phase 3 clinical designs and plans and have obtained the FDA's answers and comments which will be strictly followed by us.

The following table sets forth a detailed chronology of the material communications with the HREC and the FDA regarding phase 1/2 clinical trial conducted in Australia and phase 3 clinical trial to be conducted in the U.S.

<u>Clinical trials</u>	<u>Jurisdiction</u>	<u>Application to the HREC/ FDA</u>	<u>Approval received from the HREC/ FDA</u>	<u>Materials reviewed by the FDA</u>	<u>IND application time</u>
Phase 1/2	Australia	26 May 2022: application to conduct phase 1/2 submitted to the HREC 9 June 2022: amendment to phase 1/2 clinical trial protocol submitted to the HREC	6 June 2022: the HREC approved the first version of phase 1/2 clinical trial protocol 21 June 2022: the HREC approved the amendment on protocol	None ⁽¹⁾	N/A
Phase 3	the United States	28 July 2023: pre-IND application submitted to the FDA	21 September 2023: the FDA issued comments indicating that it has no objection for us to proceed with phase 3 in the U.S. ⁽²⁾	A briefing package including summarised data of CMC, non-clinical and phase 1/2 clinical trial results, and the synopsis of the proposed phase 3 clinical trial	July 2024

Notes:

- (1) The phase 1/2 clinical trial for CBT-009 conducted in Australia did not require prior communication with or approval from the FDA. Instead, we submitted the investigator brochure and clinical study protocol to the HREC for its review and approval before the commencement of phase 1/2 clinical trial in Australia.
- (2) The preliminary comments issued by the FDA indicating that it has no objection for us to proceed with phase 3 clinical trial in the United States demonstrated that the FDA accepted the phase 1/2 clinical trial results in Australia, and had no concerns in this regard.

We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular toxicity study to support phase 3 clinical trial. On 16 September 2024, we received an approval letter from the FDA stating that it had no objection to us proceeding with phase 3 clinical trial for CBT-009.

In addition, we submitted a pre-IND application to the NMPA on 29 January 2024 and received written feedback from the NMPA in batches from March 2024 to May 2024. In its feedback, the NMPA requested us to conduct an additional toxicity study on juvenile animals before submitting the IND application for phase 3 clinical trial in China. The NMPA also provided guidance on safety and efficacy endpoints for phase 3 clinical trial in China which we will strictly follow. We have commenced the toxicity study on juvenile animals in February 2025, and will submit IND application to the NMPA once the toxicity study is completed. We expect to submit IND application to the NMPA in the third quarter of 2025.

Other than the above, as of the Latest Practicable Date, we had not had any material regulatory communications with the FDA, the NMPA or other comparable regulatory authorities for CBT-009, and we were not aware of any material concerns or objections from any regulatory authorities in connection with CBT-009.

Commercialisation Plan

We plan to conduct similar market education activities as CBT-001 has, in preparation for the commercialisation of CBT-009 once its phase 3 clinical trial commences. Our goal is to educate ECPs prior to the regulatory approval of CBT-009 and to commercialise CBT-009 as a safe and effective pharmacotherapy for juvenile myopia. We will work on expanding the penetration rate of non-aqueous based eye drop, by emphasising the advantages of CBT-009 over its aqueous-based competitors. In advance of CBT-009's full commercial launch, we plan to raise the awareness of juvenile myopia through educating KOLs and eye care clinicians at academic medical centers and private practices in the United States by presenting the phase 1/2 clinical data and scientific data of CBT-009 and communicating the epidemiology and diagnosis rate data at major eye care conferences. Our proposed medical scientific liaison team will work on engaging national and regional KOLs at various stages of the drug development, regulatory approval and commercialisation of CBT-009 as appropriate. In addition, we will utilise public relations, media coverage and digital strategies similar to those to be used for CBT-001, to promote our public presence and communicate with the public about our pipeline and the Core Product CBT-009. We will also gather insights via our ongoing marketing research assessments to understand the unmet medical needs from patients, ECPs and leading national insurance payers.

Once approved, we plan to commercialise CBT-009 in the United States and China via direct-to-consumer campaign and ECP education campaigns working closely with KOLs and professional associations. We plan to make a more detailed commercialisation strategy when CBT-009 progress toward commercialisation, which may include setting up a disease state awareness website to enhance public awareness and to facilitate patients to approach eye care specialists potentially offering CBT-009, or engaging dedicated market access personnels to conduct payer education and secure placement for CBT-009 in medical insurance plans. We will also consider partnership with other market players in addition to building our own sales and marketing team for the commercialisation of CBT-009. Similar to our plan for CBT-001, for commercialisation of CBT-009 in the United States and China, we will build our in-house sales and marketing team in addition to exploring partnership opportunities. For any future commercialisation plans in other countries and regions, we will mainly consider partnerships such as out-license arrangements with potential partners and leverage their strong local sales and marketing network. As of the Latest Practicable Date, there was no pricing guidance or centralised procurement requirement set by the PRC government on CBT-009 or our other drug candidates. In order to gain market share against existing and future competitors, we will seek inclusion of CBT-009 into the NRDL and other reimbursement programs through active negotiations with the relevant authorities. However, inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion.

There might be a number of financing options available to us once we commercialise CBT-009 in the future. For example, we may use equity or debt financing to fund the commercialisation activities for CBT-009, or seek partnership opportunities or enter into out-licensing arrangements to obtain proceeds. We may also apply for government grants and subsidies if CBT-009 is eligible. Our approach to fund commercialisation activities of CBT-009 will depend on various factors, such as our strategies plans, market conditions, evolving landscape of industry regulations, and the availability of different source of funds at that time.

Pricing Strategies

Currently, other than surgical options for myopia which are generally high in costs and are not recommended for those under 18 years of age, there are therapies that use off-label drugs to alleviate certain symptoms of myopia. However, therapies do not directly address the disease pathogenesis and cost approximately US\$55.0 for monthly supply. The goal of myopia treatment option is not solely to replace the use and cost associated with a need of wearing life-time high diopter Rx eye glasses, contact lenses or to reduce the need for LASIK refractory surgery. Studies show that more time spent outside by children and the use of a daily eye drop to prevent myopia is the ideal approach to reduce the risk of myopia. In the United States, there is no approved atropine product available currently. However, due to growing interest in myopia management, eye care professionals (“ECP”)s are able to purchase atropine from compounding pharmacies for three different strengths at 0.01%, 0.025% and 0.05%, priced at an average price of US\$39 for 5ml. These atropine products are often sold directly by ECPs to their patients for US\$58.3 to US\$91.7 for monthly supply. The formations of these products all have a short shelf life of less than four months and a low pH that can cause stinging resulting in reduced patient compliance. We plan to price CBT-009 competitively with these treatment options indicated for myopia. It is

anticipated that CBT-009 with a longer shelf life of two years or more and a higher comfort level could be priced at US\$75.0 to US\$100 (average wholesale price per bottle which would last for three months, amounting to an annual cost of US\$300 to US\$400) direct to the pharmacies and eye doctor offices for distribution, which will be accepted by parents for their children to prevent the progression of myopia, at the dosage of one drop on each eye at night just before bedtime, subject to regulatory approvals. At this pricing level, we believe CBT-009 will offer a better alternative than the current off-label therapies for juvenile myopia, and will be a more cost-effective option. We are still in consideration of the pricing of CBT-009 in China. Subject to various factors such as costs of production, regulatory requirements, potential competitor pricing, differences in features between our drugs and future competing drugs, market trends and changes in the levels of supply and demand, we currently plan to price CBT-009 to be higher than atropine sulphate from Shenyang Xinqi (annual cost per patient is at RMB3,625) by approximately 50% upon commercialisation, as CBT-009 potentially has better tolerability and longer shelf-life.

Approved products and drug candidates under development indicated for juvenile myopia contribute to a competitive landscape for CBT-009. As our potential competitors commercialise their drug candidates after obtaining regulatory approvals, we anticipate facing substantial pricing pressure and increased competition. Such situation may impact our market position and pricing power, potentially affecting the adoption rate of CBT-009. See “Risk Factors – Risks Relating to the Development, Clinical Trials and Regulatory Approval of Our Drug Candidates – The market opportunities for our drug candidates may be smaller than we anticipate for reasons including the presence of existing multiple prevention methods and treatment options, which could render some drug candidates ultimately unprofitable even if commercialised”.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CBT-009 SUCCESSFULLY.

Our Clinical-stage Product – CBT-006

Overview

CBT-006 is a potential first-in-class clinical-stage drug candidate, which is a cholesterol dissolving molecule indicated for the treatment of MGD associated DED. We commenced pre-clinical studies for CBT-006 in the United States in 2016. We have completed phase 2 clinical trial for CBT-006 in the United States in May 2022, and we expect to commence additional clinical research in Hong Kong by the end of 2025.

CBT-006 was developed under the 505(b)(2) pathway in the United States. We applied for the IND approval for CBT-006 under the 505(b)(2) pathway in the United States in October 2020, and the FDA issued an approval letter in November 2020 stating that it had no objection to us proceeding with phase 2 clinical trial in the United States. We commenced phase 2 clinical trial for CBT-006 in September 2021, and completed phase 2 clinical trial in May 2022.

Mechanism of Action and Advantages

CBT-006 is a cholesterol dissolving molecule, and contains hydroxypropyl beta-cyclodextrins (“**HP-β-CD**”) as the API indicated for the treatment of MGD. HP-β-CD can absorb cholesterol, and cholesterol at abnormally high levels can lead to poor health of ocular surface lipids and lipid-secreting glands on the eye. These lipids are crucial to prevent water loss from the eye.

MGD is a chronic, diffuse abnormality of the meibomian glands, which secrete complex lipids named meibum onto the ocular surface. These complex lipids form the outermost layer of the tear film to prevent water evaporation and thus maintain tear film stability. MGD is characterised by terminal duct obstruction along with qualitative or quantitative changes in the glandular secretion. Multiple subtypes of MGD have been identified and as shown by previous studies, all subtypes of MGD can lead to various symptoms of MGD. The symptoms of MGD can be observed in the forms of tear film abnormalities, which can cause evaporative DED, ocular surface irritation, inflammation, or ocular surface disease. MGD is the leading cause of evaporative DED, as meibomian glands play an important role in providing lipids to the tear film, which helps to retard the evaporation of tears from the ocular surface. MGD is a contributing factor in 70% to 86% of DED cases globally, and DED could also result in severe consequences as it progresses, such as visual disruption or reduction in visual function. MGD also commonly occurs with an eyelid problem called blepharitis, which causes inflamed eyelids and a crusty discharge at the base of the eyelashes. High risk groups of MGD include Asian population and aged population.

CBT-006 is in the form of eye drops with a novel mechanism of action of sequestration of excess cholesterol at the meibomian gland orifice and in the meibum, to improve meibum secretion. We believe this mechanism can improve tear film quality and meibum mobility in patients with MGD and DED, thus relieving signs and symptoms associated with MGD and DED.

There is a wide range of treatment options for DED. Among them, Miebo™ (perfluorohexyloctane ophthalmic solution), indicated for the treatment of the signs and symptoms of DED and approved by the FDA on 18 May 2023, was the first and only FDA-approved drug therapy for DED that directly targets tear evaporation, which is often associated with MGD by forming a monolayer at the air-liquid interface of the tear film to reduce evaporation, as of the Latest Practicable Date. Before the approval of Miebo™ by the FDA, topical ophthalmic prescription drug therapies would only attempt to alter various factors that may contribute to DED, such as inflammation, bacterial growth, inadequate tear production. These drug therapies do not target the key driver of the disease (i.e., excessive evaporation), while CBT-006, once approved, could potentially treat the MGD associated DED by dissolving cholesterol and other lipids deposited at the orifice of meibomian glands and thus improve meibum quality and the health of meibomian gland, according to the F&S Report. None of the launched products or drug candidates indicated for MGD associated DED use the same active ingredient as CBT-006 does. CBT-006 uses cyclodextrin as the active ingredient while other drugs use perfluorohexyloctane, selenium disulfide, minocycline or lotilaner. We believe that CBT-006, has the potential to be the first-in-class product for the treatment of MGD associated DED, once approved.

Current Therapies and Limitations

According to the F&S Report, MGD is a contributing factor in 70% to 86% of DED cases globally, and DED is a common public health concern with a prevalence rate of approximately 10% out of total global population. DED could also result in severe consequences as it progresses, such as visual disruption or reduction in visual function. DED is a multifactorial disease of the tear film, characterised by increased tear film osmolarity, ocular inflammation, deterioration of ocular surface and neurosensory abnormalities, can cause some ocular symptoms such as ocular discomfort and visual disturbance. Patients are diagnosed with DED based on their symptoms and tear film stability. Patients with moderate to severe dry eye symptoms often complain of significant itching and limitation of daily activities which may lead to deterioration in quality of life and even depression. Patients with clogged meibomian glands and mites have less stable tear film. Therefore, preventing and relieving meibomian glands clog and mites are effective ways to avoid the development of DED. At present, mild DED is generally managed with artificial tears in addition to education and environmental modifications. As severity progresses, additional strategies such as anti-inflammatory therapies (e.g. topical cyclosporine, steroids, lifitegrast), lid hygiene, punctal occlusion, thermal pulsation, amniotic membrane bandage, autologous serum, and in the most severe cases, surgery may be required to treat DED. Current treatment options for MGD associated DED mainly include drug therapies, therapeutic devices and surgery, most of which have certain limitations and thus present unmet medical needs worldwide.

Various mechanisms exist for the treatment of DED, including artificial tears, anti-inflammatory drugs, corneal repair, stimulating mucoprotein secretion, mite removal and reducing evaporation. Artificial tears may be prescribed for patients with mild DED to replenish tears, lubricate the ocular surface, and dilute the soluble inflammatory mediators on the surface, but they may cause temporary blurry vision and lacrimal gland malfunction in the long term. Anti-inflammatory agents may be prescribed to treat mild or moderate DED but it may cause ocular surface pain and require long-term use. Other unconventional drug therapies, such as corneal repair drugs or mucoprotein secretion-stimulating drugs, are not stable for long-term storage. The option of mite removal wipes normally requires an overall treatment period of one to two months, and is difficult to achieve a satisfying therapeutic effect in the short term.

Therapeutic devices for the treatment of DED mainly include soft therapeutic contact lenses and therapeutic neurostimulation devices. Soft therapeutic contact lenses may be used for DED with corneal injury, but it may cause corneal edema and hyperaemia when being worn for long hours. Therapeutic neurostimulation devices might cause nasal irritation and lower the comfort level for patients.

Lacrimal duct surgery is performed to embolise lacrimal duct to keep tears and artificial tears on eyes and relieve the symptoms of DED. While lacrimal duct surgery is believed to be generally effective and safe, it brings adverse reactions like rejection, local inflammation, redness and pain during the procedure. It might also induce chronic ophthalmic disease such as chronic dacryoadenitis when the tear duct is blocked for a long time and bacteria and tear fluids gathered in the tear sac. In addition, patients with inflammation in eyes and poor duct conditions, such as ectropion and narrow duct, may not be suitable for lacrimal duct surgery.

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Market Opportunity and Competition

According to the F&S Report, MGD is a contributing factor in 70% to 86% of DED cases globally. Globally, the patient population of MGD associated DED reached 843.6 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 885.7 million in 2028 and 922.5 million in 2033, respectively, representing a CAGR of 1.0% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively. The patient population of MGD associated DED in the United States reached 23.7 million in 2023, with a CAGR of 0.8% from 2019 to 2023. It is estimated to reach 24.6 million in 2028 and 25.5 million in 2033, respectively, representing a CAGR of 0.8% from 2023 to 2028 and 0.7% from 2028 to 2033, respectively. The patient population of MGD associated DED in China reached 285.8 million in 2023, with a CAGR of 1.0% from 2019 to 2023. It is estimated to reach 291.4 million in 2028 and 295.3 million in 2033, respectively, representing a CAGR of 0.4% from 2023 to 2028 and 0.3% from 2028 to 2033, respectively.

The global market size of drug therapies indicated for MGD associated DED is expected to reach US\$3,784.8 million in 2028 and US\$8,543.8 million in 2033, representing a CAGR of 17.7%. The market size of drug therapies indicated for MGD associated DED in the United States is expected to reach US\$2,246.7 million in 2028 and US\$3,932.1 million in 2033, representing a CAGR of 11.8%. The market size of drug therapies indicated for MGD associated DED in China is expected to reach US\$1,288.5 million in 2028 and US\$2,926.6 million in 2033, representing a CAGR of 17.8%.

There is a wide range of treatment options for DED. Among them, Miebo™ (perfluorohexyloctane ophthalmic solution), indicated for the treatment of the signs and symptoms of DED and approved by the FDA on 18 May 2023, was the first and only FDA-approved drug therapy for DED that directly targets tear evaporation, which is often led by MGD by forming a monolayer at the air-liquid interface of the tear film to reduce evaporation, as of the Latest Practicable Date. The following table illustrates the competitive landscape of drug therapies indicated for MGD associated DED globally as of the Latest Practicable Date:

Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Indications	Active ingredients	Mechanism	First posted date ⁽²⁾
Miebo (NOV03) ⁽³⁾	Bausch & Lomb Inc. ⁽⁴⁾	The United States and the EU	Approved	DED ⁽⁵⁾	Perfluorohexyloctane ⁽⁵⁾	Not publicly disclosed	N/A
SHR8058 eye drops/NOV03 eye drop ⁽⁶⁾	Jiangsu HengRui Pharmaceuticals Co Ltd	China	NDA	MGD associated DED	Perfluorohexyloctane ⁽⁷⁾	Not publicly disclosed	N/A
AZR-MD-001	Azura Ophthalmics Ltd/ ORA, Inc.	The United States	Phase 3	MGD associated DED	Selenium Disulfide ⁽⁸⁾	Keratolytic agent	26 March 2024
HY02	Hovione Scientia Ltd	The United States	Phase 2	MGD associated DED	Minocycline ⁽⁸⁾	Not publicly disclosed	25 March 2019
AXR-270	AxeroVision, Inc.	The United States	Phase 2	MGD associated DED	Not publicly disclosed	Glucocorticoid receptor agonist ⁽⁸⁾	14 July 2020
TP-03	Tarsus Pharmaceuticals, Inc.	The United States	Phase 2	MGD associated DED	Lotilaner	Non-competitive gamma-aminobutyric acid receptor antagonist ⁽⁹⁾	12 July 2022

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Drug name/ code	Company	Clinical trial region ⁽¹⁾	Clinical trial stage	Indications	Active ingredients	Mechanism	First posted date ⁽²⁾
CBT-006	Our Group	The United States	Phase 2	MGD associated DED	Cyclodextrin	Supramolecular catalysts	12 May 2021

Notes:

- (1) Clinical trial region in the competitive landscape chart in this section represents the place of conducting clinical trials and may differ from the place where regulatory approval is going to be pursued by respective product/drug candidate.
- (2) First posted date denotes the date on which the study record is first available on www.ClinicalTrials.gov or www.chinadrugtrials.org.cn.
- (3) The price of Miebo™ is US\$771 for one month's supply, and the patent expiry date is 21 June 2037. Perfluorohexyloctane, the active ingredient of Miebo™, forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce the evaporation.
- (4) Bausch & Lomb Inc. acquired the rights to develop and commercialise NOV03 from Novaliq GmbH in the United States and Canada in December 2019.
- (5) Although on FDA approved label, the indication of Miebo™ is DED (i.e. all types of DED), the patients from the clinical trials of Miebo™ were patients with MGD associated DED only.
- (6) Novaliq GmbH entered into a strategic collaboration arrangement with Jiangsu Hengrui Pharmaceuticals to develop, manufacture and commercialise NOV03 for the treatment of MGD associated DED in Greater China.
- (7) Perfluorohexyloctane is a novel substance that has been approved as a medical device NovaTears(r), which is a nonblurring wetting agent for the ocular surface.
- (8) AZR-MD-001, HY02, and AXR-270 are anti-inflammatory antibiotics.
- (9) TP-03 is an antiparasitic agent.

Source: the FDA, the CDE, ClinicalTrials.gov, F&S Report

Drug development timeline

The chart below summarises the development timeline of CBT-006:



Summary of Clinical Results

1. Summary of phase 2 clinical trial in the United States

We applied for the IND approval for CBT-006 under the 505(b)(2) pathway in the United States in October 2020, and the FDA issued an approval letter in November 2020 stating that it had no objection to us proceeding with phase 2 clinical trial. We commenced phase 2 clinical trial for CBT-006 in September 2021, and completed it in May 2022.

Objective. The objective of phase 2 clinical trial for CBT-006 was to evaluate the safety and efficacy of CBT-006 topical ophthalmic solution for treating MGD and MGD associated DED.

Study design. The phase 2 clinical trial is a multicentre, double masked, randomised, vehicle controlled, parallel group study on patients with MGD associated DED. The primary safety outcome measures of phase 2 clinical trial are incidence of treatment-emergent adverse events in terms of visual acuity, biomicroscopy, intraocular pressure, ophthalmoscopy, and the secondary outcome measure is ocular discomfort score measured on a scale between 0 and 4, both of which measured in a three-month timeframe.

In the first stage of the clinical trial, the vehicle, 2.5% and 10% of CBT-006 was dosed to patients three times a day for three months, and the primary efficacy endpoints include change in ocular discomfort score (“ODS”, a score corresponding to the categorical scale used to determine symptoms associated with dry eye) and cornea staining grade (a numerical value derived from a scale used to characterise corneal aberrations observed after sodium fluorescein is instilled, representative of breakdown of the epithelial barrier of the cornea) change at week 12. In the second stage (i.e., pharmacokinetics study), a single dose in one eye was applied and blood level of CBT-006 was assessed.

Pharmacokinetics. CBT-006 was undetectable in patients’ blood after a single dose in the eye at both dose concentrations of 2.5% and 10%, which means there was minimal risk of systemic side effect.

Safety. The safety of CBT-006 was demonstrated in patients with MGD associated DED. There was no severe adverse effect observed in the study. Overall, the phase 2 clinical trial demonstrated that CBT-006 has a safe and well-tolerated profile in patients with MGD associated DED receiving CBT-006 three times a day for three months.

Efficacy. The primary endpoints are cornea staining and ocular discomfort score in the third month (i.e., the end of the treatment period in the first stage). The secondary endpoints include, among others, ODS and corneal staining, the tear break up time (“TBUT”, a measure of the number of seconds that elapse between a blink and the appearance of the first dry spot in the tear film, representative of a deficiency in the aqueous, mucin, or lipid layer of the tear film, and a score >10 seconds is considered normal), the meibum quality score (“MQS”, the number value derived from the sum of expressing upper and/or and lower eyelid meibomian glands. The lower the grade, the less the gland is expressible and is indicative of a dysfunction in meibomian gland secretion), and the visual analog scale (“VAS”, a type of scale where the participant marks their response which is then measured

by distance from the two possible extreme responses to the question). Neither the primary efficacy endpoints, i.e, ODS or corneal staining grade change from baseline at week 12, showed significant differences between the treatment and vehicle groups. Most ODS and corneal staining grade secondary endpoints tested at other time points (i.e. week 2, 4 and 8) were not met neither, with an exception that CBT-006 10% group showing significant improvement in corneal staining grade compared with the CBT-006 vehicle group at week 2.

In a post hoc analysis, a subgroup showed a significant advantage in corneal staining grade at all time points in favour of the CBT-006 10% group over the CBT-006 vehicle group. Similar result was also observed in the CBT-006 2.5% group at week 2 and week 8. Another subgroup showed no such significant differences between treatment and vehicle groups in this measurement. The potential efficacy of CBT-006 in the first subgroup could be further explored.

In the second stage of the clinical trial, all plasma (i.e., the cell-free portion of blood which separates on centrifugation after being treated with an anticoagulant. When detected, the drug elimination rate can be determined by the corresponding plasma concentration level) samples of all patients were below the limit of quantification for CBT-006, demonstrating the lack of systemic exposure with topical ocular administration of CBT-006.

Conclusion. Further clinical development of CBT-006 is warranted to explore the potential efficacy and the possible differences in a certain measurement of HP- β -CD in patients with MGD associated DED.

2. *Summary of pre-clinical studies*

CBT-006, also known as 2-hydroxypropyl-beta-cyclodextrin, is formulated as a topical ocular solution for the treatment of MGD associated DED via sequestering cholesterol accumulated at the orifice of meibomian glands. 2-hydroxypropyl-beta-cyclodextrin has been approved by the FDA as an inactive ingredient in many drug products in the strength up to 33% in intramuscular injection solution, 20% as lyophilised powder in intravenous injection solution, 33% as injection solution in intravenous infusion, 400mg/mL as solution in oral dosing and 15 mg in oral tablet with brand names of Mitozytrex, Sporanox, Dexacort, Vibativ[®] and Perindopril Erbumine respectively. Furthermore, Indocollyre 0.1% eye drop, containing 10% 2-hydroxypropyl-beta-cyclodextrin as a formulation excipient, has been approved in Europe and Asia. Multiple drugs have adopted Perindopril Erbumine as the active ingredient. The following table sets out the active compound, manufacturer, first approval year, indications, patent applicant holder and patent expiry year of Mitozytrex, Sporanox, Dexacort, Vibativ[®] and Indocollyre.

Reference drug	Active compound	Manufacturer	First approval year	Indications	Patent applicant holder	Patent expiry year
Mitozytrex	Mitomycin	Supergen	2002	Disseminated adenocarcinoma of the stomach or pancreas	Supergen	2022

BUSINESS

Reference drug	Active compound	Manufacturer	First approval year	Indications	Patent applicant holder	Patent expiry year
Sporanox	Itraconazole	Janssen	1992	Oropharyngeal and esophageal candidiasis	Janssen	2012
Dexacort	Dexamethasone sodium phosphate	UCB	1982	Endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states and so on	UCB	2002
Vibativ®	Telavancin hydrochloride	Cumberland Pharmaceuticals	2009	Complicated skin and skin structure infections caused by susceptible gram-positive bacteria	Cumberland Pharmaceuticals	2029
Indocollyre	Indomethacin	BAUSCH & LOMB	1989	Ocular inflammatory processes of various origin	BAUSCH & LOMB	2009

We planned to take reference from selected non-clinical safety data of 2-hydroxypropyl-beta-cyclodextrin under the 505(b)(2) regulatory pathway. Therefore, our non-clinical testing strategy focused on conducting ocular safety evaluation of CBT-006 in two relevant toxicity species of rabbits and monkeys.

Two ophthalmic formulations have been used to support the clinical and non-clinical development program, which were used as an investigational product to support phase 2 clinical trial for the treatment of MGD associated DED, and used in GLP ocular toxicity studies of six-month rabbits and nine-month monkeys, respectively.

Clinical Development Plan

We are currently planning additional clinical research for CBT-006 in Hong Kong which is expected to commence by the end of 2025. After the completion of phase 2 clinical trial in May 2022, we took time to conduct analysis on the results and prepare for initiating additional clinical research in Hong Kong to verify the positive signal observed in the phase 2 clinical trial and the subsequent post-hoc analysis. The commencement of phase 3 clinical trial depends on the results of the additional clinical research in Hong Kong. We may hold an EOP2 meeting with the FDA or a pre-IND meeting with the NMPA, depending on the combined clinical results of phase 2 clinical trial in the United States and additional clinical research in Hong Kong.

We plan to outsource large-scale manufacturing of CBT-006 for phase 3 clinical trial and commercial production, once approved.

Regulatory Communications

We applied for the IND approval for CBT-006 under the 505(b)(2) pathway in the United States on 30 October 2020. On 10 November 2020, the FDA inquired about the microbiological control of the manufacturing process and we provided responses on 13 November 2020. On 30 November 2020, the FDA issued an approval letter stating that it

had no objection to us proceeding with phase 2 clinical trial. In the approval letter, the FDA also provided guidance on the study design for CBT-006, including (i) demonstrating the efficacy of CBT-006 with the use of lid hygiene, (ii) demonstrating a difference in a sign and a symptom to establish efficacy of CBT-006 for indications such as MGD associated DED, (iii) performing PK assessment for the final to-be-marketed product of CBT-006 at the final clinical dosage regimen, and (iv) strengthening the study protocol for CBT-006 based on the FDA's understanding that the clinical trial we were planning to conduct was an exploratory study.

Other than the above, as of the Latest Practicable Date, we had not had any material regulatory communications with the FDA, the NMPA or other comparable regulatory authorities for CBT-006, and we were not aware of any material concerns or objections from any regulatory authorities in connection with CBT-006.

Pricing Strategies

Unlike MieboTM already approved by the FDA and other currently available treatment options before the approval of MieboTM, CBT-006 uses a different active ingredient and mechanism of action. Once approved, it is expected to become a first-in-class product for the treatment of MGD associated DED by dissolving cholesterol and other lipids deposited at the orifice of meibomian glands and thus improve meibum quality and the health of meibomian gland, which could potentially be disease-modifying. MieboTM was approved in the United States in May 2023 and its list price was US\$771 for monthly supply at launch, which is at premium compared to the listed prices of other drugs (Restasis and Xiidra) indicated for dry eye. We expect CBT-006 to be priced competitively with MieboTM and offer a better alternative than current treatment options.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CBT-006 SUCCESSFULLY.

Our Clinical-stage Product – CBT-004

Overview

CBT-004 is a potential first-in-class drug candidate, which is a multi-kinase inhibitor targeting VEGFRs and PDGFRs indicated for the treatment of vascularised pinguecula. We commenced pre-clinical studies for CBT-004 in China in 2019. We obtained the IND approval from the FDA on 18 February 2021 and submitted the IND amendment on 29 September 2023 for CBT-004. We commenced phase 2 clinical trial in December 2023, and completed it in May 2025.

We developed CBT-004 through our proprietary MKI technology platform. We expect CBT-004 to be the first drug available targeting vascularised pinguecula once approved, the current standard of care for which can only temporarily alleviate symptoms.

CBT-004 was developed under the 505(b)(2) pathway in the United States. We applied for the IND approval for CBT-004 under the 505(b)(2) pathway in the United States in December 2020, and obtained the IND approval from the FDA in February 2021. Since then,

our R&D team has developed an improved formulation to enable higher doses for CBT-004. Consequently, we decided to conduct additional formulation stability and GLP ocular toxicity studies in rabbits and dogs, which is the reason of the time gap between the IND approval and the IND amendment. The IND amendment was submitted in September 2023 to amend our previous IND submission and phase 2 clinical trial protocol.

Mechanism of Action and Advantages

CBT-004 is indicated for vascularised pinguecula. Pinguecula is a round, yellowish, elevated tissue that develops on the conjunctiva adjacent to the cornea. In general, an asymptomatic pinguecula requires no treatment, but its yellowish and raised contour can cause mechanical or poor tear film-related ocular surface irritation. When the lesion becomes vascularised and/or inflamed, it may lead to symptoms of ocular hyperaemia, discomfort, pain, foreign body sensation, tearing, and itching. There is no FDA-approved therapy for the indication of vascularised pinguecula.

CBT-004 is a potent VEGFRs inhibitor with sub nanomolar potency. It can also inhibit PDGFRs that are responsible for blood vessel maintenance. Cumulative exposure to UV light is the main cause of pinguecula. UV-induced mutations of the gene may promote abnormal cell growth of pinguecula lesion. At later stages, pinguecula often shows increased vascularisation that is dependent on the VEGF pathway. The mechanism of CBT-004 for treating vascularised pinguecula is to block VEGF signal to reduce the abnormal vascularity associated with late stage pinguecula and stop or reverse the progression of the lesion.

The current existing treatment options for vascularised pinguecula, including lubricating eye drops and off-label use of non-steroidal anti-inflammatory drugs or steroid eye drops, are insufficient to fulfil the clinical needs due to safety concerns and lack of efficacy. CBT-004 is a potential first-in-class ocular drug using breakthrough multi-kinase inhibitor targeting VEGFRs and PDGFRs, and is expected to have advantages over the current standard of care for which can only temporarily alleviate symptoms of pinguecula.

Current Therapies and Limitations

There is currently no approved drug therapy for the treatment of vascularised pinguecula globally. Nevertheless, there exist two major intervention methods (rather than treatment options) to manage pinguecula, which are pharmacological intervention and surgical intervention, both of which have certain limitations and thus present unmet medical needs worldwide.

Pharmacological intervention such as artificial tears and ointment is mainly symptomatic and temporary, usually adopted in mild cases of dryness or foreign body sensation. If inflammation is more severe, a short course of topical steroids or topical antibiotic-steroid in tapering dose may be indicated. Topical non-steroidal anti-inflammatory drugs are also effective for pinguecula. However, long-term use of topical steroid therapy might cause adverse side effects, such as IOP elevation, cataract formation and increased risk of infection. Surgical intervention, including conjunctival autografting, argon laser photocoagulation, cryotherapy and adjunctive therapy is usually considered only for cosmetic

reasons. Common complications of surgical intervention include recurrence of pinguecula and pigmentary changes at the site of removal. Moreover, the costs of surgeries for vascularised pinguecula and associated treatment are relatively high in the United States and China.

Market Opportunity and Competition

Globally, the patient population of vascularised pinguecula reached 1,161.1 million in 2023, with a CAGR of 1.1% from 2019 to 2023. It is estimated to reach 1,213.2 million in 2028 and 1,262.1 million in 2033, respectively, representing a CAGR of 0.9% from 2023 to 2028 and 0.8% from 2028 to 2033, respectively. The patient population of vascularised pinguecula in the United States reached 45.7 million in 2023, with a CAGR of 0.9% from 2019 to 2023. It is estimated to reach 47.3 million in 2028 and 48.8 million in 2033, respectively, representing a CAGR of 0.7% from 2023 to 2028 and 0.6% from 2028 to 2033, respectively. The patient population of vascularised pinguecula in China reached 207.0 million in 2023, with a CAGR of 0.8% from 2019 to 2023. It is estimated to remain relatively stable at 207.4 million in 2028 and 207.8 million in 2033, respectively.

There is currently no approved drug therapy for the treatment of vascularised pinguecula globally. According to the F&S Report, the global market size of vascularised pinguecula drug therapies is expected to reach US\$1,539.3 million in 2033. The market size of vascularised pinguecula drug therapies in the United States and China are expected to reach US\$940.6 million and US\$92.2 million in 2033, respectively.

As of the Latest Practicable Date, CBT-004 was the only clinical-stage drug therapy indicated for vascularised pinguecula globally. According to the F&S Report, Inlyta, manufactured by Pfizer is the reference listed drug for CBT-004, which was approved by the FDA in 2012 and is indicated for the treatment of advanced renal cell carcinoma. The active compound of Inlyta is axitinib, the patent holder of which is PF PRISM CV, and the relevant patent will expire in 2032.

Summary of Clinical Results

1. Summary of phase 2 clinical trial in the United States

We applied for the IND approval for CBT-004 under the 505(b)(2) pathway in the United States in December 2020, and obtained the IND approval from the FDA in February 2021. The IND amendment was submitted in September 2023 to amend our previous IND submission and phase 2 clinical trial protocol. We commenced phase 2 clinical trial in December 2023, and completed it in May 2025.

Objective. The objective of phase 2 clinical trial for CBT-004 was to evaluate the safety, efficacy and pharmacokinetics of CBT-004 in patients with vascularised pinguecula and associated conjunctival hyperaemia.

The clinical trial report, which includes additional details on pharmacokinetics, efficacy and efficacy, was not available as of the Latest Practicable Date. The result available as of now is as follows.

Study design. The phase 2 clinical trial is a multicentre, randomised, double-masked, vehicle-controlled study in which patients are dosed three times daily for 28 days and with additional 28 days of follow-up observations in the eyes with vascularised pinguecula with 0.05% or 0.075% of CBT-004. The key inclusion criteria is pinguecula in at least one eye of generally healthy adults who are 18 years of age or older with associated conjunctival hyperemia grade ≥ 2 on a 5-point (0-4) scale as determined by an independent reading center. 88 subjects were enrolled at a single clinical trial site, and were randomly assigned to one of three treatment arms (0.05% CBT-004, 0.075% CBT-004, or vehicle in a 1:1:1 ratio) at the baseline (day 1) visit.

The primary efficacy endpoints is the change from baseline of conjunctival hyperemia by digital image grade at day 28 (week 4). The grades were assigned by an independent reading center's analysis using a 5-point scale of digital images obtained at the clinical site. The secondary efficacy variables include (i) change from baseline of conjunctival hyperemia by digital image grade at days 7 (week 1) and day 56 (week 8); (ii) the proportion of subjects with ≥ 1 grade reduction from baseline of conjunctival hyperemia by digital image grade at day 7 (week 1), day 28 (week 4), and day 56 (week 8); (iii) change from baseline of conjunctival hyperemia by direct visual observation at day 7 (week 1), day 28 (week 4), and day 56 (week 8); (iv) the proportion of subjects with ≥ 1 grade reduction from baseline of conjunctival hyperemia by direct visual observation at day 7 (week 1), day 28 (week 4), and day 56 (week 8); (v) change from baseline of eye symptom score at day 7 (week 1), day 28 (week 4), and day 56 (week 8); and (vi) change from baseline of visual analog scale (VAS) scores at day 7 (week 1), day 28 (week 4), and day 56 (week 8), regarding current ocular discomfort related to the pinguecula including burning/stinging, itching, foreign body sensation, eye discomfort, eye dryness, photophobia, and pain.

Safety. The topline data analysis revealed that subjects in the clinical trial were well tolerated and no drug-related systemic or ocular adverse events was reported.

Conclusion. CBT-004 was able to meet the primary endpoint in efficacy. Both 0.5% and 0.75% CBT-004 groups demonstrated significantly more reduction from baseline than vehicle (-0.6 and -0.8 vs -0.3), and the dose relationship was observed. Several secondary endpoints also met the pre-set specifications.

2. *Summary of pre-clinical studies*

CBT-004, also known as axitinib free base, is formulated as a topical ocular solution for the treatment of vascularised pinguecula. Since Inlyta (axitinib), with the active pharmaceutical ingredient of axitinib, has been approved by the FDA as an oral tablet for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy, we planned to take reference from selected non-clinical safety data of axitinib including systemic toxicity studies under the 505(b)(2) regulatory pathway. Therefore, our non-clinical testing strategy focuses on conducting ocular safety evaluation of axitinib in two relevant toxicity species of rabbits and monkeys and on evaluating efficacy in relevant animal disease models of *in vivo* corneal suture rabbit model.

Drug development timeline

The chart below summarises the development timeline of CBT-004:



Clinical Development Plan

We just completed the phase 2 clinical trial for CBT-004 on the Latest Practicable Date. We plan to prepare the clinical trial report in the upcoming several months which will reveal additional details and conduct more analysis on the clinical trial results. In general, continuous data (i.e., varying data at different timepoints) will be summarised with descriptive statistics (including number of patients, mean, standard deviation, median, minimum and maximum) and will be analysed using analysis of variance (“ANOVA”) techniques (a set of statistical testing method to analyse the differences between the means of two or more treatment groups. It takes into account the variation within each group relative to the variation between each group) with contrasts for between-group comparisons, and paired t-tests for within-group analyses. Categorical variables will be summarised by sample size (N), frequency count and percent, and analysed using Pearson’s chi-square test or Fisher’s exact test. Ordinal variables will be analysed using Kruskal-Wallis test with contrasts for between-treatment comparisons and the signed-rank test for within-treatment comparisons.

We plan to schedule an EOP2 Meeting with the FDA after we complete the clinical trial report for phase 2 clinical trial.

Regulatory Communications

We applied for the IND approval for CBT-004 under the 505(b)(2) pathway in the United States on 29 December 2020, and obtained the IND approval from the FDA on 18 February 2021. On 29 September 2023, we submitted the IND amendment to the FDA.

Other than the above, as of the Latest Practicable Date, we had not had any material regulatory communications with the FDA, the NMPA or other comparable regulatory authorities for CBT-004, and we were not aware of any material concerns or objections from any regulatory authorities in connection with CBT-004.

Pricing Strategies

Currently, moderate to severe vascularised pinguecula is treated with a variety of over-the-counter artificial tears as well as relatively high-priced off-label prescription products. These off-label prescription products on average cost approximately US\$600 per month. For cases of vascularised pinguecula at an advanced stage, surgery is usually performed which can cost more than US\$5,000 per procedure and cause a significant amount of post-operative pain. We plan to price CBT-004, our potential first-in-class ophthalmic

drug indicated for the treatment of vascularised pinguecula, slightly below the pricing level of prescription products which are currently used off-label for vascularised pinguecula. We believe our planned competitive pricing will reduce the need to use multiple high-priced products in off-label use and will be a more cost-effective option for patients with moderate to severe vascularised pinguecula.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CBT-004 SUCCESSFULLY.

Pre-clinical Stage Drug Candidates

CBT-007

Mechanism of Action and Advantages

CBT-007 is developed for improving success rate of glaucoma filtration surgery (“GFS”). GFS is believed to be an effective way to lower high intraocular pressure (“IOP”) in patients with glaucoma. However, excess scarring and fibrosis after surgery can lead to blockage of the drainage and cause failure of GFS over time. The usage of anti-fibrotic cytotoxic antimetabolite drugs such as mitomycin C (“MMC”) can improve the success rate of GFS but these cytotoxic drugs can also cause various adverse complications.

CBT-007 as an eye drop is developed for improving the success rate of GFS. It is intended to be used as adjunct therapy with MMC to potentially lower the amount of MMC needed. CBT-007 targets key pathogenic pathways that contribute to GFS failure, including the VEGFs and the fibroblast growth factor (“FGF”) signalling pathways. Attenuation of these pathways is expected to slow down the post-surgery excess fibrosis that blocks the drainage made by surgery, thus enhance the success rate of GFS.

Market Opportunity and Competition

Globally, the patient population of glaucoma reached 81.5 million in 2023, with a CAGR of 2.3% from 2019 to 2023. It is estimated to reach 91.5 million in 2028 and 101.3 million in 2033, respectively, representing a CAGR of 2.3% from 2023 to 2028 and 2.1% from 2028 to 2033, respectively.

According to the F&S Report, the global market size of glaucoma drug therapies increased from US\$5.8 billion in 2019 to US\$6.4 billion in 2023, with a CAGR of 2.8%. It is expected to reach US\$7.4 billion in 2028 and US\$8.6 billion in 2033, representing a CAGR of 2.7% from 2023 to 2028 and 3.2% from 2028 to 2033, respectively.

Near-term Plans

We began the drug discovery process for CBT-007 in China in 2021, and as of the Latest Practicable Date, certain pre-clinical studies, as well as the pharmacology study for CBT-007 had been conducted. We will perform PK and toxicology studies once the formulation for CBT-007 is ready for testing. We intend to submit the IND application to the FDA in the third quarter of 2025.

We plan to complete all pre-clinical work for CBT-007 in our Guangzhou R&D centre and Suzhou R&D centre. Our Suzhou R&D centre is also expected to manufacture clinical trial supplies and perform release testing of CBT-007's drug products for phase 1 and phase 2 clinical trials.

CBT-199

Mechanism of Action

CBT-199 is indicated for the treatment of presbyopia, a condition caused by an age-related process. During aging, the lens in the eye gradually becomes thicker and loses flexibility. With less elasticity, it will be difficult for the eye to focus up close. It is a new formulation invented by us, designed to shrink the pupil size, allowing increased depth of field of focusing to counter the lens inflexibility problem, and improve focus up close.

Market Opportunity and Competition

Globally, the patient population of presbyopia reached 2,029.2 million in 2023, with a CAGR of 1.3% from 2019 to 2023. It is estimated to reach 2,244.8 million in 2028 and 2,474.8 million in 2033, respectively, representing a CAGR of 2.0% from 2023 to 2028 and 2.0% from 2028 to 2033, respectively.

According to the F&S Report, the first drug product indicated for presbyopia was approved in the year of 2021. The global market size of presbyopia drug therapies reached US\$0.2 billion in 2023. It is expected to reach US\$3.4 billion in 2028 and US\$5.6 billion in 2033, representing a CAGR of 86.6% from 2023 to 2028 and 10.3% from 2028 to 2033, respectively.

Pre-clinical Studies

Presbyopia is a very common, age-related vision disorder characterised by a progressive inability to focus on close objects. The aetiology of presbyopia is not fully understood yet. Recent studies suggest that an increase in lens rigidity may be the primary causative mechanism of this condition. Another proposed cause is the gradual loss of function of the ciliary muscles. Both mechanisms lead to the loss of focal point change and as a result, it is difficult for the eye to focus up close.

Current treatment options for correct presbyopia include both fixed and variable focus lens systems, as well as surgical interventions. More recently, a topical pharmacological eyedrop has become a new option for treating presbyopia. The FDA approved Vuity™ is a well-known muscarinic receptor agonist called pilocarpine. Its miotic (pupil shrinking) activity is the mechanism for treating presbyopia. The miotic effect increases the depth of focus and improves near vision. Most of the other drug therapies currently being developed by several companies also exploit this miotic mechanism.

Near-term Plans

We began the drug discovery process for CBT-199 in China in 2023. CBT-199 has been evaluated for safety and tolerability in pre-clinical animal studies since June 2023, and such studies are expected to facilitate future clinical trials. We intend to submit the IND application to the HREC in the second quarter of 2025.

We plan to complete all pre-clinical work for CBT-199 in our Guangzhou R&D centre and Suzhou R&D centre. Our Suzhou R&D centre is also expected to manufacture clinical trial supplies and perform release testing of CBT-199's drug products for phase 1 and phase 2 clinical trials.

CBT-145*Mechanism of Action*

CBT-145 is indicated for the treatment of presbyopia. It is a new chemical entity invented by us, designed to shrink the pupil size by acting on muscarinic receptors, allowing increased depth of field of focusing to counter the lens inflexibility problem, and improve focus up close.

Market Opportunity and Competition

See “– CBT-199 – Market Opportunity and Competition” above for information on prevalence of presbyopia and market opportunity and competition of CBT-145 indicated for presbyopia.

Pre-clinical Studies

See “– CBT-199 – Pre-Clinical Studies” above for information on our pre-clinical studies on presbyopia.

Near-term Plans

We began the drug discovery process for CBT-145 in China in 2022. CBT-145 has been evaluated for pharmacology in pre-clinical animal study, which has been completed in April 2024. Pursuant to the study results, we decided to prioritise the clinical development of CBT-199 and make CBT-145 a back-up project for CBT-199. As a result, the IND application for CBT-145 is to be determined based on the progress of CBT-199. We plan to complete all pre-clinical work for CBT-145 in our Guangzhou R&D centre and Suzhou R&D centre. Our Suzhou R&D centre is also expected to manufacture clinical trial supplies and perform release testing of CBT-145's drug products for phase 1 and phase 2 clinical trials.

CBT-011

Mechanism of Action and Advantages

CBT-011 is an ADS conjugate indicated for the treatment of DME, a disease with retinal thickening caused by the accumulation of intraretinal fluid. DME is believed to be a result of hyperpermeability of the retinal vasculature. CBT-011 is developed on our proprietary ADS technology platform. The multi-targeting mechanism to be adopted can potentially generate synergism to augment the treatment more effectively than the sum of individual drugs.

DME is one of the retinal diseases. Retinal diseases are often characterised by leakage of fluid, haemorrhage and fibrous scarring in the eye, and develop from the back surface of the eye (i.e., fungus) and the vitreous around it. Major retinal diseases include DME, wet age-related macular degeneration (“**wAMD**”), retinal vein occlusion (“**RVO**”), and myopic choroidal neovascularisation (“**mCNV**”). According to the F&S Report, the major competitors of CBT-011 are indicated for these four subtypes of retinal diseases, and similar to CBT-011, their component are all consisted of anti-VEGF agents (“**the major retinal diseases**”). The major retinal diseases are the primary causes of visual impairment and blindness, which can have a major impact on patients’ vision-related quality of life and overall wellbeing.

Market Opportunity and Competition

Globally, the patient population of the major retinal diseases reached 82.1 million in 2023, with a CAGR of 1.7% from 2019 to 2023. It is estimated to reach 89.0 million and 96.3 million in 2028 and in 2033, respectively, representing a CAGR of 1.6% from 2023 to 2028 and 1.6% from 2028 to 2033, respectively.

According to the F&S Report, the global market size of the major retinal diseases drug therapies increased from US\$11.7 billion in 2019 to US\$14.5 billion in 2023, with a CAGR of 5.5%. It is expected to reach US\$23.7 billion in 2028 and US\$36.1 billion in 2033, representing a CAGR of 10.4% from 2023 to 2028 and 8.8% from 2028 to 2033, respectively.

Pre-clinical Studies

Previous studies show that DME is caused by diabetes over time and it is believed to be a result of hyperpermeability of the retinal vasculature. The pathology of DME involves both VEGF and inflammation, thus CBT-011 is expected to offer advantages over current drug therapies that target one pathway only.

Near-term Plans

We began the drug discovery process for CBT-011 in the United States in 2021. We are currently investigating the effectiveness of CBT-011 in an animal model to determine whether the concept of ADS is valid. We intend to submit the IND application to the FDA for CBT-011 by the end of 2025.

RESEARCH AND DEVELOPMENT**Overview**

We believe R&D is essential to the success of our ophthalmic drug candidates throughout different development stages, and we have established an innovative pipeline of drug candidates covering major anterior and posterior ophthalmic diseases. All of the drug candidates in our pipeline are proprietarily developed, and we believe they have the potential to become first-in-class or best-in-class therapies to address unmet medical needs in the global ophthalmic drug market. For the years ended 31 December 2022, 2023 and 2024, our R&D expenses amounted to US\$15.3 million, US\$27.5 million and US\$37.9 million respectively.

To capture the potential in the global ophthalmic pharmaceutical market, we have built strong R&D capabilities enabling us to cover the entire lifecycle of drug translational science – from early-stage discovery through to large-scale multi-regional clinical trials and global product registration process. We carry out in-house drug discovery and development led by senior scientists who have accumulated decades of pharmaceutical R&D and entrepreneurship experience in global ophthalmology giants and renowned research institutions, including our founder and CEO, Dr. Ni, and members of our scientific advisory board. We have three R&D centres located in the United States and China, and conduct clinical trials in strategically selected regions worldwide, with a view to maximising the long-term commercial potential of our future products across the global market.

Leveraging our deep understanding of ophthalmic diseases pathogenesis and mechanism of actions for different treatment options, as well as scientific know-how we have accumulated through our drug discovery and development experience, we have developed two proprietary technology platforms, namely, MKI and ADS platforms, designed for developing drug candidates targeting anterior and posterior ophthalmic diseases, respectively. Each of MKI platform and ADS platform targets the development of small molecule drugs and conjugates between an antibody and a small molecule drug, respectively. The combination of our two technology platforms offers comprehensive solutions to cover a wide range of ophthalmic diseases. Each of our MKI and ADS platforms is an innovative platform for developing drug candidates targeting anterior and posterior ophthalmic diseases, respectively:

- Our MKI platform is able to effectively identify, validate and develop novel MKI drug candidates targeting anterior ophthalmic diseases and is intended for any ocular diseases with abnormal neovascularisation as a key disease component. Its mechanism is to reduce the number and density of abnormal vessels and leakage of vessels. Some of the selected MKIs could potentially attenuate fibrosis and inflammation to some extent. We are developing clinical-stage drug candidates for the treatment of anterior ophthalmic diseases based on the MKI platform. MKIs have already been clinically proven to achieve better therapeutic effects compared to the more common single-kinase inhibitor therapies, as many diseases progress involving the action of multiple kinases rather than just one. Simultaneously targeting multiple kinases for anterior ophthalmic diseases achieves synergistic effects for better treatment outcome. Leveraging our know-how in small molecule

MKI drugs and a deep understanding of pathogenesis of various anterior ophthalmic diseases, we have developed a unique set of techniques to select and combine multiple targets that form our MKI candidates on our MKI platform, with topical application to achieve optimal efficacy and patient compliance. The platform has supported the development of three of our drug candidates, namely, CBT-001, CBT-004 and CBT-007. These drug candidates have so far demonstrated an optimisation of PK/PD characters and high potency in animal models. Future pipelines developed on our MKI platform may target glaucoma filtration surgery failure, corneal transplant failure, and other potential indications involving corneal neovascularisation; and

- Our ADS platform is able to develop drug entities by combining an antibody with a small molecule drug via a proprietary linker that target posterior ophthalmic diseases. These conjugates overcome the limitations of single-modality treatment and produce synergistic effects on treatment efficacy by simultaneously targeting multiple pathogenic pathways. The technology used by the ADS platform is fundamentally different from the approach taken by traditional antibody-drug conjugate (“ADC”) technology, which uses the antibody as a carrier only to deliver small molecule to cancer cells to kill them. Our ADS platform is an innovative ADS platform in the global ophthalmology field. There exists multiple biologics for the treatment of ophthalmic diseases. While large-sized biologics have shown higher specificity in treatment than small molecule drugs, they are limited in treating posterior ophthalmic diseases as it is difficult for biologics to penetrate through vitreous humour and might require high frequency of intraocular injection that significantly impacts patient compliance. Increased dosage could also lead to increased side effects. Our ADS platform is highly compatible with our technology in antibody and small molecule agent, in that its innovation involves conjugating an antibody drug to a small molecule drug, using a cleavable linker proprietarily designed to be enzymatically hydrolysed in the vitreous humour in a controlled manner. In an ADS compound, the role of antibody is no longer limited to acting solely as a carrier as the approach taken by traditional ADC technology. By enabling the antibody to exert therapeutic effect and to act as a sustained delivery vehicle for the small molecule which normally lasts for only a few hours if not linked to a large molecule, our ADS compound is able to generate synergistic effects between antibody and small molecule to magnify efficacy and response rate, and prolong the duration of effects. In developing our drug candidates on the ADS platform, we select different combinations of antibody and small molecule agents with favourable validated efficacy and safety profiles depending on the requirements of different ophthalmic diseases. We also tailor the design of the cleavable linker or small molecule and antibody ratio specifically for the treatment of posterior ophthalmic diseases.

We have also adopted a drug development model that adopts multiple R&D pathways, including using drug re-purposing to obtain an NDA under the 505(b)(2) pathway, as well as using new chemical entities or new biologics. We believe our drug development model enables more predictable and sustainable discovery and development of novel and effective ophthalmic drugs.

Our R&D Centres, R&D Team and In-house R&D Activities

We have established three R&D centres located at Irvine, California, the United States, Guangzhou, Guangdong, China, and Suzhou, Jiangsu, China, respectively. Our Irvine R&D centre is mainly involved in early pipeline design and proof of concept (“POC”) research, pre-clinical study design, clinical study design and the execution of clinical trials by collaborating with various CROs at clinics and research institutions, communication with various consultants, KOLs and regulatory agencies. Our Guangzhou R&D centre focuses on chemistry manufacturing and control (“CMC”) research, as well as formulation development and evaluation. Our Suzhou R&D centre focuses on clinical development, as well as good manufacturing practice (“GMP”) plant to support our ongoing clinical trials. Our R&D team at the three R&D centres work seamlessly together to build up our pipeline of drug candidates, and advance our drug development.

We have assembled an experienced R&D team with both academic excellence and rich industry experience in the biotechnology and ophthalmology field. Our R&D team is led by our founder and CEO, Dr. Ni, who has almost 30 years of experience in the life sciences industry, and has served in a leading global ophthalmic company and a research institute. Other members of our senior scientists team, including Van Son Dinh, our co-founder and chief operating officer, Elizabeth Capan, our chief patent officer and chief compliance officer, and Dr. Rong Yang, our chief scientific officer, also have extensive work experience across the ophthalmology industry from leading international pharmaceutical companies, reputable research institutions and regulatory authorities, with complimentary expertise covering the entire drug development lifecycle. See “Directors and Senior Management” in this prospectus for details of the expertise and experience of senior members of our R&D team. We have also established a scientific advisory board composed of two industry experts including Dr. Scott Whitcup and Dr. John Hovanesian, who have extensive experience in the field of ophthalmology.

Dr. Scott Whitcup served as an executive vice president, and a research and development and chief scientific officer at Allergan, where his leadership was vital in building the clinical research program and promoting new ophthalmic therapeutic discoveries. His work in Allergan involved obtaining major product approvals in multiple therapeutic areas. Prior to working at Allergan, Dr. Whitcup served in various leadership positions at the National Eye Institute.

Dr. Whitcup obtained his bachelor of Arts from Cornell University and doctor of Medicine from Cornell Medical College. He also completed his residencies in internal medicine at the UCLA Medical Center and in ophthalmology at Harvard Medical School, followed by a fellowship in uveitis and ocular immunology at the National Eye Institute.

As the chairman of our scientific advisory board, Dr. Whitcup provided consulting services for the development of clinical and regulatory strategies for our drug candidates, including CBT-001. In addition, Dr. Whitcup assists in the review of clinical protocols, participates in regulatory meetings with the FDA and engages in strategic discussions with KOLs to form R&D and commercial strategies for our Company. In addition, Dr. Whitcup is an author of the scientific posters and abstracts presented at scientific and medical conferences for CBT-001.

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Dr. John Hovanesian is a board-certified ophthalmologist, a faculty member of the UCLA Jules Stein Eye Institute, and an internationally recognised leader in the fields of corneal, cataract, refractive and laser surgery. He has published two eye surgery textbooks – one on the subject of refractive cataract surgery and one on pterygium surgery. Dr. Hovanesian has been invited to conduct lectures for surgeons globally, authored a number of peer-reviewed articles, and produced surgical teaching videos.

Dr. Hovanesian received his medical degree from the University of Michigan Medical School and completed his residency at Henry Ford Hospital in Detroit, the United States, where he was selected to serve as chief resident. He also completed a two-year fellowship in refractive and corneal surgery at the Jules Stein Eye Institute at University of California, Los Angeles. He joined Harvard Eye Associates in 1999.

As a member of our scientific advisory board, Dr. Hovanesian provides valuable insights on the latest standard-of-care treatment of pterygium diseases and serves as a KOL for CBT-001. In addition, Dr. Hovanesian is an author of the scientific posters and abstracts presented at scientific and medical conferences for CBT-001.

As of the Latest Practicable Date, we had 20 employees in charge of R&D activities, including five members from our senior management and 15 members from our R&D department, and seven of them hold a master's degree or higher including five with doctor's degrees. Except for the chief operations director who is responsible for managing researchers and facilitating the execution of research activities, all the R&D team members majored in fields related to pharmacy, chemistry and health care, and seven of them had more than ten years of work experience in the pharmaceutical industry. In addition, we have more than ten experienced scientific and medical advisers contributing to our strategic and operational development. In the longer term, we plan to expand our R&D team globally to support new drug discovery, development and innovation by recruiting additional seasoned scientists in the ophthalmic and pharmaceutical industry.

Our R&D centres and R&D team manage our drug development process primarily through our internal R&D resources. We have adopted standard operating procedures that govern both drug discovery and the clinical development stage of our drug development process.

R&D Pathways

We strategically pursue a variety of R&D pathways to develop novel drugs, including using drug re-purposing under the 505(b)(2) pathway, and using new chemical entities or new biologics.

The 505(b)(2) pathway allows the applicant for an NDA to rely, in part, on the previous findings of the FDA on safety and efficacy for a product with the same API or published literature. We adopt the 505(b)(2) pathway to reduce risks arising out of the drug development process when we determine it is most suitable for a particular drug candidate. It is a commonly adopted approach for drug development in the United States, and has been validated by successful launch and sale of many ophthalmic drugs with considerable sales revenue, according to the F&S Report. Under the risk-balanced, efficient and cost-effective

R&D approach adopting the 505(b)(2) pathway, we are able to utilise validated molecules or compounds with well-established safety and efficacy profiles currently applied in other therapeutic areas and develop them into novel ophthalmic drugs with new indications, dosage forms and therapeutic profiles.

The 505(b)(2) pathway presents unique value for ophthalmic drug development in particular because ophthalmic drugs which are developed for topical use do not face any competition from their reference drugs which are in the form of oral medication (which is a form of systemic administration). Due to blood-ocular barrier, oral drugs may deliver insufficient amount of active ingredient to the ocular surface due to poor bioavailability, or cause adverse effects to liver or kidney by increasing systemic drug dosing, due to relatively low blood flow to various targets of receptors in human eyes. As a result, none of the oral drugs which were used as the reference drugs under the 505(b)(2) pathway are used to treat ophthalmic diseases. We also believe that off-label use of drug products adopting systemic administration (including oral drugs) poses minimal commercial threat to our ophthalmic drugs due to safety concerns and lack of efficacy, according to the F&S Report.

We are pursuing 505(b)(2) pathway for all of our clinical-stage drug candidates. They have demonstrated a number of advantages, including:

- **Profile certainty in drug profile.** For example, by utilising validated mechanisms in angiogenesis and fibrosis inhibition for CBT-001 and CBT-004, we were able to apply our scientific know-how in ophthalmic diseases and focus on the development of new indications, dosage forms and regimens, routes of administration and formulations on the approved reference drugs under the 505(b)(2) pathway as an innovative treatment for pterygium and vascularised pinguecula.
- **Multiple intellectual property rights protection.** The 505(b)(2) pathway offers us the opportunities to develop and register new patents in a number of aspects, such as method of use, formulation and indication, without infringing on existing patents of the reference drugs, with a term of 20 years. These patents will work in tandem with regulatory hurdles to create barriers to entry that potential competitors would need to overcome to compete in our commercialisation space. We have established a strong intellectual properties protection system with multiple layers of patent protection covering various aspects of our clinical-stage drug candidates.
- **Expedited drug development process.** The 505(b)(2) pathway enables us to make full use of existing data on the clinical profiles of approved reference drugs and avoid certain lengthy duplicative clinical trial processes. For example, we were able to rely on certain existing human and animal safety data in the development of CBT-001 in the United States without the need to repeat these studies. Further, after reviewing the phase 2 clinical trial results in the United States for CBT-001 and conducting a pre IND meeting with us, the NMPA granted the IND approval for us to proceed with phase 3 MRCT in China.

- **High technological barriers for competitors.** The appropriate drug candidate identification and effective reformulation of and changes to the reference drugs under the 505(b)(2) pathway requires a deep understanding of ophthalmic disease pathogenesis and extensive scientific know-how. Consequently, developing new drug therapies under the 505(b)(2) pathway creates high technological barriers for potential competitors to enter into the market, and we believe it is an effective approach for developing potential first-in-class drug therapies in the ophthalmic field.

The FDA's interpretation of Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act has remained substantially unchanged for over 20 years, and the FDA has given no indication that it intends to make any significant changes to its interpretation of Section 505(b)(2) in the near future. Our Directors are of the view that in the unlikely event when the FDA changes its interpretation of Section 505(b)(2) such that we would not be able to rely on the 505(b)(2) regulatory pathway, we may be required to complete additional animal studies in the absence of being able to rely on previous studies to fulfil NDA submission requirements. These additional non-clinical study requirements will unlikely have an impact on the eligibility of the drug candidates that were initially planned to be approved under the 505(b)(2) regulatory pathway and, depending on the extent to which we plan to use the 505(b)(2) pathway to rely on previous studies, as well as the manner the FDA might change its interpretation, will probably only prolong the process for NDA approval in the worst case scenario, and would not invalidate the eligibility of the Core Products for regulatory approvals. It will be extremely unlikely that the clinical trials that have already been completed and regulatory approvals that have already been granted will be retroactively invalidated. Having considered the discussions above, nothing came to the Joint Sponsors' attention that would cause them to question the eligibility of the Core Products even if the FDA changes its interpretation of Section 505(b)(2). See "Risk Factors - Risks Relating to Obtaining Regulatory Approvals, commercialisation of Our Drug Candidates, and Doing Business Outside of China - If the FDA does not conclude that our drug candidates satisfy the requirements for the Section 505(b)(2) NDA regulatory approval pathway, or if the requirements under Section 505(b)(2) are not as we expect, the approval pathway for some of our drug candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful." for details of the risks relating to seeking regulatory approvals under the 505(b)(2) pathway.

In addition to adopting the 505(b)(2) pathway for some of our drug candidates, we have also leveraged our strong R&D capabilities to discover and develop new chemical entities or new biologics with a view to address unmet medical needs. For example, CBT-011, developed through our ADS platform, is designed to target two pathways via antibodies and small molecules, respectively, and potentially generates synergism and improves the treatment result for DME.

Drug Discovery and Pre-clinical Research

Our R&D process begins with the discovery of new drug candidates. We conduct new drug discovery process and pre-clinical research to identify potential target to be progressed to clinical trial stages. We encourage our R&D staff to pay close attention to the

international frontier ophthalmic pharmaceutical market, and raise any idea that was generated in observing the latest scientific research in ophthalmology and drug development from peer companies. Our R&D team takes these ideas for further discussion, and the factors we consider in determining whether a certain target will be selected for further studies including, among others, whether there is unmet medical needs and commercial potential, whether there is opportunity to obtain and maintain potential intellectual property protection, and the feasibility to test the idea for target selection. The target selection process is based on our corporate strategy and business goals, and we will also take into consideration the balance of our portfolio of drug candidates, and whether we are able to maximise the R&D strengths we currently possess if we will further explore the potential of a certain target.

Once a target is selected for further studies and validation, we would engage CROs to conduct pre-clinical research and testing to progress the drug development process, and such activities normally involve screening for and identifying compounds that may safely alter the activity of a particular target before its efficacy is tested in clinical trials. Based on the results of our pre-clinical research and testing, including critical efficacy data, toxicokinetics/pharmacokinetics modelling and tolerability data, as well as patient tailoring strategies, we select the drug candidates that warrant further clinical studies for which to apply for the IND approval.

Clinical Development

We are currently conducting clinical trials and MRCTs in the United States and China, and will strategically select clinical trial locations with patient populations that best suit our target diseases. We closely monitor and manage the progress of our clinical trials, including the clinical trial design, trial implementation, pilot production of drugs used for clinical trials, collection and analysis on clinical trial data, and collaboration with CROs and CDMOs we engage. As of the Latest Practicable Date, we had four clinical-stage drug candidates, comprising (i) one drug candidate that is in phase 3 MRCT in the United States, China, New Zealand, Australia and India (namely CBT-001); (ii) two drug candidates that have completed phase 1/2 or phase 2 clinical trial in Australia and the United States, respectively (namely CBT-009 and CBT-006); and (iii) one drug candidate that has commenced phase 2 clinical trial in the United States (namely CBT-004). Our two Core Products CBT-001 and CBT-009 are in more advanced clinical development stage, while other drug candidates, including CBT-006, CBT-004, and the four pre-clinical stage drug candidates, are in relatively earlier stage.

We have kept an up-to-date knowledge on regulatory requirements of new drug development standard and proactively communicate with regulatory authorities. Our extensive experience in regulatory affairs provide us with insight in regulatory requirements for new drug development in major markets, and we believe the effective communication channel we have built with the regulators including the FDA and the NMPA will enable us to resolve potential regulatory barriers and accelerate the clinical development progress of our drug candidates in various jurisdictions.

Collaboration with CROs and CDMOs

In addition to our proprietary discovery and development of drug candidates in-house, we also outsource certain R&D work to third-party CROs and CDMOs which we consider to be cost-efficient and in line with market practice. During the Track Record Period, we engaged experienced and qualified third-party CROs and CDMOs to support our clinical trials in the United States, China and Australia, which is in line with the general practice in the industry. Depending on the complexity and workload of a specific trial, we outsource all non-clinical studies (which require facilities to conduct studies on animals) and certain clinical work to qualified CROs, which provide us with a suite of logistics execution and operation services to assist us in implementing and managing clinical trials in accordance with agreed trial design and under our supervision. We are responsible for designing the protocol for clinical trials including efficacy and safety endpoints and measurements, and we monitor all the clinical work outsourced. Prior to May 2023 before our pilot production facility in Suzhou was put into use, we outsourced all drug product manufacturing work (which needs to comply with GMP requirements) to qualified CDMOs. All of the CROs and CDMOs we engaged in the Track Record Period are Independent Third Parties.

We have engaged Independent Third Party CROs to provide us with certain services necessary for complex pre-clinical studies and clinical trials. During the Track Record Period, we engaged a number of reputable CROs. We select CROs based on a number of factors, including their professional qualifications, reputation, research experience and available clinical trial equipment and resources. The CROs we engaged are in general responsible for preparing clinical trial plans, reviewing the clinical trial data, managing the logistic matters at the clinical trial sites and performing other supportive jobs for our clinical trials.

We have developed and maintained a standard operating procedure for the selection of, and the qualification requirements on, our CROs. We also closely monitor our CROs to ensure they perform their duties to a standard in line with our clinical trial protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies. Our specialised clinical development team under the R&D department for respective drug candidate review and approve multiple trial-related plans prepared by our CROs, including plans on site monitoring, data management plan, safety management and safety reporting. We have designed and adopted an electronic data capture system for certain of our clinical trials as a joint effort between our clinical development team and our CRO's data management team, which enables our CROs and us to collect and analyse data in a more effective and accurate way. Our CROs also provide training to the site personnel during site initiation visits on topics such as trial procedures and data collection. We have established a standard procedure to ensure that our CROs obtain appropriate and sufficient informed consent forms and other documents designed to protect human subjects. To monitor the progress of our clinical trials, we hold regular meetings with our CROs to review the clinical trial progress and make timely adjustments when necessary.

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The following table sets forth a summary of key terms in a typical agreement we enter into with our CROs:

Services:	The CRO provides services related to CMC, pre-clinical studies and clinical trials in certain phases as specified in the agreement or a work order.
Term:	The CRO is required to complete the work within an agreed time period as specified in the agreement or a word order.
Payments:	We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
Credit terms:	We usually arrange payment within 30 days of receipt of invoice from the CRO. Installment payments will be made in accordance with the milestone payment arrangements specified in the agreements entered into with our CROs.
Intellectual property rights:	All intellectual property rights created by the CRO directly related to or arising from the clinical trials (excluding any proprietary information owned by the CRO) are owned by us.
GCP compliance:	We require the CRO to conduct clinical trials in accordance with international GCP standards.
Confidentiality:	The CRO has non-disclosure obligation and undertakes not to disclose our trade secrets or other business information to any third party without our prior consent.
Liabilities and termination:	The liability of a CRO usually arises at the occurrence of its negligence or wrongful acts or omission, and our liability arises at the failure to make timely arrangements for payment in accordance with credit terms. We may terminate the agreement without cause by providing prior written notice to the CRO.

Prior to May 2023 when the Suzhou pilot production facility was put into use, we engaged CDMOs to provide manufacture services for all of our clinical trials. We select our CDMOs by reviewing a number of factors, including their qualifications, relevant expertise, production capacity, industry reputation, track record, product quality, reliability in meeting delivery schedules, and the financial terms offered by them.

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The following table sets forth a summary of key terms in a typical agreement we enter into with our CDMOs:

Services:	The CDMO provides services such as manufacture, inspection and packaging, in-process tests, post-manufacture review, storage and delivery of the drug candidates.
Term:	The CDMO is required to perform its services within the prescribed time limit set out in the agreement and in accordance with the key performance indicators agreed by both parties.
Payments:	The CDMO bills us in accordance with milestones agreed by the parties and usually we are required to make payments within certain period of time from the invoice date.
Credit terms:	We usually arrange payment within 30 days of receipt of invoice from the CDMO. For some agreements with our CDMOs, the installment will be made in accordance with the milestone payment arrangements specified in the agreements.
Intellectual property rights:	All intellectual property rights in connection with the services provided by the CDMO shall be owned solely by us except as necessary for use in performing the services.
GMP compliance:	We require the CDMO to produce our drug candidates in accordance with GMP standards.
Confidentiality:	Subject to certain terms and conditions, all information disclosed by a party in connection with the agreement shall be the confidential information.
Liabilities and termination:	The liability of a CDMO usually arises at the occurrence of its negligence or wrongful acts or omission, and our liability arises at the failure to make timely arrangements for payment in accordance with credit terms. Each party may terminate the agreement if, among others, the other party materially breaches any of the terms in the agreement. In some of the agreements with CDMOs, we are the only party which may terminate the agreement with prior written notice.

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During the Track Record Period, we engaged 18, 22 and 41 CROs in 2022, 2023 and 2024, respectively. We also engaged seven, four and six CDMOs in 2022, 2023 and 2024, respectively.

MANUFACTURING

Our Production Facility in Suzhou

We have built a pilot production facility located in Suzhou New District (蘇州高新技術產業開發區), a specially designated region for technological and industrial development. Our pilot production facility has a total GFA of 1,226.43 sq.m, and was designed and built with a view to complying with GMP standards in the United States, China and EU, which will be able to support our global clinical trials and global commercialisation of our future products. The pilot production facility consists of four areas, namely, GMP production area, warehouse area, quality control area and office area, and was put in to use in May 2023. The pilot production facility supported the GMP manufacturing of CBT-004 and CBT-006 drug products for phase 2 clinical trials, GMP stability studies for CBT-004 and certain GLP toxicology studies, and is expected to provide for all future clinical supplies for phase 1 and phase 2 clinical trials, and GMP stability studies for CBT-009 and CBT-006. Since the pilot production facility was put into use, we no longer outsource GMP stability studies for phase 1 and phase 2 clinical trials. We also expect it to be the central quality control laboratory for all future GMP stability studies. The current production scale of our pilot production facility is expected to have a designed annual production capacity of 3.5 million to 5.3 million bottles (0.2ml per bottle as the minimum filing capacity) to fulfil our future manufacturing needs for clinical trials in the PRC and early-stage commercialisation plans.

In the year ended 31 December 2023 and 2024, the utilisation rate of our pilot production facility was approximately 80% and 83% respectively, calculated based on the actual production volume of the period after the facility was put into use in May 2023, divided by the manufacturing capacity of the production lines that were put into operation for the same period, multiplied by 100%. The actual production volume of our facility was consistent our production plan, which in turn was made based on the production demand derived from our R&D progress for both clinical trials and non-clinical studies. There were additional production lines that were yet to be put into operation which could provide additional production capacity. As of the Latest Practicable Date, the pilot production facility had manufactured the clinical trial supplies for CBT-009, CBT-006 and CBT-004, and non-clinical supplies such as scale up manufacturing for CBT-009.

The production for clinical supplies for CBT-001 was outsourced to CDMOs as of the Latest Practicable Date. The clinical supplies for phase 3 MRCT for CBT-001 will be provided by one CDMO and shipped to all jurisdictions where phase 3 MRCT are being conducted. Once the NDA approval of CBT-001 is obtained, the commercial supplies of CBT-001 in Greater China will be provided by Grand Pharma as stipulated in our commercialisation licensing arrangement with Grand Pharma. We expect to manufacture the commercial supplies for CBT-001 in other countries and regions using our own manufacturing facility once the respective NDA approval is obtained. Our pilot production

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facility in Suzhou has been providing all clinical and non-clinical supplies for CBT-009 and CBT-006 projects, starting in December 2024. The pilot production has also been providing all clinical and non-clinical supplies for CBT-004 projects since late 2023.

As the pilot production facility is mainly a pre-commercial production system designed and built for the purpose of clinical trials and early-stage commercialisation plans, it is not equipped with a full-scale production system and thus is not suitable for mass production, we also plan to build a sizeable commercial production facility in Suzhou. It will be based on our clinical development progress and commercialisation needs that meets various quality standards set by relevant regulatory authorities globally, including GMP standards in the United States, China and EU, to prepare for the anticipated commercialisation of our drug candidates.

In particular, we would like to develop specific blow-fill-seal (“BFS”) manufacturing technology, which is essential for phase 3 clinical trials and commercial production for our existing and future products (especially those with aqueous formulation which contain no preservatives and thus require the BFS technology), including our most advanced drug candidate CBT-001. The BFS manufacturing technology demands expansion of the production facility, because BFS equipment and other equipment such as inline leak detector, visible particulate detector, pouch assembly and labelling equipment for BFS unit dose manufacturing need to be purchased, placed and validated in the facility. The sizeable commercial production facility in Suzhou will enable us to test and conduct staff training on the BFS technology prior to placing the above-mentioned equipment and put them into use for commercial production.

We were assigned the land use right of a parcel of land in Suzhou, Jiangsu, with a site area of 33,332.9 sq.m. in May 2023. See “– Land and Properties” for details. We plan to build the commercial production facility on this parcel of land. The phase 1 construction work has a planned GFA of 14,429 sq.m., and the scale of phase 2 and phase 3 construction work is to be determined based on our clinical and commercialisation needs in the long term. The planned commercial production facility has commenced construction in December 2024. It is expected to support manufacturing of all our clinical-stage and non-clinical-stage drug candidates for phase 3 clinical trials and commercial production (except when we enter into commercialisation licensing arrangements or other collaboration agreements with third parties). The phase 1, 2 and 3 construction work is expected to be completed in 2026, 2028 and 2033, respectively. The designed annual production capacity is expected to grow towards 6 million bottles (3ml per bottle) with an estimated utilisation rate of approximately 70% after all three phases are completed. We believe our established pilot production facility, together with our future commercial production facility, will position us well to meet manufacturing needs in clinical trials and after product launch.

Once the commercial production facility is put into use and meets the demands of our clinical development and commercial production plans, the operation of our pilot production facility (which is currently producing clinical trial supplies for CBT-004 only) will gradually phase out, and upon this, we expect to gradually relocate all equipment and personnel in the pilot production facility to the commercial production facility. The table below sets forth the development plan for the drug candidates by the two production facilities respectively, for the years indicated.

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	Pilot Product Facility	Commercial Production Facility
CBT-001	2024: API comparison batches 2025: compounding scale up batches	N/A
CBT-009	2024: toxicology studies 2025: phase 3 clinical batches and compounding scale up batches 2026: phase 3 clinical batches and re-supplies	2027: GMP registration batches
CBT-006	2025: compounding scale up batches and phase 2b clinical batches	2026: GMP phase 3 clinical batches 2026: GMP registration batches 2027: commercial product
CBT-004	2024: phase 2 batches 2025: compounding scale up batches	2026: phase 3 clinical batches 2026: GMP registration batches 2027: commercial product
Pre-clinical stage drug candidates	2024: GLP batches for toxicology studies 2025: GMP clinical batches and compounding scale up batches	2026: GMP registration batches 2027: commercial product

Our Manufacturing Team and Collaboration with CDMOs

We have a dedicated manufacturing team which possesses the qualifications and techniques required in various stages of the manufacturing process. Our manufacturing team is led by Dr. John Qiu, a Project Management Professional (“PMP”) certificate holder with extensive experience in project management related roles including serving as an operational leader in certain multinational companies. As of 31 December 2024, our manufacturing and quality control and quality assurance function was led by 17 key personnel divided into five functional units, including the engineering unit which is in charge of maintaining a stable working surrounding complying with GMP standards, the material management unit which transfers the raw materials for production and distributes the final products to our clinical trial sites and manages our supply chain and coordinating with other functional units on the delivery of final products, the quality control unit and the quality assurance unit working jointly in an effort to ensure the quality of final products is in line with our targeted production plan and the quality management system requirements, as well as the production unit which executes the production of our drug candidates.

During the Track Record Period, we have also engaged certain qualified third parties as CDMOs to provide manufacture services for our clinical trials for CBT-001 in the United States. See “ – Research and Development – Collaboration with CROs and CDMOs” in this section for details. Our pilot production facility is expected to support all GMP manufacturing of investigational products for phase 1 and phase 2 clinical trials of our drug candidates, and all GMP stability studies for our ongoing and future clinical development projects. Since the pilot production facility was put into use, our collaboration with CDMOs

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were significantly reduced as we no longer outsource GMP stability studies for phase 1 and phase 2 clinical trials to CDMOs. The work outsourced to CDMOs has no overlap with our planned commercial production facility either which is expected to support manufacturing of drug products for phase 3 clinical trials and commercial productions once the construction is completed and the facility is put into use.

Quality Management System

We have established a quality management system for the manufacturing of our drug candidates to facilitate the progress of our clinical trials. The quality management system is designed to identify the responsibilities of the five functional units of our manufacturing team, and is strictly complied with by us to ensure safe delivery of qualified final products.

We follow stringent quality control standards when we procure raw materials from our suppliers. The procurement unit is responsible for selecting suppliers which are able to provide qualified and sufficient supplies to fulfil our production needs. The procurement unit also conducts annual review on the certification status of our suppliers with the support from the quality assurance unit, to ensure that we maintain an up-to-date list of qualified suppliers. Throughout the production process, we monitor the production lines closely and conduct test of semi-finished products selectively, to ensure that our manufacturing facility, equipment and machinery operate in a way that is in accordance with applicable quality standards, laws and regulations and the GMP requirements. Responsible persons at our R&D centres conduct review on samples collected during the production and the finished products, and prepare deviation reports to be issued to the quality assurance unit or relevant suppliers if any of the finished products does not meet the quality standards. For finished products to be delivered to patients for our clinical trials, we carefully inspect each batch of the products before they are packed. We also maintain an accurate and complete inspection record on various aspects of the quality of the finished products.

COMMERCIALISATION

During the Track Record Period and as of the Latest Practicable Date, we did not have any commercialised product. Our preparation for commercialisation in the near-term will be focused on CBT-001, our most advanced drug candidate, assuming that we obtain the NDA approval from the FDA in the United States and from the NMPA in China. In the United States, we plan to maintain close relationship with PIs to support our phase 3 MRCT and raise awareness on pterygium among ECPs by educating KOLs and clinicians as part of our pre-launch market education efforts for CBT-001. Once approved, we plan to commercialise CBT-001 in the United States via paralleled direct-to-consumer campaign and ECP education campaign, and pursue third party reimbursement from government and private insurance providers to cover the costs for CBT-001. We may also seek collaboration with leading pharmaceutical companies for the manufacturing and commercialisation of CBT-001 in the United States. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 1. Commercialisation plan in the United States” in this section for details. In China, we entered into a commercialisation licensing arrangement with Grand Pharma in April 2020, pursuant to which Grand Pharma was granted an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in Greater China. Notwithstanding the above, we retain the right of

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applying for the NDA and expect to be the market authorisation holder of CBT-001. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 2. Commercialisation Plan in China, through Licensing Arrangement with Grand Pharma” in this section for details. In Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”), we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be mutually agreed by Santen and us in writing (the “**Field**”) in the Territory; and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. See “– Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” in this section for details. We plan to conduct similar market education activities in preparation for the commercialisation of CBT-009 once its phase 3 clinical trial for CBT-009 commences.

We will also gradually build and expand our own sales and marketing team in anticipation of the launch of our future products, and our efforts will be in line with the progress of the clinical trial development plan for our pipeline of drug candidates. We will provide comprehensive training to our dedicated sales force in advance of product launches that enables them to educate the ophthalmic community on the benefits of our drug candidates. We plan to leverage our experience on collaborating with Grand Pharma and seek partnership opportunities with industry leading pharmaceutical companies in the United States, China, and rest of the world, for the commercialisation and promotion of our future products, which we believe will be a cost-effective way to expand our future sales into global markets.

SUPPLIERS AND RAW MATERIALS

During the Track Record Period, our suppliers primarily included (i) service providers such as CROs and CDMOs, and (ii) suppliers of raw materials and consumables for clinical trials.

We engage CROs and CDMOs to support our clinical trials. See “– Research and Development – Collaboration with CROs and CDMOs” in this section for details of our contractual arrangements with CROs and CDMOs. We also engage suppliers, mainly in the United States and China, to provide raw materials and consumables for our clinical trials, and we have established a four-step operating procedure to manage them. Firstly, we source suitable potential suppliers based on their ability to consistently supply materials to our required specifications and in the quantities we order, and our past experience with them. We also review the qualification certification of the potential suppliers and consider the prices they offer and their ability to provide technical support where needed. Once we identify a prospective supplier, we review and document its manufacturing and quality control practice for further assessment, which include sample testing, on-line testing and in-house testing in clinical trials. Prospective suppliers which manage to proceed to the third

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step will start the negotiation process with us and finalise the specifications of our orders. The last step of our operating procedure for supply chain management involves continuous monitoring on deliverables by suppliers to ensure compliance with our agreed specifications, and to record relevant data such as the amount of rejected supplies for future assessment. We also maintain a list of qualified suppliers in the process, and conduct regular qualification review and on-site audit to update the list from time to time. Suppliers that fail to pass such review will be removed from the list of qualified suppliers.

For the years ended 31 December 2022, 2023 and 2024, our purchases from our five largest suppliers were US\$7.9 million, US\$8.1 million and US\$18.4 million, respectively, in each year accounted for 67.4%, 72.2% and 83.4% of our total purchases for the respective year. The purchases from our largest supplier were US\$5.1 million, US\$5.6 million and US\$14.0 million in each year in the Track Record Period, respectively, in each year accounted for 44.0%, 50.2% and 63.5% of our total purchases for the respective year. The tables below set forth our top five suppliers for the years ended 31 December 2022, 2023 and 2024, respectively:

For the year ended 31 December 2022

Name of the supplier	Transaction amount (US\$' 000)	Percentage of total purchase amount %	Business activities	Commencement of business relationship	Credit terms offered by the supplier	Payment method
A	5,148	44.0	Providing clinical research services	2022	30 days	Bank transfer
B	825	7.0	Providing drug product manufacturing services	2020	30 days	Bank transfer
C	748	6.4	Providing clinical trial services	2021	30 days	Bank transfer
D	657	5.6	Providing clinical research services	2021	30 days	Bank transfer
E	520	4.4	Providing clinical trial services	2021	30 days	Bank transfer

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For the year ended 31 December 2023

Name of the supplier	Transaction amount (US\$' 000)	Percentage of total purchase amount %	Business Activities	Commencement of business relationship	Credit terms offered by the supplier	Payment method
A	5,631	50.2	Providing clinical research services	2022	30 days	Bank transfer
F	868	7.7	Providing pre-clinical services	2021	30 days	Bank transfer
G	669	6.0	Providing pre-clinical services	2020	30 days	Bank transfer
D	485	4.3	Providing clinical research services	2021	30 days	Bank transfer
H	445	4.0	Clinical trial equipment provider	2017	30 days	Bank transfer

For the year ended 31 December 2024

Name of the supplier	Transaction amount (US\$'000)	Percentage of total purchase amount %	Business activities	Commencement of business relationship	Credit terms offered by the supplier	Payment method
A	13,989	63.5	Providing clinical research services	2022	30 days	Bank transfer
I	1,777	8.1	Providing medical affairs services and marketing services	2022	30 days	Bank transfer
J	1,190	5.4	Providing clinical research services	2022	30 days	Bank transfer
K	953	4.3	Providing central reading services	2022	30 days	Bank transfer
B	456	2.1	Providing drug product manufacturing services	2020	30 days	Bank transfer

We have established an average of approximately three years of relationship with our five largest suppliers in each year in the Track Record Period. None of our Directors, their respective close associates and any Shareholder who, to the knowledge of our Directors, own more than 5% of the issued share capital of our Company have any interest in any of our top five suppliers.

During the Track Record Period, we did not experience any material disputes with suppliers, difficulties in the procurement, interruptions in our operations due to a shortage or delay of supplies or significant fluctuations in prices. We also expect to be able to maintain adequate sources of quality supplies in the future.

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INVENTORY MANAGEMENT

As we currently focus on the development of our drug candidates and do not conduct manufacturing activities for commercial sale, we do not maintain any significant inventories. As of the Latest Practicable Date, our inventory primarily consisted of raw materials, testing materials, packaging materials and consumables for our clinical trials. We procure such materials and consumables based on the estimated clinical progress and production volume of our drug candidates. We closely monitor our clinical trial progress to better plan our production and control our inventories.

We have established an inventory management system to monitor each stage of the warehousing process. Warehouse personnel are assigned to carry out standard count and reconciliation stock checking process periodically through physical check of stock items against our recorded stock volume, and file the counting data properly with classifications of different types of inventories. A deviation report is required to be filed if difference occurs between the book value and the count value of the materials or the consumables, to record the stock gain or loss, and help identify the reason for the deviation and determine whether the such materials or consumables can be cleared for use or shall be rejected. We will continue to maintain and develop our inventory management system for our R&D activities and manufacturing activities for future commercialisation.

INTELLECTUAL PROPERTY

Overview

As a clinical-stage ophthalmology biotechnology company, we attach great importance in maintaining and protecting our intellectual property rights. Our chief patent officer, Ms. Elizabeth Sharon Capan, is in charge of our overall intellectual property strategy development and execution, patent application and prosecutions. We have filed a number of patent applications for our drug candidates and our proprietary technology platforms in various jurisdictions, and expect to rely on a combination of patents, trade secrets, trademarks and other intellectual property rights, as well as employee and third-party confidentiality agreements, to safeguard our intellectual properties. See “– Employees” in this section, and “Directors and Senior Management – Key Employment Terms” in this prospectus for details of the confidentiality agreements entered into by our senior management and some of our employees.

As of the Latest Practicable Date, we had 60 granted patents and 168 pending patent applications, consisting of 45 in the United States including 20 granted patents and 25 pending patent applications, 17 in the PRC including three granted patents and 14 pending patent applications, 166 in other jurisdictions worldwide including 37 granted patents and 129 pending patent applications (including seven pending PCT applications). As of the Latest Practicable Date, we had 45 granted patents and 64 pending patent applications worldwide for our Core Product CBT-001, as well as two granted patents and 23 pending patent applications worldwide for our Core Product CBT-009. The following table sets forth the patent and patent applications that are material to our clinical-stage drug candidates, and the total number of patent and patent applications by each patent family for each of our clinical-stage drug candidates:

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Drug candidates	Title of Patent Family ⁽¹⁾	Total number of patents and patent applications ⁽²⁾	Patent holder/applicant	Jurisdiction of registration	Date of application ⁽³⁾	Expiry date/expected expiry date if granted ⁽⁴⁾
CBT-001 ⁽⁵⁾	Compositions and Methods for Treating Pterygium ⁽⁶⁾⁽⁷⁾	14 granted patents including: – three U.S. granted patents under the U.S. “Method Family” category – one Chinese granted patent under the Chinese “Method Family” category	Cloudbreak USA, Cloudbreak Guangzhou	The United States, Australia, the PRC, Hong Kong, Japan, Mexico, Taiwan, Europe, South Korea	3 June 2016	3 June 2036
		8 patent applications	Cloudbreak USA	Australia, Europe, Japan, Canada, South Korea, Hong Kong	3 June 2016	N/A
	Use of Nintedanib for Treating Pterygium	One granted patent	Cloudbreak USA	Brazil	3 June 2016	3 June 2036
	Compositions and Methods for Treating Hyperaemia	One granted patent under the U.S. “Method Family” category	Cloudbreak USA	The United States	3 June 2016	3 June 2036
	Compositions and Methods for Treating Pterygium Recurrence ⁽⁶⁾	Two U.S. granted patents under the U.S. “Method Family” category	Cloudbreak USA	The United States	3 June 2016	3 June 2036
		One pending patent application	Cloudbreak USA	The United States	3 June 2016	N/A
	Emulsion Formulations of Multikinase Inhibitors ⁽⁸⁾	Six granted patents including: – one U.S. granted patent under the U.S. “Formulation Family” category – one Chinese granted patent under the Chinese “Formulation Family” category	Cloudbreak USA, Cloudbreak Guangzhou	The United States, the PRC, Hong Kong, India, Japan, Europe	28 August 2019	28 August 2039
		13 patent applications including: – three U.S. patent applications under the U.S. “Formulation Family” category – one Chinese patent application under the Chinese “Formulation Family” category	Cloudbreak USA, Cloudbreak Guangzhou	The United States ⁽⁹⁾ , Australia, Brazil, Japan, South Korea, Mexico, the PRC, Europe, Hong Kong	28 August 2019	N/A
	Methods for Alleviating Pterygium-associated Worry about Eye Appearance ⁽¹⁰⁾	Ten pending applications including: – one U.S. patent application under the U.S. “Additional Method Family” category – one Chinese patent application under the Chinese “Additional Method Family” category	Cloudbreak USA, Cloudbreak Guangzhou	The United States, Australia, Brazil, Canada, the PRC, Europe, Hong Kong, Japan, South Korea, Mexico	10 September 2020	N/A
CBT-009	Topical Ophthalmological Atropine Free Base Compositions	One granted patent	ADS USA	The United States	11 May 2021	11 May 2041
	Topical Ophthalmological Compositions	11 patent applications	ADS USA, Cloudbreak Guangzhou	The United States, Australia, Brazil, Canada, the PRC, Europe, India, Japan, South Korea, Mexico, Hong Kong	8 October 2021	N/A

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Drug candidates	Title of Patent Family ⁽¹⁾	Total number of patents and patent applications ⁽²⁾	Patent holder/applicant	Jurisdiction of registration	Date of application ⁽³⁾	Expiry date/expected expiry date if granted ⁽⁴⁾
CBT-006	Topical Ophthalmological Compositions	One granted patent	ADS USA	The United States	2 February 2022	2 February 2042
		Ten patent applications	ADS USA	The United States, Australia, Canada, Europe, Brazil, India, Japan, South Korea, Mexico, Hong Kong	2 February 2022	N/A
	Compositions and Methods for delivery of Ophthalmological Actives	One patent application	ADS USA	The PRC	2 August 2024	N/A
	Compositions for Treating Meibomian Gland Dysfunction	One granted patent	Cloudbreak USA	The United States	16 October 2019	16 October 2039
	Compositions and Methods for Treating Eye Diseases	One granted patent	ADS USA	The United States	15 June 2020	15 June 2040
		Ten patent applications	ADS USA, Cloudbreak Guangzhou	The United States, Australia, Brazil, Canada, the PRC, Europe, India, Japan, South Korea, Mexico	15 June 2020	N/A
	Compositions and Methods for Treating Hyperaemia	One granted patent	Cloudbreak USA	The United States	3 June 2016	3 June 2036
	Compositions and Methods for Treating Pterygium	Eight granted patents	Cloudbreak USA	The United States, Australia, South Korea, Mexico, Japan	3 June 2016	3 June 2036
		Six patent applications	Cloudbreak USA	Canada, South Korea, the PRC, Hong Kong, Europe	3 June 2016	N/A
	Use of Pazopanib, Cediranib, Regorafenib, and/or Axitinib for Treating Pterygium	One patent application	Cloudbreak USA	Brazil	3 June 2016	N/A
CBT-004	Compositions and Methods for Treating Pterygium Recurrence	One U.S. granted patents	Cloudbreak USA	The United States	3 June 2016	3 June 2036
	Emulsion Formulations of Multikinase Inhibitors	Five granted patents	Cloudbreak USA, Cloudbreak Guangzhou	The PRC, Hong Kong, India, Japan, Europe	28 August 2019	28 August 2039
		12 patent applications	Cloudbreak USA, Cloudbreak Guangzhou	The United States, Brazil, Japan, South Korea, Mexico, the PRC, Europe, Hong Kong, Australia	28 August 2019	N/A

Notes:

- (1) Each patent family contains multiple patents or patent applications, some of which had been granted and others were still pending as of the Latest Practicable Date.
- (2) The number of U.S. and Chinese patent and patent applications correspond with the number of those under each patent family category (i.e., the “Method Family”, the “Formulation Family” and the “Additional Method Family”) mentioned in “The U.S. Patent Family of CBT-001” and “The Chinese Patent Family of CBT-001” respectively under the sub-section headed “– Patent Family of CBT-001” below.

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Some of the patent family categories include more than one patent families, and the total number of patents and patent applications under these categories equal to the aggregate number of patents and patent applications under each patent family. For example, as of the Latest Practicable Date, there were three, one and two granted patents under “Compositions and Methods for Treating Pterygium”, “Compositions and Methods for Treating Hyperaemia” and “Compositions and Methods for Treating Pterygium Recurrence” respectively, which add to six granted patents in total under the U.S. “Method Family” category.

The patents and patent applications under the “Other Method Families” as mentioned in the discussions below are not included in this table, as they are mainly designed for pre-clinical stage drug candidates and thus are relatively immaterial.

- (3) Refers to the international filing date, the date on which the patent application is filed with an international patent office under the PCT.
- (4) Patent expiration does not include any applicable patent term extensions.
- (5) In addition to the patents and patent applications that are material to our clinical-stage drug candidates set out in this table, we also have certain ancillary granted patents and patent applications that we consider are immaterial to commercialisation of our current drug candidates. On 13 March 2024, the European Patent Office had received an opposition filed by a third party on European Patent Application No. 1780726.3.EP (counterpart of PCT/2017/034795) which we consider an ancillary and immaterial patent for CBT-001 after the patent was granted in June 2023 (the “**Opposition Action**”) in Europe. As of the Latest Practicable Date, the European Patent Office had issued a written notification stating that the European Patent Application No. 1780726.3.EP has been revoked. Nevertheless, our contemplated near-term commercialisation of CBT-001 in the U.S. and China will not be affected as we maintain a pending application in Europe in the same patent family, and accordingly its impact on our business operation and financial position will be very limited.
- (6) The U.S. patents which include U.S. Patent No. 10,149,820, U.S. Patent No. 9,980,901, U.S. Patent No. 9,987,223 and U.S. Patent No. 10,980,741, as well as Chinese Patent No. CN108135737B, under this title, are part of the Method Family (as defined and disclosed in “ – Patent Family of CBT-001 – The U.S. Patent Family of CBT-001” below) of CBT-001 patent families.
- (7) The pending worldwide applications are part of the Method Family of CBT-001 patent families.
- (8) The U.S. Patent No. 11,666,533 and Chinese Patent No. CN112770724B under this title are part of the Formulation Family (as defined and disclosed in “ – Patent Family of CBT-001 – The U.S. Patent Family of CBT-001” below) of CBT-001 patent families.
- (9) The pending U.S. App. No. 18/307,449 and other pending applications worldwide are part of the Formulation Family.
- (10) The pending U.S. Patent App. No. 17/640,889, pending Chinese Patent App. No. 202080061833.2, and other pending worldwide applications under this title are part of the Additional Method Family (as defined and disclosed in “ – Patent Family of CBT-001 – The U.S. Patent Family of CBT-001” below) of CBT-001 patent families.

In addition, we attach great importance to maintaining sufficient intellectual property protection for our proprietary-developed MKI and ADS platforms. As of the Latest Practicable Date, we had 55 granted patents and 88 pending applications relating to individual compounds and drug candidates developed using our MKI and ADS platforms worldwide, and we will continue to enhance the intellectual property protection of drug candidates developed through our proprietary technology platforms to maintain our competitive edge.

We rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our trade secrets and know-how, in part, by executing confidentiality agreements with our employees and third parties including our collaborators, scientific advisers, consultants and other third parties. We have also entered into employee proprietary information and inventions agreements with non-competition clauses with key members of our R&D team who have access to our trade secrets and other proprietary or confidential information relating to our business.

Patent Family of CBT-001

For our most advanced drug candidate CBT-001, we have filed multiple patent families globally, including in jurisdictions where we have near-term commercialisation plans, namely, the United States and China.

The U.S. Patent Family of CBT-001

As of the Latest Practicable Date, we had filed and had been granted multiple patent families in the United States directed to CBT-001. The U.S. patent family of CBT-001 is discussed in detail below.

In the first patent family (the “**Method Family**”), there are four granted U.S. patents claiming medical uses of nintedanib including treating pterygium and hyperaemia or neovascularisation in pterygium. These U.S. patents will expire in the year of 2036. This patent family also has a U.S. patent and patent application claiming combination of nintedanib and certain antimetabolites.

In the second patent family (the “**Formulation Family**”), there is one granted U.S. patent claiming an emulsion formulation of nintedanib. This patent will expire in the year of 2039. This patent family also has three pending U.S. patent applications.

In the third patent family (the “**Additional Method Family**”), there is one pending U.S. patent application claiming the use of nintedanib to reduce worry or anxiety about an ocular disease such as pterygium. This patent application may expire in 2040 if granted.

There are three additional patent families (the “**Other Method Families**”) relating to potential new ocular indications of nintedanib, including granted U.S. patents and pending U.S. patent applications: (i) improving success rate of glaucoma surgery, (ii) treating ocular hyperaemia in combination with an anti-angiogenic agent and an α adrenergic receptor agonist, and (iii) treating corneal graft rejection after corneal transplant and treating abnormal neovascularisation, including neovascularisation caused by alkali burns, ocular pemphigoid, and contact lens induced neovascularisation.

The Chinese Patent Family of CBT-001

We have also filed and been granted multiple patent families in China directed to CBT-001, providing multiple layers of patent protection in China covering different aspects of CBT-001. In China, CBT-001's patent families include:

- (i) the method family (including one granted Chinese patent claiming medical uses of nintedanib for treating pterygium without surgically excising the pterygium by inhibiting neovascularisation, which will expire in the year of 2036);
- (ii) the formulation family (including one granted Chinese patent claiming an emulsion formulation of nintedanib, which will expire in the year of 2039. This patent family also has a pending Chinese patent application);
- (iii) the additional method family (including one pending Chinese patent application claiming the use of nintedanib to reduce worry or anxiety about an ocular disease such as pterygium, which may expire in 2040 if granted); and
- (iv) three additional patent families relating to potential new ocular indications of nintedanib (including one granted Chinese patent claiming improving success rate of glaucoma surgery, and pending Chinese patent applications claiming (a) treating corneal graft rejection after corneal transplant, (b) treating ocular hyperaemia in combination with an anti-angiogenic agent and an α adrenergic receptor agonist, and (c) treating corneal graft rejection after corneal transplant and treating abnormal neovascularisation, including neovascularisation caused by alkali burns, ocular pemphigoid, and contact lens induced neovascularisation).

Inter Partes Review of '820 Patent for CBT-001

Background

On 14 December 2023, the Federal Circuit entered a mandate solidifying our win before the United States Patent Trial and Appeal Board ("**PTAB**") in an *Inter Partes Review* proceeding regarding the validity of a patent owned by us relating to one of our Core Products, CBT-001. The background of the proceeding is set out below.

On 7 August 2020, Allgenesis Biotherapeutics Inc. ("**Allgenesis**") requested that the PTAB initiate an *inter partes* review ("**IPR**") of U.S. Patent No. 10,149,820 (the "**'820 Patent**") owned by Cloudbreak USA (the "**IPR Proceeding**"). The '820 Patent is one of the four granted U.S. patents in the CBT-001 Method Family (as defined below).

There were multiple claims in the '820 Patent that were challenged by Allgenesis's request. Following PTAB's institution of the IPR proceeding, Cloudbreak USA disclaimed all challenged claims except claims 4 and 5 and PTAB reviewed only those two claims. Claims 4 and 5 are directed to methods for reducing hyperaemia or symptoms thereof in pterygium without surgically excising a pterygium, by administering nintedanib topically to the affected eye in the form of topical ocular formulation. Allgenesis alleged that claims 4 and 5 are unpatentable.

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To our knowledge we have no existing or previous relationships with Allgenesis, and we have not hired any key scientific employees who were previously employed by Allgenesis. Our Directors are not aware of any participation by Allgenesis in the development of CBT-001.

On 15 February 2022, we received a favourable final written decision in the IPR, issued by the PTAB, determining that Allgenesis had not proven claims 4 and 5 of the '820 Patent unpatentable.

On 31 August 2022, Allgenesis appealed the decision of PTAB to the United States Court of Appeals for the Federal Circuit ("**Federal Circuit**"), requesting that the Federal Circuit reverse the PTAB decision and declare claims 4 and 5 invalid (the "**IPR Appeal**").

On 7 November 2023, a three-judge panel of the Federal Circuit published an opinion dismissing Allgenesis' appeal on the basis of its failure to meet the U.S. constitutional requirements for accessing the U.S. judiciary. On 14 December 2023, the Federal Circuit entered its mandate finalising the panel's decision to dismiss the appeal, and signifying the formal final resolution of the appeal before the Federal Circuit. This means that Allgenesis can no longer petition for rehearing by the panel that dismissed the appeal nor for a hearing in front of the full Federal Circuit to reconsider the panel's decision. Allgenesis also can no longer request review of the panel's decision by filing a petition for certiorari with the Supreme Court of the United States seeking review of the decision, because the deadlines for taking any of the legal actions have passed. Accordingly, the dismissal of the IPR Appeal has become final. There is no alternative proceeding for Allgenesis to challenge the outcome regarding this IPR Proceeding of the '820 Patent. Furthermore, our success in the IPR Proceeding leaves Allgenesis unable to challenge the '820 Patent in any future IPR before the PTAB.

View from Our External IP Counsel, Junhe

1. The IPR Proceeding Has Not Affected and Will Not Affect the Freedom to Operate ("FTO") for CBT-001

Neither we nor our IP Counsel Junhe is aware of any granted U.S. or Chinese patents that would cover the current formulation or the current indication of CBT-001 and consequently block the expected launch of CBT-001 in the United States or China. Junhe has also advised us that an IPR proceeding is not for the purpose and does not have the effect of establishing or eliminating FTO.

2. The IPR Appeal Related to the Validity of '820 Patent Only

As advised by Junhe, an appeal of an IPR is only an appeal of the PTAB's final written decision on the validity of the '820 Patent, and therefore not a broad appeal of the validity of the entire patent family. Further, Art. III, Sec. 2, Cl. 1 of the U.S. Constitution limits jurisdiction to current cases or controversies. Accordingly, Junhe is of the view that the Federal Circuit can only address the issues on appeal relating to the '820 Patent, and a negative decision in the IPR Appeal would not mean that any of our other patents, existing or future, is invalid.

As advised by Junhe, the IPR Appeal related only to our ability to exclude others from practicing the specific claims 4 and 5 of the '820 patent, but did not affect or determine whether we are free to use the methods under claims 4 and 5, and accordingly did not impact or restrict our FTO for CBT-001.

3. The IPR Appeal Has Not Impacted and Will Not Impact Our Ability to File and Prosecute Continuation Applications

Under 35 U.S.C. § 120 the requirements for obtaining the benefit of a prior filing date (i.e., filing a continuation application) are only (i) filing the application “before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application”, and (ii) that the application “contains or is amended to contain a specific reference to the earlier filed application”. We have already filed continuation applications, and there is at least one application currently pending in each relevant patent family (e.g., U.S. App. No. 17/227,877 in the Method family). We have thus fulfilled the statutory requirements for filing of continuation applications and can continue to do so in the future. Based on the above, Junhe is of the view that the IPR Appeal has not impacted and will not impact our ability to file and prosecute any continuation applications to further protect CBT-001.

Furthermore, as advised by Junhe, in addition to the '820 patent, our other granted U.S. patents covering method of treatment using nintedanib in topical formulations and topical formulations of nintedanib, which are currently in force, are able to block others from commercialising nintedanib in a topical formulation for the claimed method of uses or the same topical formulation as CBT-001's, and thus sufficiently protect the claimed method of use via topical route of administration as well as the current topical formulation of CBT-001.

4. The '820 Patent is of Limited Importance in the Patent Portfolio of CBT-001

Junhe is of the view that in addition to the '820 Patent, our other granted U.S. patents covering method of treatment using nintedanib in topical formulations and topical formulations of nintedanib, which are currently in force, are able to block others from commercialising nintedanib in a topical formulation for the claimed method of uses or the same topical formulation as CBT-001's, and thus sufficiently protect the route of administration as well as the current topical formulation of CBT-001 regardless of the validity of the '820 Patent.

Based on the above and the combined scope of coverage of the patent portfolio for CBT-001, Junhe is of the view that the '820 patent is not indispensable in blocking others from commercialising nintedanib for the same or similar claimed method of use as CBT-001, and even without the '820 Patent, our remaining IP rights covering CBT-001, our ownership of such IP rights, our ability to block competitors from commercialising the nintedanib in a topical formulation for the method of uses claimed in such IP rights, our ability to block competitors from commercialising the same topical formulation as CBT-001, and our FTO for R&D and commercialisation of CBT-001 will not be materially adversely changed.

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Directors' View

Our Directors are of the view that the '820 Patent is not necessary in blocking third party commercialisation attempts with same or similar method of use as CBT-001, and, without additional challenges to other patents of CBT-001, even without the '820 Patent, the IP rights, ownership, competition, R&D and commercialisation of CBT-001 will not be materially adversely changed. We have also been advised by our legal advisers as to Hong Kong laws that, based on the view of Junhe above, it concurs that the '820 Patent does not appear to be absolutely necessary as a practical matter for the commercialisation of CBT-001. Our Directors accordingly consider the impact of the IPR Proceeding of the '820 Patent on our business operation and financial position has been very limited.

Joint Sponsors' View

Taking into account the views of Junhe and advice from the Company's legal advisers as to Hong Kong laws and based on the due diligence work conducted, nothing has come to the Joint Sponsors' attention to disagree with our Directors' view above in material aspects.

Other than the IPR proceeding regarding the '820 Patent and the Opposition Action disclosed above, our Directors confirm that we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringements of, any third-party intellectual property that are threatened or pending during the Track Record Period and up to the Latest Practicable Date. However, we are still subject to risks relating intellectual property rights. See "Risk Factors – Risks Relating to Intellectual Property Rights" in this prospectus for more details.

COMPETITION AND COMPETITIVE LANDSCAPE

The pharmaceutical and biotechnology industries are highly competitive and subject to rapid changes. While we believe that our pipeline of innovative drug candidates in clinical and pre-clinical trial stages, R&D capabilities, technology platforms and leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications as our drug candidates are indicated for, in particular in the fields of ophthalmology. These include major pharmaceutical companies as well as specialty pharmaceutical and biotechnology companies of various sizes and research institutions. Any drug candidates that we successfully develop and commercialise will compete both with existing drugs and with any new drugs that may become available in the future.

For more information on the competitive landscape of our drug candidates, see "– Market Opportunity and Competition" in this section for each drug candidate above.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business and is in line with the industry norm. We maintain clinical trial insurance covering us against liability or compensation in respect of injury to any trial participant caused by or arising out of participation in our clinical trials. We also maintain a

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number of insurance policies against our operation risks including insurance for office contents, business interruption insurance, electronic equipment insurance for computers and public liability insurance. Our insurance policies also cover medical insurance for our employees and director and officer insurance for our management team. However, our insurance coverage may still not be sufficient to cover all the potential risks we may face in our business operation. See “Risk Factors – Risks Relating to Our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources” for details.

During the Track Record Period and up to the Latest Practicable Date, we had not involved in any material insurance disputes.

EMPLOYEES

As of 31 December 2024, we had 51 full-time employees in total, with 34, nine, seven and one employees located in the PRC, the United States, Hong Kong and Germany, respectively. The following table sets forth the number of our employees categorised by function.

Function	Number of employees
Management	7
R&D	12
Manufacturing	5
Quality control and quality assurance	11
Administrative	16
Total	51

As of 31 December 2022, 2023 and 2024, and the Latest Practicable Date, we had 15, 17, 17 and 20 employees in charge of R&D activities, respectively. The following table sets forth the number of our R&D employees categorised by geographical location and by our three R&D centres as of the Latest Practicable Date.

Locations	R&D centres	Number of employees
Irvine, the United States	Irvine R&D centre	8
Guangzhou, China	Guangzhou R&D centre	7
Suzhou, China	Suzhou R&D centre	2
Hong Kong	N/A (support R&D matters of the above three R&D centres)	3
Total		20

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Among the 20 employees in charge of R&D activities as of the Latest Practicable Date, five members are from our senior management and 15 members are from our R&D department, and seven of them hold a master's degree or higher including five with doctor's degrees. Except for the chief operations director who is responsible for managing researchers and facilitating the execution of research activities, all the R&D team members majored in fields related to pharmacy, chemistry and health care, and seven of them have more than ten years of work experience in the pharmaceutical or ophthalmology industry.

Core R&D Personnel

The following table sets forth the roles and responsibilities of our core R&D personnel and their involvement and contributions to the R&D activities since the discovery of our drug candidates. All of our core R&D personnel have stayed since joining us.

Identities	Positions	Expertise	Roles and responsibilities	Involvement and contributions	Date of joining our Group
Dr. Ni Jinsong	CEO	Almost 30 years of experience in life sciences industry	Promote a culture that encourages innovation and R&D to improve patient outcomes and maintain competitive advantage. Supervise overall drug development, daily operations and management, as well as strategic and business development of our Group	Develop R&D strategic direction, plan and serve as the chair in our Group's weekly R&D strategy discussion meeting. Oversee drug discovery, development progression, regulatory submission, and participate in weekly discovery and development update meetings. Engage discussions with external key stakeholders, such as regulatory authorities and KOLs	September 2015
Mr. Van Son Dinh	Chief operating officer	Over 26 years of experience in pharmaceutical industry, especially in drug development and business management	Supervise the operation and logistics of our Group's R&D activities and clinical development milestones	Supervise our Formulation Development and Research Lab and GMP production facilities. Oversee all CMC functional areas and activities. Provide scientific strategies for non-clinical and clinical studies/programs. Oversee the regulatory submissions including IND and future NDA. Manage the R&D project management function group	September 2015
Dr. Yang Rong	Chief scientific officer	Approximately 24 years of experience in drug development	Supervise and manage drug development of our Group	Participate in team decision-making on all levels from early-stage to late stage clinical studies, and the key decisions include what project to initiate, what are the directions and approaches of each project, whether certain drug candidates can be taken to late-stage development, whether to continue certain projects, and also collaboration/ licensing related decisions. Heavily involved in the clinical development of all of our clinical-stage drug candidates	February 2016

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Identities	Positions	Expertise	Roles and responsibilities	Involvement and contributions	Date of joining our Group
Dr. Fang Wenkui Ken	Chief innovation officer	Over 20 years of experience in drug discovery	Drive innovation and foster a culture of creativity and entrepreneurial thinking, lead our innovation strategy, identify and evaluate new opportunities, technologies, and partnerships to accelerate growth and enhance our competitive advantage. Work closely with cross-functional teams, research institutions, and external stakeholders to promote continuous improvement and develop solutions that address unmet medical needs. Develop pipelines, manage patent portfolio and assist in fundraising and licensing related activities	Involved in the early research and development of all of our drug candidates since joining the Group. Serve as one of the contributors to several drug candidates, and an important strategist, implementer and contributor to other currently undisclosed early discovery programs and formulation platform development	September 2020
Ms. Leng Bing	Clinical operation vice president	Approximately seven years of experience in biology and pharmaceutical industry	Lead and manage clinical trial operations for multiple phase 2 clinical trials and clinical research projects. Lead group restructure and assist with fund raising activities	Lead and manage clinical trial operations for phase 2 clinical trials for CBT-006 and CBT-004, lead multiple hospital use projects including those for CBT-145 and clinical research projects for CBT-006	September 2018
Ms. Kimberly L Root	Clinical operations director	Over 10 years of experience in pharmaceutical industry	Lead and oversee clinical research activities: being responsible for implementing strategic plans, managing a team of researchers, and ensuring the successful execution of clinical trials with qualified professionals and vendors	Responsible for execution of all phase 3 clinical trials, including being responsible for operational oversight and strategic planning of CBT-001 phase 3 MRCT studies. Oversee clinical operations and vendors	June 2021
Mr. Zhang Tao (張濤)	R&D director	Over 15 years of experience in pharmaceutical industry	Manage our clinical trial sites in China, formulation laboratory, analytical lab and scientists to support drug analysis and formulation development work, and make sure the labs are in compliance with safety requirements and departmental standard operating procedures. Manage drug development projects and work with other key R&D personnel to support IND and future NDA submission milestones. Manage and select CROs in China. Prepare and propose budgets for formulation laboratory	Involved in discussion with the NMPA regarding CBT-001 phase 3 clinical trial in China, and search vendors for CBT-001's API production. Design and prepare ophthalmic solutions and submit tox study samples, to push forward the stability study for CBT-004. Summarise all the experimental data and support the IND submission in the U.S. for CBT-009; and search for CDMO, API, excipients and PET bottles vendors for CBT-009. Involved in formulation development and stability study, test method development and validation for CBT-145 and provide patent application support	March 2021

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Identities	Positions	Expertise	Roles and responsibilities	Involvement and contributions	Date of joining our Group
Dr. Abu P Abraham	Chief medical officer ^(note)	Approximately 14 years of pharmaceutical and clinical experience in ophthalmology and internal medicine	Lead the medical strategy and oversee all clinical and medical affairs and being responsible for providing medical and scientific leadership, ensuring the safety and efficacy of our products, and driving our clinical development and regulatory strategies. Supervise and manage all clinical trials, employees, consultants and third parties providing clinical-related services for our Group	Responsible for overseeing the pre-clinical and clinical aspects of all R&D programs through all phases of clinical trials. Oversees clinical development group, medical affairs, drug safety, and commercial function. Responsible for medical and operational aspects, as well as strategic planning of CBT-001 phase 3 MRCT studies. Lead the initiative to increase the visibility of CBT-001 in the external ophthalmic and business community by managing medical affairs and commercial teams. Also responsible for the advancement of CBT-009 to phase 3 in the U.S. and China. Provide clinical and medical guidance for CBT-004	June 2022

Note: before Dr. Abraham and Ms. Capan joined our Group as the chief medical officer in June 2022 and the chief patent officer in September 2022 respectively, (i) Dr. Ni Jinsong assumed the responsibilities of a chief medical officer since September 2015 till Dr. Abraham joined, which included supervising and managing clinical trials, employees, consultants and third parties providing clinical-related functions for our Group; and (ii) Dr. Rong Yang who joined our Group since February 2016 as the head of research and assumed the responsibilities of a chief patent officer till Ms. Capan joined, which included managing our Group's patent portfolio and advising on intellectual property protection when necessary.

Since our inception, we have successfully established a pipeline of drug candidates with a lean and highly capable team. As a clinical-stage ophthalmology biotech company, we have focused our internal R&D initiatives on drug discovery and identifying appropriate drug candidates while supervising other work customarily conducted by CROs and CDMOs. With suitable and adequate educational background, qualifications and working experience, our R&D team staff are capable of handling required duties and tasks covering the full cycle of drug development progress, from drug discovery, pre-clinical research, to clinical trials and regulatory registration. Consistent with market practice, we have outsourced certain R&D work to qualified CROs and CDMOs which have been strictly selected and the collaborations with which have been smooth, and the responsible R&D staff would supervise their work in accordance with agreed trial design/ manufacturing plan. Based on the reasons above, we believe that we have sufficient resources to conduct and oversee our R&D activities and efficiently compete with other market players with a relatively limited number of R&D staff.

In order to further enhance our R&D capabilities, subject to changes based on our actual needs and market conditions at the relevant time, we plan to recruit a medical director for our ongoing and future clinical trials and a vice president supervising our medical affairs in the year of 2024 and/or 2025. In 2024, we also intend to engage a few specialist(s), scientist(s), and manager(s) specialising on quality assurance, quality control and regulatory affairs.

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We recruit our strategic hires primarily through third-party recruiters. Other employees are recruited primarily through recruiting websites. We conduct new employee training, as well as professional and safety training programmes for all employees in accordance with our internal procedures to upgrade their skills and knowledge. We enter into employment agreements with our employees to cover matters such as wages, bonus, benefits, confidentiality obligations and grounds for termination.

During the Track Record Period, we did not make contributions to social insurance and housing provident funds in full for our employees based in the PRC. See “– Legal and Regulatory Matters – Legal Proceedings and Compliance” in this prospectus for details.

To remain competitive in the labour market, we provide various incentives and benefits to our employees. Our employees’ remuneration consists of wages, bonuses, allowances, employees’ provident fund, as well as social security contributions and other welfare payments. We have also adopted the Equity Incentive Arrangements to incentivise and recognise the contribution of certain employees, adviser and officers of our Company. Please refer to “History, Development and Corporate Structure – Equity Incentive Arrangements” in this prospectus for further details of the Equity Incentive Arrangements.

We have entered into confidentiality agreements with some employees which provide that all relevant intellectual properties developed by our staff during their employment with us become our intellectual properties and are treated as trade secrets, and that our employees are refrained from disclosing any trade secrets to third parties. We also enter into non-competition agreements with selected employees.

None of our Company or any of our subsidiaries have any labour union. We believe that we maintain a good working relationship with our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any significant labour disputes or strikes, which had a material effect on our business, financial condition or results of operations.

LAND AND PROPERTIES

As of the Latest Practicable Date, we have obtained the appropriate land use certificate for one parcel of land with a site area of 33,332.9 sq.m in Suzhou, Jiangsu. We plan to build a sizeable commercial production facility on this parcel of land in Suzhou based on our clinical development progress and commercialisation needs. See “Business – Manufacturing – Our Production Facility in Suzhou” for details.

As of the Latest Practicable Date, we did not own any properties and we leased a number of properties with an aggregate gross floor area of approximately 3,043.77 sq.m. in Guangzhou, Suzhou, Yixing, Wenzhou, Hong Kong and the United States, which were primarily used for administrative and R&D functions. The following table sets the properties leased by us:

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No.	Location	Gross floor area (sq.m)	Functions	Lease term
1.	Room 202, Tower 3, No. 19 Yongan Road, High-Tech Zone, Suzhou, Jiangsu Province, the PRC	1,226.43	Manufacturing and office use	16 December 2021 to 15 December 2027
2.	8921 Research Drive, Irvine, CA 92618, Orange County, California, the United States	459.87	Office use for R&D	1 June 2022 to 31 May 2026
3.	Block 327, Building G1, No. 31 Kefeng Road, Development Zone, Guangzhou, Guangdong Province, the PRC	307.00	Office for R&D and manufacturing purposes	1 November 2024 to 31 October 2026
4.	Rooms 1408 & 1409, Tower 2, No. 21 Chengji Road, High-Tech Zone, Suzhou, Jiangsu Province, the PRC	194.35	Office use	16 December 2024 to 15 December 2027
5.	Block 527, Building G1, No. 31 Kefeng Road, Development Zone, Guangzhou, Guangdong Province, the PRC	178.00	Office for R&D and manufacturing purposes	1 November 2024 to 31 October 2026
6.	Room 1101, Block 137, Huifeng Garden, No.15 Huifeng Street, Hushuguan Town, Huqiu District, Suzhou City, Jiangsu Province, the PRC	137.00	Corporate housing for an employee	8 May 2025 to 7 May 2026
7.	Office 2308, 23rd Floor, Tower One, Lippo Centre, No. 89 Queensway, Hong Kong	114.96	Office use	18 July 2022 to 17 July 2025
8.	Room 804, Area C, Environmental Technology Building, 501 Luyuan Road, Yixing Environmental Technology Park, Yixing, Wuxi, Jiangsu Province, the PRC	129.20	Office use	1 December 2024 to 30 November 2025
9.	Room 1609, Block C, Xiangxue International Apartment, No. 98 Xiangxue Eight Road, Huangpu District, Guangzhou, Guangdong Province, the PRC	120.00	Corporate housing for an employee	10 October 2024 to 9 October 2025
10.	Flat 2303, Unit 6, East Block, Shui'an Haoting, No. 65 Xincheng Road, Yixing, Wuxi, Jiangsu Province, the PRC	85.44	Corporate housing for an employee	1 August 2024 to 31 July 2025
11.	Rooms 1410, Tower 2, No. 21 Chengji Road, High-Tech Zone, Suzhou, Jiangsu Province, the PRC	59.52	Office use	16 December 2024 to 15 December 2027
12.	Room 323, Unit A, No. 100 Luodong North Road, Yongzhong Street, Longwan District, Wenzhou, Zhejiang Province, the PRC	32.00	Corporate housing for an employee	1 May 2025 to 1 July 2025

As of the Latest Practicable Date, the lessors for three of our ten leased properties in the PRC had not provided valid title certificates or authorisations evidencing their rights to lease the properties. These three leased properties, with a total GFA of 289.00 sq.m. accounting for approximately 11.71% of the GFA of our leased properties in the PRC, are primarily for office use, as well as corporate housing for certain employees. See “Risk Factors – Risks Relating to Our Operations – Some of our leased properties have title

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defects and did not complete registration procedures at relevant authorities. We may be required to cease occupation and use of such leased properties if there is a valid claim for them, or subject to penalties arising from the non-registration of lease agreements” in this prospectus.

Our Directors believe that the title defects of the relevant leased properties will not have any material adverse effect on our business and results of operations, given that (i) as advised by our PRC Legal Advisers, the title defects of our relevant leased properties will not have material adverse effect on our operation and financial position; (ii) during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any fines or administrative penalties from any PRC government authorities, nor had we received any notice of legal proceedings, claims or challenges from any third party in respect of the defects in these rights; (iii) these title defects of the relevant leased properties did not resulted in any increase or discount on the rents we contracted to pay; and (iv) if we fail to legally occupy and use the relevant leased property, we are entitled to claim against the lessor of the relevant leased property for our losses in accordance with the relevant PRC laws and regulations.

According to Chapter 5 of the Listing Rules and section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this prospectus is exempted from compliance with the requirements of section 342(1)(b) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which require a valuation report with respect to all our Group’s interests in land or buildings, for the reason that we had no single property with a carrying amount of 15% or more of our total assets in the most recent audited consolidated balance sheet.

RISK MANAGEMENT AND INTERNAL CONTROLS

Risk Management

We recognise that risk management is critical to the success of our business operations. Key operational risks faced by us include changes in general market conditions and the regulatory environment of the global market, our ability to develop, manufacture and commercialise our drug candidates, and our ability to compete with other pharmaceutical and biotechnology companies. See “Risk Factors” in this prospectus for a discussion of various risks and uncertainties we face. We also face certain risks such as market risk, credit risk and liquidity risk.

We continuously evaluate and determine the nature and extent of the risks we are willing to take in achieving our strategic objectives. In order to ensure that our Company establishes and maintains an appropriate and effective risk management mechanism, we do not adopt any of the standard guidelines on risk management directly. Rather, we tailor the following standard guidelines to the specific circumstances of our Company, including ISO 31000:2018 – Risk management, and the Committee of Sponsoring Organisations of the Treadway Commission (the “COSO”) – Enterprise Risk Management – Integrating with

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Strategy and Performance (2017), together with a series of risk management policies which set out a risk management framework for us to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

There are three lines of defence in our risk management system, consisting of first defence line on operating management executed by our business division and supporting departments which implement our standard operating and quality assurance procedures on a daily basis, second defence line on risk management executed by our chief compliance officer and Compliance Adviser, the Audit Committee and the joint company secretaries, and third defence line on auditing executed by our internal and external auditors, the Board and the Audit Committee. The respective functions of the key risk management function units in our risk management system are set out below:

- Our Board of Directors is responsible for evaluating and determining the nature and extent of the risks in achieving our strategic objectives, and ensuring that we establish and maintain appropriate and effective risk management and internal control policies. The Board also oversees our management team in designing, implementing and monitoring of the risk management and internal control systems;
- Our management team is responsible for formulating the quality assurance procedures, standard operating procedures and other risk management policies. The relevant teams in our Company, such as our compliance team, finance team and the human resources team, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice;
- Each of our department is responsible for identifying and evaluating risks associated with its working scope. In order to standardise risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) identify the source of the risks and potential impact, (ii) monitor the development of such risks, and (iii) prepare risk management reports periodically for our office of the president's review;
- Our internal auditor is responsible for conducting monitor and review on risk mitigating activities, and reporting risks regularly at appropriate management levels within our Group and providing assurance on the progress of solutions for existing or potential risks;
- Our Audit Committee is responsible for making recommendations to our Directors on the appointment and removal of external auditors, and reviewing the financial statements and rendering advice in respect of financial reporting as well as overseeing risk management procedures of our Group;
- Our chief compliance officer, Elizabeth Capan, will be responsible for carrying out the risk prevention and management activities with relevant department and conduct irregular reviews; and

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- Our finance team will be responsible for (i) reviewing the risk management information collected regularly, (ii) reviewing annual risk management report of the Company, and (iii) overseeing the promulgation of annual risk evaluations.

Risk control functions operating at the different levels share information and coordinate with other internal departments and external providers of assurance and consulting services to ensure proper coverage and minimise duplication of efforts.

Internal Control

We have implemented internal control policies, together with our risk management structure, to facilitate our business operation. We make references to the COSO – Internal Control – Integrated Framework: An Implementation Guide for the Healthcare Provider Industry (2013), a mechanism that enables organisations to effectively and efficiently develop systems of internal control when establish our internal control system, which is able to adapt to changing business and operating environments, mitigate risks to acceptable levels, and support our sound decision making and corporate governance. During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management and protection of intellectual property. See “– Intellectual Property” in this section for details. We also plan to provide periodic training about these measures and procedures to our employees as part of our future employee training program. Our internal audit personnel will conduct audit field work to monitor the implementation of our internal control policies, report the weakness identified to our management and audit committee and follow up on the rectification actions;
- We have adopted various internal control measures to mitigate the risks relating to cyber-attacks including, (i) all payment transactions must be reviewed and approved in accordance with certain payment approval matrix. In particular, dual authorisation from the financial controller and the chief financial officer is required for transaction with the payment amount greater than US\$50,000, (ii) accounting vouchers must be independently reviewed by authorised management personnel to ensure the a certain transaction is valid, accurately recorded and properly supported; (iii) an email password expiration policy has been established, requiring password changes every 60 days. Failure to change the password within this time frame will result in the expiration of password; (iv) a sender policy framework which is an email authentication method that deters spammers from sending messages on behalf of the staff’s own domain has been established, to enhance the integrity and authenticity of email system; (v) changes to settings, including firewall configurations and other administrative controls, are set to only to be performed by our IT administrators so as to restrict unauthorised modifications; (vi) physical access to facilities is strictly supervised by our HR team to ensure that only authorised personnel can be granted the entry; (vii) logical access to systems is to be managed by a third-party IT service provider,

and any access or changes, such as those related to router passwords, are made only with approval from the chief executive officer or personnel at the financial controller's level; (viii) role-based access control has been implemented, under which access to the systems was granted based on roles and is controlled by each department head, and any exceptions to such policy must be approved by the chief executive officer, and the access will then be granted by the IT department; (ix) the mandatory access control is in place for different types of data, including our finance, human resources and clinical trial data so as to ensure that sensitive information could only be accessed by authorised individuals.

- We have established a data compliance policy that outlines the guiding principles of data protection, the data compliance management framework, data security and protection requirements, an emergency plan in case of a data security incident, and data classification management, which are in connection with the data collected from our clinical trials. A suite of internal control measures has been adopted to safeguard personal data and clinical results, ensuring compliance with relevant laws and regulations, and key measures of which include, (i) all trial human subjects are required to sign a consent letter, which outlines the approach to handle their personal data, to ensure that clinical trials participants are fully informed and have given their consents for their data to be used in the clinical trial; (ii) the personal data and clinical results are stored on access-restricted platforms that are ISO-27001 certified, making sure the high security standards of these data platforms. These platforms are equipped with firewalls, continuous logging, encrypted data transfer, and regular backup procedures. Access to these platforms is password-protected, with password complexity requirements in place and the implementation of two-factor authentication. Furthermore, there exists the continuous monitoring and control of the access list to the data storage platforms, with all access logged. This monitoring procedure enables the tracking of user activity and timely identification of any unauthorised access attempts; and (iii) all employees are required to receive training on topics regarding cybersecurity, data security, and personal data protection at the Group level. Additionally, email alerts are sent to our employees from time to time to enhance their awareness on the risks associated with hacking, phishing and IT security breaches;
- We have established an investment management policy, stimulating (i) the requirements on know-your-customer ("KYC") procedures focusing on key areas such as identification of key money laundry risk areas and action, customer due diligence measures, customer acceptance policy and identification procedures, ongoing monitoring procedures, and record maintenance; and (ii) the requirements on investment decisions, responsibilities of different roles in an investment decision-making process and the approval matrix as well as the reporting requirements, and that the investment made by us shall be periodically reviewed by appropriate personnel;
- We require all of our employees to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We strictly prohibit bribery or other improper payments in our business operation and maintain strict anti-corruption policies among our

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employees, and we will closely monitor our employee's compliance with anti-bribery and anti-corruptions policies. In addition, we have established a whistleblowing reporting system to ensure that our employees are able to report concerns of any action, situation or circumstance that appears to be in violation of our code of conduct, anti-corruption policy or any applicable laws, regulations or our other internal policies, in an anonymous way without fear of retaliation;

- Our Directors together with our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the Listing;
- Our Audit Committee will be in charge of our communications with and engagement of external auditors, and establish a whistleblowing system for employees to raise concerns on any matters relating to our business operation and financial performance. The Audit Committee will also oversee our overall internal control system, and review our financial statements to be reported to our Board of Directors;
- We have engaged Fosun International Capital Limited as our Compliance Adviser to provide advice to our Directors and management team until the end of the first fiscal year after the Listing regarding matters relating to the Listing Rules. Our Compliance Adviser is expected to ensure our use of funding complies with the section headed "Future Plans and Use of Proceeds" in this prospectus after the Listing, as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion; and
- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest applicable laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

AWARDS AND RECOGNITIONS

We have received various awards and recognitions from governmental authorities or other professional organisations in China. The table below sets forth the details of the awards and recognitions we received in respect of our business development.

Award	Awarding authority	Award year
Top 100 Biomedicine Companies – 2023 China Future Healthcare Rankings (2023年中國創新生物醫藥榜- 未來醫療100強)	VB100, BDATA.cn (動脈網), and VCBeat Research (蛋殼研究院)	2023
Top 10 Fastest Growing Small Molecule Innovative Drug Enterprises in 2022 (2022年最具成長 性小分子創新藥企業)	Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會) and Shanghai Yiyun Information Technology. Co., Ltd. (上海醫耘信息科技有限公司)	2022

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Award	Awarding authority	Award year
Top 10 Most Influential Small Molecule Innovative Drug Enterprises – 2022 China Biomedicine Technology Innovation Rankings (2022年中國生物醫藥科技創新價值榜–最具影響力小分子創新藥企業)	China Biotechnology and Pharmaceutical Innovation Forum Organising Committee (中國生物技術與醫藥創新論壇組委會)	2022
Hurun Global Gazelle Enterprise of 2022 (2022年胡潤全球瞪羚企業)	Hurun Research Institute (胡潤研究院)	2022

LEGAL AND REGULATORY MATTERS

Licenses, Permits and Approvals

We are required to obtain and renew certain licenses, permits and approvals for our business operations in different jurisdictions, including various licenses, permits and approvals for our Suzhou GMP-certified pilot manufacturing facility. During the Track Record Period and up to the Latest Practicable Date, we had obtained all necessary licenses, permits and approvals from competent authorities that are mandatory to our operations. See “Regulatory Overview” in this prospectus for details. During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, permits and approvals that are material for our operations, and all of such licenses, permits and approvals were within their respective effective periods. We had not experienced any material difficulty in renewing such certificates, permits and licenses during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. During the Track Record Period and up to the Latest Practicable Date, we had not been penalised by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits and approvals.

Legal Proceedings and Compliance

We may from time to time be involved in legal proceedings in the ordinary course of business.

As of the Latest Practicable Date, there were no litigation or arbitration proceedings brought by us, or pending or threatened against us or any of our Directors, that could have a material adverse effect on our financial condition or results of operations.

During the Track Record Period, we have made contributions to social insurance funds, including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance, and housing funds for our employees in China. During the Track Record Period, we did not make contributions to social insurance and housing provident funds in full for our employees based in the PRC. We have been paying for social insurance premium and housing provident funds for all our employees based in the PRC in compliance with applicable laws and regulations since August 2023.

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Pursuant to relevant PRC laws and regulations, the relevant PRC authorities may demand us to pay the outstanding social insurance contributions within a stipulated deadline and we may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay. If we fail to make such payments, we may be liable to a fine of one to three times the amount of the outstanding contributions. With respect to a failure to pay the full amount of housing funds as required, the housing funds management centre in China may require payment of the outstanding amount within a prescribed period. If the payment is not made within such time limit, an application may be made to the PRC courts for compulsory enforcement. See “Risk Factors – Risks relating to doing business in China – We may be subject to additional social insurance fund, housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.”

Our Directors believe that such non-compliance would not have a material adverse effect on our business or results of operations, considering that: (i) we had not been subject to any administrative actions, fines or penalties during the Track Record Period and up to the Latest Practicable Date due to such non-compliance; (ii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing funds; (iii) we were neither aware of any employee complaints filed against us nor involved in any labour disputes with our employees with respect to social insurance and housing funds during the Track Record Period and up to the Latest Practicable Date; (iv) we would make full payment within the stipulated deadline as required by relevant PRC authorities once we receive the notifications from the relevant PRC authorities requiring us to pay the shortfalls; and (v) as advised by our PRC Legal Advisers, based on the above and provided that the relevant regulations and policies issued by PRC governments are still in effect, as long as we could make full payment within the stipulated deadline if required by relevant authorities in the future, the likelihood that the relevant social insurance authorities would collectively take initiative to recover the historically unpaid social insurance from us and/or impose the administrative penalties on us due to our failure to make full payment of the social insurance is remote, and the likelihood that the relevant housing provident fund authorities would impose any other administrative penalties on us due to our failure to make full payment of the housing provident funds is remote. We made provisions of approximately US\$321,000 as of 31 December 2024 in connection with the historical shortfall amount of the social insurance and housing provident fund contribution. We have been paying for social insurance premium and housing provident funds for all our employees based in the PRC in compliance with applicable laws and regulations since August 2023.

We have enhanced our internal control measures, including implementing a policy on social insurance and housing provident fund contribution in compliance with relevant PRC laws and regulations. In addition, we have designated our human resources department to review and monitor the reporting and contributions of social insurance and housing provident fund and we will consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to keep us abreast of relevant regulatory developments.

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incident which our Directors believe would, individually or in the aggregate, have a material adverse effect on our financial condition or results of operations.

Data Security and Data Privacy

Cybersecurity and Cyber Data Security

On 28 December 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective from 15 February 2022. On 30 August 2024, the State Council promulgated the Cyber Data Security Regulation (《網絡數據安全管理條例》), which became effective on 1 January 2025. See “Regulatory Overview – Regulations relating to the PRC – Regulations relating to Personal Information and Data Protection – Cybersecurity” in this prospectus for further details.

Our PRC Legal Advisers conducted a telephonic consultation (the “Consultation”) on 25 September 2023 with the China Cybersecurity Review Technology and Certification Center (the “Center”). The Center is authorised by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. According to the Center, (i) the listing in Hong Kong does not fall within the scope of “listing abroad”; and (ii) critical information infrastructure operators are identified by the governmental authorities of corresponding industry.

As of the Latest Practicable Date, as (i) we have not been notified of the results of any determination that we have been identified as a critical information infrastructure operator or that any of our systems have been identified as critical information infrastructure by the relevant governmental authorities; (ii) the MCR provides no further explanation or interpretation for “online platform operator” and “list abroad”, and does not stipulate that an online platform operator which intends to list in Hong Kong will be subject to cybersecurity review; (iii) Hong Kong is not a foreign country or region and does not fall within the scope of “abroad” under the MCR, and there is no specific guidance or implementation rules to indicate otherwise; (iv) the MCR provides no further explanation or interpretation for “affect or may affect national security”, which remains to be clarified and elaborated by the CAC, and we had not received any notification of cybersecurity review from relevant governmental authorities due to our impact or potential impact on national security; and (v) the volume of personal information we process is far less than one million people; based on the Consultation and the above, and as advised by our PRC Legal Advisers, our Directors believe that as long as there is no material change to our current business and no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

Furthermore, based on the facts that (i) while the MCR has come into effect, its implementation and interpretation is still subject to uncertainties, and (ii) we have not been involved in any investigations on cybersecurity review initiated by the CAC on such basis and nor have we received any inquiry, notice, warning, or sanctions in such respect, we believe such regulations would not have a material adverse impact on our business operations or our Global Offering. We are of the view that the likelihood that our business operation or the Global Offering might give rise to national security risks is remote, considering that (i) we have not been involved in any cybersecurity review or investigation

by the CAC or other authorities with respect to the MCR; (ii) we have not been informed that we are recognised as a crucial information infrastructure operator by any relevant authority; (iii) the data processed by us has not been included in the effective core data and important data catalogs by any authority; and (iv) we have taken reasonable and adequate technical and management measures to ensure data security. However, the MCR was released within a recent year, and certain provisions of which are still unclear and are subject to the finalisation or clarifications by relevant authorities. As such, the PRC regulatory authorities may have broad discretion in the interpretation of “affect or may affect national security”. If we were deemed as a data processor that “affects or may affect national security” by the PRC regulatory authorities under their broad discretion, we may be subject to cybersecurity review. If we fail to pass such cybersecurity review, our Global Offering may be impeded, our business operations may be adversely affected, and/or we may be subject to other severe penalties and/or action by the competent government authorities.

Data Cross-border Security

On 7 July 2022, the CAC promulgated the Measures for the Security Assessment of Data Cross-border Transfer (《數據出境安全評估辦法》), which took effect on 1 September 2022. On 22 February 2023, the CAC issued the Measures for the Standard Contract for Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》) (the “**Standard Contract Measures**”), along with the formal version of the standard contractual clauses for cross-border transfer of personal information stipulated under the Personal Information Protection Law. The Standard Contract Measures came into effect on 1 June 2023, and a six-month grace period is provided.

On 22 March 2024, the CAC issued the Provisions on Facilitating and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》) (the “**Cross-Border Data Flows Provisions**”). See “Regulatory Overview – Regulations relating to the PRC – Regulations relating to Personal Information and Data Protection – Cybersecurity” in this prospectus for details of the Cross-Border Data Flows Provisions. In accordance with the Cross-Border Data Flows Provisions, and with the assistance of our PRC Legal Advisers, our PRC subsidiary, Cloudbreak Guangzhou, has conducted a personal information protection impact assessment, concluded a standard contract for personal information to be provided abroad with relevant signing parties. Our PRC legal advisers are of the view that as of the Latest Practicable Date, no material non-compliance in relation to personal information and cross-border transfer of data (including patient clinical data) had come to their attention during their assistance with our personal information protection impact assessment report (個人信息保護影響評估報告) to be submitted to the Guangdong Cyberspace Affairs Office.

Some of the clinical trial data, collected by certain PRC research institutions (such as hospitals and medical institutions) that collaborate with us in connection with our clinical trials in the PRC, contains the participants’ individual information in connection with the clinical trials which has been referred to in the patient consent letter. Such information, excluding personal identification information that can be used to directly identify the participant such as names, name initials, addresses, or phone numbers, would be sorted and sent to us, and then stored on our server located in the United States by directly logging onto and uploading on the server system using an access-controlled account. Other than the aforementioned information which only relates to clinical trials, no other individual

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information will be transmitted overseas. The server is operated in secured systems, which have implemented measures such as access control, firewall settings, encrypted transmission, regular backups, and other safeguards to ensure data security. For details, see the internal controls measures on personal data and clinical results protection in “– Risk Management and Internal Controls – Internal Control” in this prospectus.

In response to the evolving cybersecurity regulatory requirements and in order to maintain prudent compliance with the abovementioned cybersecurity laws and regulations, on 14 June 2024, Cloudbreak Guangzhou has proactively submitted a Standard Contract Filing to the Guangdong Cyberspace Affairs Office through the Outbound Data Transfer Filing System (數據出境申報系統) website for the outbound transfer of personal information transmitted in our clinical trials in the PRC. The Guangdong Cyberspace Affairs Office responded to our filing application on the Outbound Data Transfer Filing System dated 22 January 2025, confirming that the responsibility for the Standard Contract Filing in connection with our clinical trials in the PRC rests with the PRC research institutions we collaborate with, such as hospitals and medical institutions, which collect and transmit the clinical trial data. It also confirmed that, under the current regulations, we are not required to proceed with the Standard Contract Filing for our current clinical trials in the PRC.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE (“ESG”) MATTERS

Governance on EHS Matters

We are committed to operating our business in an environmentally, socially and economically responsible manner and providing our employees with a healthy and safe workplace. In order to ensure that our R&D and the future production are in compliance with the applicable laws and regulations, we have implemented a series of rules, standard operating procedures and measures with effect from 7 April 2023 on environmental, workplace health and safety matters (“EHS”), which we believe are in line with industry standards and in compliance with the requirements of the Listing Rules.

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Our EHS policies include general EHS risk assessment methodology and risk management measures for EHS. Specifically, for environmental matters, we have adopted plan for environmental management system, management measures for hazardous chemical substance and other waste, and procedures for manufacturing area and building cleaning, covering (i) treatment of solid waste, (ii) adoption of materials that cause minimum environmental concerns to the extent possible, and (iii) hygiene sampling of airborne contaminants, among other aspects. For employee safety and welfare matters, we have adopted procedures for manufacturing area and building cleaning, procedures for first aid, policies on personal protective equipment, and the internal training measures for EHS, covering (i) clinical trial safety, (ii) employee health, promotion, compensation and benefits, and (iii) employee training, wellness and professional and personal development, among other aspects. We are also committed to complying with environmental, social and governance (“ESG”) reporting requirements upon listing.

We believe that our EHS management system enables us to actively identify and monitor the actual and potential impact of EHS related risks on our business, strategy and financial performance, and incorporate considerations for these issues into our business, strategic and financial planning. The four-level EHS management structure established by our Group for overseeing ESG risks consists of:

- our Board, which has overall responsibility for overseeing and determining our Group’s environmental, social, and climate-related risks and opportunities impacting our Group, establishing and adopting the ESG policy and targets, assessing ESG-related risks on a regular basis to ensure we fulfil our responsibilities with respect to ESG matters, reviewing risk management information and the annual risk management report of the Group, reviewing our Group’s performance annually against the ESG targets and revising the ESG strategies as appropriate if significant variance from the target is identified, overseeing the ESG working group to promulgate annual risk evaluations, engaging and overseeing external experts to assist in assessing material ESG risks and reviewing existing strategies, objectives and internal control policies and to make recommendations accordingly, and communicating with management, the ESH manager and the ESG working group from time to time so as to ensure that all material ESG areas are identified and reported;
- our specifically designated EHS manager, who is responsible for maintaining, implementing and continuously monitoring the implementation of EHS-related policies and procedures, keeping abreast of the latest ESG-related laws and regulations, including the applicable sections of the Listing Rules, keeping our management informed of any changes in such laws and regulations, and updating our ESG Policy in accordance with the latest regulatory updates. The EHS manager would also identify our key stakeholders based on our business operations and understand such stakeholders’ influences with respect to ESG matter. The EHS manager facilitates internal and external communication on EHS-related matters, and reports on the performance of the EHS management system to our management for review and as a basis to further develop and improve our EHS management system;

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- our ESG working group, which consists of the head of global human resources department, the joint company secretaries, the Suzhou facility head/ government relations director, a director of R&D and a clinical research assistant with a goal to addressing ESG-related risks, formulating working rules on corporate governance and measures for sustainable development, is responsible for assessing and managing our ESG related risks and opportunities, deliberating on the formulation of our ESG strategic plans, management structure and implementation rules, making guidelines for and reviewing the identification and ranking of our ESG issues, reviewing our ESG work and internal monitoring systems and making recommendations on their appropriateness and effectiveness, reviewing our ESG-related disclosure documents (such as the future annual ESG reports), monitoring ESG-related risks and making inquiries on and formulating corresponding measures for major issues that affect our performance of ESG-related work, and reviewing and supervising how such issues are handled. Our ESG working group will report to the Board annually. ESG working group meetings are divided into regular and ad hoc meetings. Regular meetings are held at least once a year, and ad hoc meetings are held at the initiative of ESG working group members; and
- upon identification of any EHS risks, our EHS team is responsible for conducting investigation, composing risk assessment report and emergency response plan, and making filings with local governmental authority if required under local laws and regulations, and taking all applicable measures to reduce the impact of such risks or incidents.

We are committed to establishing a layered training design system to ensure every employee receive appropriate and sufficient training as needed. Our EHS manager is responsible for identifying specific training needs for each employee group determined by their job functions, which form the basis of the training matrix. Our EHS coordinator then develops the internal training schedule based on the training matrix for each employee group. The respective area manager and team leaders are in charge of supervising completion of various training programs for all of our employees.

We are adopting various strategies and measures to identify, assess, manage and mitigate ESG and climate-related risks, including but not limited to:

- Reviewing and evaluating ESG reports of comparable companies in the industry so as to ensure timely identification of all ESG-related risks;
- Discussing with the management from time to time so as to ensure that all material ESG areas are identified and reported;
- Discussing key ESG principles and practices with key stakeholders to ensure that important aspects are covered;

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- Formulating specific ESG risk management approaches and quantified performance indicators so as to identify and consider ESG risks and opportunities and separate ESG risks and opportunities from other business risks and opportunities; and
- Setting targets for environmental key performance indicators (“KPIs”), including emissions, pollution and other impacts on the environment, so as to reduce emissions and consumption of natural resources.

We will review the ESG-related progress and risks identified on a regular basis through direct supervision by the Board and senior management.

Potential ESG-related Risks

As a clinical-stage ophthalmology biotechnology company focused on the development of novel and differentiated treatments, we face a variety of environmental, health or safety-related risks associated with our R&D. For example, our R&D activities in our pilot production facility in Suzhou and our R&D centre in Guangzhou, Guangdong, China and Suzhou, Jiangsu, China involve the use of hazardous materials, including chemicals, and may produce hazardous waste to the environment. In addition, we cannot eliminate the risks of contamination or personal injury from these materials. If we use hazardous materials in a manner that causes injury, we could be liable for damages as we do not maintain work injury insurance for injuries to our employees resulting from the use of hazardous materials. We also do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties’ disposal of hazardous materials, we could be held liable for any resulting damages. Potential risks to premises, operations, supply chains, transportation needs, and employee safety also impact our finances. We may also incur significant costs associated with civil, administrative or criminal fines and penalties.

In addition to above, we may also be exposed to climate-related risks, which can be divided into two broad categories, namely, physical and transition risks. We define physical risks as risks related to the physical impacts of climate change, consisting of (i) acute physical risks, such as increased severity of typhoon or floods, and (ii) chronic physical risks that are affected by long-term changes in climate patterns, such as changes in average annual rainfall or temperature. We define transition risks as the transition from dependence on fossil fuels to a low-carbon economy, which may involve changes in policy, laws, technology markets, as well as social culture, such as possible carbon taxes, compliance disclosures, and increased use of new energy sources across businesses and households. The ESG-related risks and actual and potential impact of such risks on our business, strategy and financial performance are summarised below:

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	Type of Risks		Potential Impact
Physical risks	Acute risks	Frequent occurrence of typhoons, floods, droughts and other extreme weather	<ul style="list-style-type: none"> • Interruption of supplies or business
	Chronic risks	Rising average temperature	<ul style="list-style-type: none"> • Increased energy consumption in laboratories, factories and offices resulting in higher energy costs • Decreased employee productivity and increased labour costs
Transition risks	Policy and legal risks	Industry low-carbon policy requirements and tightening regulatory requirements	<ul style="list-style-type: none"> • Pressure on carbon costs • Government's quotas allocation on carbon emission and pressure on carbon costs
		Litigation risk	<ul style="list-style-type: none"> • Litigation risk brought from the interruption of supply chain, resulting in our failure to perform future contracts on time
	Market and technology risks	Costs for transition to low-carbon emission technology	<ul style="list-style-type: none"> • Increased cost on upgrading facilities in laboratories, factories and offices for energy saving and high efficiency
		Rising raw material costs	<ul style="list-style-type: none"> • Decreasing quantity and quality of raw materials • Increased R&D costs resulting from insufficient resources of laboratory supplies
		Changes in customer behaviour and preferences	<ul style="list-style-type: none"> • Loss of future orders and decreased future revenue resulting from insufficient disclosure of carbon neutrality goals and data • Demand from downstream future corporate customers to upstream suppliers to provide green and low-carbon biomedical products and to formulate carbon-neutral strategic goals

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Type of Risks	Potential Impact
Uncertain demand	<ul style="list-style-type: none"> Possible increased demand for medicines and other pharmaceutical products resulting from the emergence of new chronic diseases and other diseases
Reputational risk Negative publicity	<ul style="list-style-type: none"> Negative publicity on our reputation resulting from our inability to respond to shareholders' expectation caused by insufficient disclosure on the reduction targets and information on emission

In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In the case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance contributed by our Group to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make corresponding contingency and disaster preparedness plans, and we believe that we have the ability to deal with climate crisis.

During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

Our Group will conduct an enterprise risk assessment at least once a year to cover the current and potential risks faced by our Group, including, but not limited to, the risks arising from the ESG aspects and strategic risk around disruptive forces such as climate change. Our Board will assess or engage an external expert to evaluate the risks and review our Group's existing strategy, target and internal controls, and necessary improvement will be implemented to mitigate the risks. Our Board, the Audit Committee, our ESG working group and our EHS manager will maintain oversight of our Group's approach to risk management, including climate-related risks and risks monitored as part of the standard operating processes to ensure the appropriate mitigations are in place of the regular management reviews.

The decisions on the reduction, transfer, acceptance or control of the risks are affected by various factors such as government regulation and availability of energy-saving supplies. We will incorporate climate-related issues, including the analysis on physical and transition risks, into our risk assessment process and risk appetite setting. We will consider the risks and opportunities in our strategic and financial planning process if such risks and opportunities are deemed to be material. After reviewing the environmental, social and climate-related risks and our performance in response to such risks each year, we may revise and alter our ESG strategies as appropriate.

Environmental Protection

We endeavor to reduce negative impacts on the environment through our commitment to energy saving and sustainable development. We have adopted internal policies for environmental risk prevention to ensure compliance with the requirements of the applicable national, industrial and local standards, laws, regulations and policies, including, but not limited to compliance with GMP regulations and periodic environmental evaluations on resource consumption, hazardous waste disposals and waste water detection and emissions.

Metrics and Targets

We rely on various metrics to measure the impact of environmental risks, which are broadly aligned with industry standards. Such metrics are the amount of consumed resources including electricity and water, and the amount of hazardous waste. We have also set various goals to reduce our environmental impacts, and we continue to take significant steps toward these targets. The following sets forth our resource use and emission related indicators during the Track Record Period:

- **Electricity consumption.** We have monitored our electricity consumption levels and implemented measures to improve energy efficiency during the Track Record Period. In the years ended 31 December 2022, 2023 and 2024, our electricity consumption levels were 0.08 million kWh, 0.40 million kWh and 0.84 million kWh respectively. We intend to reduce the level of our per capita electricity consumption by approximately 10% per thousand dollars of R&D expense by the end of 2025 through actively promoting energy conservation and consumption reduction in our daily operations. For example, we plan to encourage the purchase and use of energy-efficient electronic equipment in our office premises, including the choice of lighting and other electrical appliances used. We will ensure lights are switched off when not in use either manually or through automatic sensors, and request employees switching off air conditioning, certain IT equipment and other power-consuming equipment or setting up automatic power shutdown for certain systems and devices when they are not in use.
- **Water consumption.** We have monitored our water consumption levels and implemented measures to promote water conservation during the Track Record Period. In the years ended 31 December 2022, 2023 and 2024, our water consumption levels were 30.0 tons, 292.09 tons and 355.02 tons, respectively. Since we have not yet started commercial-scale production, our water resources are mainly used for daily use in offices, laboratories and manufacturing facilities to support our in-house R&D activities during the Track Record Period. We intend to reduce the level of our per capita water consumption by approximately 10% per thousand dollars of R&D expense by the end of 2025 through posting slogans on saving water in our office to encourage employees to save water in their daily life, including when working in the office.

- **Hazardous waste discharge.** We have monitored our hazardous waste discharge levels on a periodic basis during the Track Record Period. In the years ended 31 December 2022, 2023 and 2024, our hazardous waste discharge levels were 0.55 tons, 4.19 tons and 10.63 tons, respectively. For any potential hazardous wastes we produce from R&D activities, we engage qualified third parties for the disposal of hazardous materials and wastes. We require their operational qualifications in accordance with relevant governmental laws and regulations. We intend to reduce the level of our per capita hazardous waste discharge by approximately 10% per thousand dollars of R&D expense by the end of 2025 through (i) regularly monitoring and assessing sources of hazardous waste generation and replacing or optimising processes, projects, materials and equipment that tend to unnecessarily generate such waste, (ii) enhancing our on-site waste treatment capacities, including installing more equipment as appropriate to reduce pollutant concentration in effluent to render it non-toxic or less harmful, (iii) working with professional waste processors, such as specialised sewage treatment centres, to make hazardous waste non-toxic or less harmful, and (iv) other measures that we may find helpful in reducing our hazardous waste discharge in the future.
- **Waste disposal.** We have procedures in place for waste management to ensure compliant waste disposal and reduce environmental impact. The waste we produce is divided into disqualified product waste, disqualified packaging waste, hard plastic waste, general waste, solvent soaked items and recycle paper and cardboard, which will be discarded into bins with respective coloured-labels, to indicate the applicable waste disposal procedures.

Measures on Minimising Impact on Environment

We have adopted various measures to minimise the impact of our business operations on the environment, including but not limited to:

- To reduce resource consumption: (i) encourage our employees to turn off lights and water supplies, equipment, and other electronic devices when the devices are not in operation and before they leave the premises, (ii) set and keep the air conditioners to a default temperature of around 24 to 26 degrees, and (iii) conduct regular inspection and maintenance of equipment in order to check for abnormal conditions, and make prompt report to avoid potential damages, (iv) encouraging our employees to avoid printing hard copies and requiring double-sided printing whenever possible, (v) encouraging teleconferences as opposed to physical meetings to reduce travel; and
- To manage waste disposal: (i) strictly comply with the GMP clinical manufacturing qualification requirements and relevant pollutant emissions standards during our R&D process to reduce pollutant emissions of waste; (ii) store hazardous substances in special warehouse and contract with qualified third parties for the disposal of hazardous materials and waste when needed, and (iii)

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conduct periodic environmental evaluations on hazardous waste disposals and waste water detection and emissions to make sure all operations are in compliance with the applicable laws and regulations.

With the expansion of our business and anticipated commercialisation of our drug candidates, we expect our resource consumption and emissions to increase. However, we target to adopt additional measures to mitigate environmental impact from our business, strategy and financial performance in the near, medium and long term, such as:

- To reduce resource consumption: (i) increase the use of clean energy and energy efficient equipment, and (ii) improve energy-saving features such as energy-saving transformers; and
- To manage waste disposal: (i) adopt exhaust gas treatment system and install active carbon filters, (ii) sewage treatment system, (iii) promote recycling schemes and seek alternative ways of disposing of and reducing waste in environmental-friendly ways, and (iv) set up hazardous waste storage sites in accordance with relevant standards and establish standardised hazardous waste management system.

At the same time, we strive to cultivate a corporate culture of environmental protection and work closely with our business partners to build an environment-friendly ecosystem. We are committed to improving the environmental performance of our entire value chain, including office operations, supplier selection, raw material inflow, laboratory experiments, manufacturing process and waste management.

Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of Appendix 27 to the Listing Rules and other relevant rules and regulations upon listing. The relevant targets on material KPI will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we have taken into account our respective historical consumption or discharge levels during the Track Record Period, and have considered our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development. Following the ESG evaluation system standards of industry pioneers, we aim to avoid or reduce the adverse impact on the environment caused by our operations, formulate environmental management plans to continuously improve our energy consumption efficiency and ensure all of our operations comply with governmental environment-related regulations and requirements. Our goal is to establish a comprehensive ESG governance mechanism and system and our historical energy consumption levels during the Track Record Period will serve as a foundation for developing more relevant energy reduction strategies and setting appropriate reduction targets for us in the future.

Considering our level of production activities this year, and referencing the average of industry peers, international standards and our historical consumption and discharge levels during the Track Record Period, our current target is to reduce per capita water

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consumption, electricity consumption and hazardous waste discharge by approximately 10% per thousand dollars of R&D expense by the end of 2025, which may lead to an increase in our operation cost in 2025.

The decision to mitigate, transfer, accept or control ESG-related risks and implement measures to minimise the impact of our business operation on environment is influenced by various factors such as government regulation and availability of energy-saving supplies. Upon periodic review of the ESG-risks and our Group's performance in addressing the risks, we may revise and adjust the above contemplated ESG strategies and measures as appropriate.

Employee Health and Work Safety

We have implemented measures to identify and address potential risks relating to employee health and work safety, as we put emphasis on providing a safe working environment for our employees. These measures include (i) the implementation of work safety guidelines on safe practices, accident prevention and accident reporting and closely monitor internal compliance with these guidelines, (ii) continuous employee training to enhance our employees' awareness of ESG issues and skills to comply with safety and operation standards, (iii) requirements that all our employees operating specialised equipment must have the requisite certifications, (iv) timely provision of protection equipment to our employees, medical examination for employees, (v) regular safety inspections of our laboratories and manufacturing facilities and (vi) establishment of procedures to appropriately handle work safety incidents. Since our operations involve the use of hazardous materials, we have implemented safety protocols that set out guidelines on potential safety hazards and procedures for operating in the laboratory and manufacturing facilities, including but not limited to the handling, use, storage, treatment and disposal of hazardous materials, as well as emergency planning and response. We also provide occupational health check-ups for employees who may be in contact with potentially toxic substances.

In addition, we provide training induction training for all new hires so that our employees are equipped with the necessary awareness and technical know-how to perform their work in a safe and effective manner, and familiarised with each other's responsibilities. Staff in specialised departments, such as the departments responsible for manufacturing, quality control and quality assurance, receive basic training in their field and gain up-to-date business knowledge. We have established an employee performance management system that provides regular reviews of compensation and development for high-performing employees.

We are committed to the in-house discovery, development and commercialisation of ophthalmic therapies that are not only effective, but also safe and well-tolerated by patients. We abide by the adopted clinical trial related policies during the patient selection and enrolment process, including (i) ensure compliance with ethical requirements for clinical trials by obtaining approval from competent authorities for our study protocol package, which includes the procedures and standards for patient selection and enrolment; (ii) design inclusion and exclusion criteria to identify patients or subjects whose condition meet the specific indicators related to the indications our drug candidates target, and exclude patients or subjects with conditions that may interfere with the analysis on study results, so

that the clinical trials could be conducted in a proper, safe and effective manner; (iii) require the patients or subjects to provide written informed consent before undergoing trial-related procedures, and make sure they are able to provide written informed consent and comply with study assessments for the full duration of the study; (iv) review and confirm that the patients or subjects meet the eligibility requirements outlined in the study protocol before enrolling them in the study; and (v) maintain an organised, accurate and consistent document management system which records the patients or subjects' information, establish and follow protocols to ensure document safety, and refrain from publishing or circulating patient enrolment information unless and until it is allowed by applicable guidelines and approved by competent authorities. We also strive to adhere to high standards of quality and safety that meet the needs of patients with ophthalmic diseases, and we have adopted a series of measures to enhance clinical trial safety through (i) regularly checking regulatory developments and updates, (ii) developing clinical trial protocols with reference to the latest regulations and guidelines on clinical trial safety, (iii) communicating with relevant employees and CROs on the regulatory compliance update and the enforcement of clinical trial protocols, (iv) establishing and enforcing internal policies and procedures on clinical trial safety, starting with monitoring adverse events of drug candidates as well as creating safety management plans and recording properly and accurately the clinical trial safety events for each clinical trial, (v) conducting comprehensive analysis on the collected adverse events and evaluating the safety risks, (vi) reporting serious adverse events and potential serious safety risks to regulatory authorities promptly, (vii) revising protocols, investigators' brochures and standard operating procedures and re-evaluating the safety risks periodically, and (viii) engaging nominated first aider among our employees with first aid certificate renewed regularly. We also recognise the importance of safety for our clinical trial participants, and ensure that our clinical trial participants properly acknowledge their understanding of safety matters at the time of enrolment and on an ongoing basis.

Our ESG deviation reporting system, which is established to ensure that all corrective actions arising from ESG-related incidents are documented, risk rated and tracked, is able to verify that the corrective actions are effective at eliminating or minimising the harm and helps us to avoid similar incidents going forward.

Compliance with ESG-related Regulations

We incurred a *de minimis* amount of costs in relation to environmental law compliance during the Track Record Period. Going forward, we do not expect our costs of complying with current and future environmental protection and health and safety laws to increase significantly.

During the Track Record Period and up to the Latest Practicable Date, we were in compliance with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any workplace accident. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

Social Responsibility

Corporate social responsibility is viewed as part of our core growth philosophy that will be pivotal to our ability to create sustainable value for our Shareholders. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics, and create a diverse and inclusive working environment. As of 31 December 2024, approximately 63% of our total employees were female. We will also focus on embracing diversity within our organisation and equal and respectful treatment of all of our employees in their hiring, training, wellness, and professional and personal development, to enable our employees to grow and realise their full potential. We strive to operate our facilities in a manner that protects the working environment, health and safety of our employees and communities. We are also committed to engaging with our future customers, employees, business partners, governmental agencies and other stakeholders from the communities in which we operate, understanding their needs and supporting community activities.

DIRECTORS AND SENIOR MANAGEMENT

OVERVIEW

The following table sets forth certain information in respect our Directors and senior management:

Name	Age	Position	Date of Joining our Group	Date of Appointment as Director	Roles and Responsibilities
Executive Directors					
Dr. NI Jinsong	57	Chairman, Executive Director and chief executive officer	September 2015	November 2020	Supervising overall drug development, daily operations and management as well as strategic and business development of our Group
Mr. Van Son DINH	56	Executive Director and chief operating officer	September 2015	July 2021	Supervising the operation and logistics of our Group's research & development activities and milestones
Dr. YANG Rong	62	Executive Director and chief scientific officer	February 2016	November 2021	Supervising and managing drug development of our Group
Non-executive Directors					
Dr. LI Jun Zhi	62	Non-executive Director	September 2015	July 2021	Supervising and managing drug development and strategic development of our Group
Mr. CAO Xu	42	Non-executive Director	November 2021	November 2021	Supervising overall development of our Group
Mr. XIA Zhidong	47	Non-executive Director	26 June 2024	26 June 2024	Supervising overall development of our Group

DIRECTORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of Joining our Group	Date of Appointment as Director	Roles and Responsibilities
Independent Non-executive Directors					
Mr. LAI Hin Wing Henry Stephen	68	Independent Non-executive Director	14 March 2025	14 March 2025	Supervising and providing independent judgment to our Board
Mr. LIU Chung Mun	65	Independent Non-executive Director	14 March 2025	14 March 2025	Supervising and providing independent judgment to our Board
Ms. NIE Sijiang	50	Independent Non-executive Director	14 March 2025	14 March 2025	Supervising and providing independent judgment to our Board

Apart from Dr. Ni Jinsong, Mr. Van Son Dinh and Dr. Yang Rong, the table below shows certain information of other members of the senior management of our Company:

Name	Age	Position	Date of Joining our Group	Date of Appointment	Roles and Responsibilities
Senior Management⁽¹⁾					
Ms. CHAN Ching Chu (陳清珠) ⁽²⁾	57	Chief financial officer	March 2022	March 2022 ⁽²⁾	Overseeing our Group's finance and operations, as well as formulating business plans of the Group for future development and maintaining financial position for sustainable growth
Dr. Abu P ABRAHAM	50	Chief medical officer	June 2022	June 2022	Supervision and general management of clinical trials, employees, consultants and third parties providing clinical-related functions for our Group

DIRECTORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of Joining our Group	Date of Appointment	Roles and Responsibilities
Ms. Elizabeth Sharon CAPAN	43	Chief patent officer and chief compliance officer	September 2022	September 2022 and November 2023	Managing our Group's patent portfolio, advising on intellectual property protection, and overseeing compliance matters of our Group
Dr. FANG Wenkui Ken	62	Chief innovation officer	September 2020	September 2020	Developing pipelines, managing patent portfolio and assisting in fundraising, licensing activities

Note: (1) For the business address of the senior management, please refer to the address of the corporate headquarters stated in “Corporate Information” in this prospectus.

(2) Ms. Chan Ching Chu has tendered her resignation as chief financial officer on 3 May 2025, and will leave our Group starting 3 November 2025. As at the Latest Practicable Date, our Company has yet to identify a suitable candidate to replace Ms. Chan Ching Chu as chief financial officer. Until a suitable candidate is appointed in her replacement, Ms. Fung Nga Fong as the financial controller of our Company, shall be responsible for overseeing our Group's financial matters. For details of Ms. Fung Nga Fong, please refer to “– Joint Company Secretaries” below in this section.

BOARD OF DIRECTORS

Our Board of Directors is the primary decision-making body of our Company, setting fundamental business strategies and policies for the management and operation of our business and monitoring their implementation. Our Board of Directors consists of nine Directors, comprising three executive Directors, three non-executive Directors and three independent non-executive Directors. Our executive Directors and independent non-executive Directors are elected to serve an initial term of three years, while our non-executive Directors are elected to serve an initial term of one year, which are renewable upon re-election and/or re-appointment.

Executive Directors

Dr. NI Jinsong, aged 57, is the chairman of our Board, an Executive Director, our chief executive officer and one of our Single Largest Shareholders. He was appointed as our Director on 20 November 2020, and was appointed as the chairman of our Board and re-designated as our Executive Director on 9 November 2023. Dr. Ni is responsible for supervising overall drug development, daily operations and management as well as strategic and business development of our Group.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Ni co-founded our Group with our Directors Mr. Dinh and Dr. Li in September 2015 when our Group's first principal operating subsidiary, Cloudbreak USA, was established. Dr. Ni was one of the founding members of Cloudbreak USA, and was the one of managers of Cloudbreak USA from December 2015 to December 2021. Dr. Ni also holds the following positions with the other members of our Group and has been primarily responsible for these companies' decision-making:

- chairman of the board of directors, general manager and legal representative of Cloudbreak Guangzhou since September 2018;
- director of Cloudbreak Cayman since November 2019;
- director of Cloudbreak HK since November 2019;
- director of Cloudbreak BVI since November 2019;
- manager of ADS USA from January 2017 to January 2021;
- executive director of Cloudbreak Suzhou since September 2021, and legal representative from September 2021 to September 2023;
- managing director of Cloudbreak Germany since May 2022;
- director of Cloudbreak Pharma HK since June 2022;
- executive director of Cloudbreak Yixing since September 2023; and
- executive director of Cloudbreak Wenzhou since June 2024

Dr. Ni has over 30 years of experience in the life sciences industry. Prior to joining our Group, Dr. Ni started as a postdoctoral research fellow at the department of medicinal chemistry, college of pharmacy at University of Utah from November 1994 to October 1996, responsible for investigating the interaction between a potential anti-tumor drug molecular and nucleic acid. In October 1996, he then joined as a research scientist at American Health Foundation, and was responsible for investigations and studies of absorption, distribution, metabolism and elimination of potent carcinogenic substances. From October 1997 to May 2000, he was a research scientist at Pfizer Inc., responsible for research and supporting drug discovery and development. From May 2000 to June 2015, he served as the scientific director of department of drug safety evaluation of Allergan, Inc., responsible for developing strategies, managing resources and non-clinical developments.

Dr. Ni obtained his doctorate degree in philosophy from University of Toronto, Canada in June 1995. He obtained his master's degree in science (chemistry) from Brock University, Canada, in June 1992, and a bachelor's degree in science in chemistry from Nanjing University, China in July 1989.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Ni held the position of president of the following dissolved company incorporated in the State of Nevada, the United States. The relevant details are as follows:

Company name	Nature of business before dissolution	Reason for dissolution	Current status and date of dissolution
Wycliffe Business Consulting	Investment holding	Cessation of business operation	Voluntarily deregistered on 4 January 2023

Dr. Ni confirmed that (i) the above company was solvent immediately prior to dissolution; (ii) there is no wrongful act on his part leading to the dissolution of the above company; (iii) he is not aware of any outstanding or potential claim that has been or will be made against him as a result of the dissolution of the above company; (iv) no misconduct or misfeasance had been involved in the dissolution of the above company; and (v) the above company that he held position in was not involved in any non-compliance incidents and/or legal proceedings prior to its deregistration.

Mr. Van Son DINH, aged 56, is our chief operating officer and an Executive Director. He was appointed as our Director on 22 July 2021 and re-designated as our Executive Director on 9 November 2023. Mr. Dinh is responsible for supervising the operation and logistics of our Group's research & development activities and milestones.

Mr. Dinh co-founded our Group with our Directors Dr. Ni and Dr. Li in September 2015 when our Group's first principal operating subsidiary, Cloudbreak USA, was established. Mr. Dinh was one of the founding members of Cloudbreak USA, and was one of the managers of Cloudbreak USA from May 2017 to December 2021. Mr. Dinh also holds the following positions with the other members of our Group and has been primarily responsible for these companies' decision-making:

- director of Cloudbreak Guangzhou since October 2020;
- director of Cloudbreak Cayman since April 2020;
- manager of ADS USA from November 2020 to January 2021; and
- director of ADS Australia since March 2021.

Mr. Dinh has over 26 years of experience in the pharmaceutical industry and has a wide range of experience from drug development to business management. Prior to joining our Group, Mr. Dinh worked at Allergan from September 1997 to July 2015, with last position served as a principal scientist of department of drug safety evaluation and was mainly responsible for scientific support for drug development projects, as well as managing study directors and analysts to ensure study plans are executed accordingly.

Mr. Dinh obtained a master's degree in business administration from Webster University, the United States in March 2016, and a bachelor's degree in science from University of California, Irvine, the United States in June 1995.

DIRECTORS AND SENIOR MANAGEMENT

Dr. YANG Rong, aged 62, is our chief scientific officer and an Executive Director. He was appointed as our Director on 24 November 2021 and re-designated as our Executive Director on 9 November 2023. Dr. Yang is primarily responsible for supervising and managing drug development of our Group.

Dr. Yang joined our Group in February 2016, serving as the head of research, responsible for development of ocular and dermal drugs. Dr. Yang was also a manager of ADS USA from January 2017 to January 2021 and was primarily responsible for the management and supervision of its business operation.

Dr. Yang has approximately 26 years of experience in drug development. Prior to joining our Group, from November 1999 to June 2015, he held the position of investigator research biology at Allergan Plc., where he was mainly responsible for drug development in ophthalmology, dermatology and neurosciences.

Dr. Yang obtained a doctorate degree in philosophy from the University of Wisconsin-Madison, the United States in December 1992. He received his master's degree in science from the University of Oklahoma, the United States in May 1989, and his bachelor's degree in science (biochemistry) from Peking University, China in July 1985.

Non-executive Directors

Dr. LI Jun Zhi, aged 62, is our Non-executive Director. He was appointed as our Director on 22 July 2021 and re-designated as our Non-executive Director on 9 November 2023. He is primarily responsible for supervising and managing drug development and strategic development of our Group.

Dr. Li co-founded our Group with our Directors Dr. Ni and Mr. Dinh in September 2015 when our Group's first principal operating subsidiary, Cloudbreak USA, was established. Dr. Li was one of the founding members of Cloudbreak USA, and was one of the managers of Cloudbreak USA from May 2017 to December 2021. Dr. Li also holds the following positions with the other members of our Group and has been primarily responsible for these companies' decision-making:

- director of Cloudbreak Guangzhou since May 2019;
- director of Cloudbreak Cayman since April 2020;
- supervisor of Cloudbreak Suzhou since September 2021;
- supervisor of Cloudbreak Yixing since September 2023; and
- supervisor of Cloudbreak Wenzhou since June 2024.

Dr. Li has extensive experience in pharmaceutical and nutraceutical sciences. Dr. Li had previously worked as a senior scientist at Cangen International, and as the president of Beijing Gingko Group (North America). Currently, he is the president of Scientific Living Inc. since November 2010.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Li had been an associate professor at the institute of medicinal biotechnology at Chinese Academy of Medical Sciences and China Union Medical College (中國醫學科學院中國協和醫科大學) (now known as Chinese Academy of Medical Sciences and Peking Union Medical College (中國醫學科學院北京協和醫學院)) in China from April 1994 to December 1994. He had also been a postdoctoral fellow and research associate at the University of Texas MD Anderson Cancer Center in the United States.

Dr. Li obtained a doctorate degree in medicine from the Chinese Academy of Medical Sciences and China Union Medical College (中國醫學科學院中國協和醫科大學) (now known as Chinese Academy of Medical Sciences and Peking Union Medical College (中國醫學科學院北京協和醫學院)), China, in October 1992. He obtained a master's degree and a bachelor's degree in medicine from the Lanzhou Medical College (蘭州醫學院) (now known as Lanzhou University Medical College (蘭州大學醫學部)), China, in December 1986 and August 1983, respectively.

Mr. CAO Xu, aged 42, is our Non-executive Director. He was appointed as our Director on 24 November 2021 and re-designated as our Non-executive Director on 9 November 2023, which was designated by Skketch Shine, a Sophisticated Investor of our Company with director appointment rights. He is primarily responsible for overall supervision of the development of our Group.

Mr. Cao has approximately 13 years of experience in investments and approximately four years of experience in the pharmaceutical industry. From July 2007 to April 2011, he held the position of lead healthcare engineer at the pharmaceutical engineering department at Bayer Technology and Engineering (Shanghai) Co., Ltd. (拜耳技術工程(上海)有限公司), where he was mainly responsible for process design and compliance certification of pharmaceutical projects. From May 2011 to June 2016, Mr. Cao served as a senior investment manager at Tianjin Binhai New Area Guiding Fund and Venture Capital Co., Ltd* (天津濱海新區創業風險投資引導基金有限公司), where he was responsible for overseeing venture capital and fund-of-funds. From July 2016 to December 2020, he became a deputy general manager at CCBI Wealth Management (Beijing) Co., Ltd.* (建銀國際產業基金管理(北京)有限公司). Currently, he is a partner at CDH Investment Co., Ltd.* (上海鼎暉百孚投資管理有限公司) since December 2020. Mr. Cao became acquainted with our Company through his designation as director in November 2021 by Skketch Shine, our Sophisticated Investor.

Mr. Cao obtained a master's degree in science in biochemical engineering from Zhejiang University, China in June 2007, and a bachelor's degree in biological engineering from Zhejiang University, China in June 2005. Mr. Cao also holds a fund practitioner qualification (基金從業資格) granted by the Asset Management Association of China (中國證券投資基金業協會) in May 2017.

Mr. XIA Zhidong, aged 47, is our Non-executive Director. He was appointed as our Non-executive Director on 26 June 2024, which was designated by Grand Diamond, a Sophisticated Investor of our Company with director appointment rights. He is primarily responsible for the overall supervision of the development of our Group.

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Mr. Xia has approximately 13 years of management experience. From January 2012 to August 2016, Mr. Xia served as the national commercial director of Wuhan Grand Pharmaceutical Group Sales Co., Ltd.* (武漢遠大製藥集團銷售有限公司) (an indirect non-wholly-owned subsidiary of Grand Pharma Group since December 2015), and has been subsequently appointed to serve as the legal representative and manager in December 2022. He has been the general manager of Xi'an Beilin Pharmaceutical Co., Ltd.* (西安碑林藥業股份有限公司) and Grand Pharmaceutical Huangshi Feiyun Pharmaceutical Co., Ltd.* (遠大醫藥黃石飛雲製藥有限公司), both of which are indirect non-wholly-owned subsidiaries of Grand Pharma Group, since July 2016 and December 2020, respectively. He also served as the assistant to the president of Grand Pharma (China) Co., Ltd.* (遠大醫藥(中國)有限公司), an indirect non-wholly-owned subsidiary of Grand Pharma Group, from April 2019 to May 2022, after which he has been appointed as the vice president from then to date. Mr. Xia became acquainted with our Company through his designation as director in June 2024 by Grand Diamond, our Sophisticated Investor.

Mr. Xia obtained a bachelor's degree in international trade from the Wuhan University of Technology (武漢理工大學) in China in June 2000.

Mr. Xia was the legal representative, executive director and general manager of the following dissolved company established in the PRC. The relevant details are as follows:

Company name	Nature of business before dissolution	Reason for dissolution	Current status and date of dissolution
Xi'an Beilin Biotechnology Co., Ltd.* (西安碑林生物科技股份有限公司)	Cultivation of Chinese herbal medicines	Cessation of business operation	Deregistered on 29 December 2016

Mr. Xia confirmed that (i) the company was solvent immediately prior to dissolution; (ii) there is no wrongful act on his part leading to the dissolution of the above company; (iii) he is not aware of any outstanding or potential claim that has been or will be made against him as a result of the dissolution of the above company; (iv) no misconduct or misfeasance had been involved in the dissolution of the above company; and (v) the above company he held directorship in was not involved in any non-compliance incidents and/or legal proceedings prior to its deregistration.

Independent Non-executive Directors

Mr. LAI Hin Wing Henry Stephen, aged 68, was appointed as our Independent Non-executive Director on 14 March 2025. Mr. Lai is mainly responsible for supervising and providing independent judgment to our Board.

Mr. Lai has over 40 years of experience in the legal industry. Mr. Lai is currently a partner and co-chairman of P. C. Woo & Co, a firm of solicitors and notaries in Hong Kong, and has been with the firm since 1980. He has experience in advising and handling IPO,

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general commercial and corporate work, merger and acquisition for listed companies, restructuring of companies and commercial documentations, cross-border joint ventures and financing business and loan transactions.

Mr. Lai received a Bachelor of Laws degree from the University of Hong Kong in November 1979. He was admitted as a solicitor in Hong Kong, England and Wales, and the State of Victoria, Australia in March 1982, August 1985, and March 1986, respectively. Mr. Lai is also a Notary Public, a China-Appointed Attesting Officer and a Civil Celebrant of Marriages in Hong Kong.

Mr. Lai also served in various public and private bodies. Mr. Lai is the immediate past chairman, and has acted as an honorary council member, fellow member and Chairman of the Corporate Governance Policies Committee of The Hong Kong Institute of Directors since July 2019, member of the Process Review Panel for the Securities and Futures Commission of Hong Kong from November 2018 to October 2024, member of the Hong Kong Professionals and Senior Executives Association since September 2012. He was appointed as a member of the Consultation Panel of the West Kowloon Cultural District Authority in March 2021, and the Board of Governors of The Hang Seng University of Hong Kong in April 2022. He is also currently a member of the Consents Committee of the Law Society of Hong Kong, member of the Association of China-Appointed Attesting Officers Limited Disciplinary Tribunal Panel, Chairman of Lock Tao Secondary School, member of the advisory board of the Hong Kong Aids Foundation Limited, a council legal adviser of the Chinese Artists Association of Hong Kong and Chairman of The Hong Kong Chinese Orchestra Limited. Formerly, he was a member of the Securities and Futures Appeals Tribunal from April 2015 to March 2021 and a member of the Resolution Compensation Tribunal from April 2018 to March 2024.

Mr. Lai has been a non-executive director of China Medical & HealthCare Group Limited (stock code: 0383) from November 2020 to October 2023, a non-executive director of Winfull Group Holdings Limited (stock code: 0183) since December 2011, an independent non-executive director of ANTA Sports Products Limited (stock code: 2020) since November 2020, and an independent non-executive director of China Resources Beer (Holdings) Company Limited (stock code: 291) since August 2022, all of which are listed on the Main Board of the Stock Exchange.

Mr. Lai was a director of a number of private companies which were incorporated in Hong Kong and dissolved by way of deregistration. The relevant details are as follows:

Company name	Nature of business before dissolution	Reason for dissolution	Current status and date of dissolution
E-Trader Limited (英企有限公司)	Property Investment	Cessation of business operation	Deregistered on 9 March 2007
Eversky Corporation Limited	Property Investment	Cessation of business operation	Deregistered on 6 September 2002
Mindway Enterprise Limited (思威企業有限公司)	Property Investment	Cessation of business operation	Deregistered on 15 July 2005

DIRECTORS AND SENIOR MANAGEMENT

Company name	Nature of business before dissolution	Reason for dissolution	Current status and date of dissolution
Smart Goal Enterprise Limited (駿成企業有限公司)	Property Investment	Cessation of business operation	Deregistered on 28 May 2004
Way China Limited	Property Investment	Cessation of business operation	Deregistered on 3 September 2004
Youth PVC-U (HK) Limited (魚峰塑鋼(香港)有限公司)	Trading	Cessation of business operation	Deregistered on 21 November 2003

Mr. Lai confirmed that (i) the above companies were solvent immediately prior to respective dissolutions; (ii) there is no wrongful act on his part leading to the respective dissolutions of the above companies; (iii) he is not aware of any outstanding or potential claim that has been or will be made against him as a result of the respective dissolutions of the above companies; (iv) no misconduct or misfeasance had been involved in the respective dissolutions of the above companies; and (v) the above companies that he held directorships in were not involved in any non-compliance incidents and/or legal proceedings prior to their respective deregistrations.

Mr. LIU Chung Mun, aged 65, was appointed as our Independent Non-executive Director on 14 March 2025. He is mainly responsible for supervising and providing independent judgment to our Board.

Mr. Liu has over 30 years of experience in providing audit and business advisory services in the mainland China, Hong Kong and Australia. Mr. Liu started his professional career with PricewaterhouseCoopers in Hong Kong and has also served in PwC Melbourne in the mid-1980s. Mr. Liu joined PricewaterhouseCoopers Zhong Tian LLP in November 1995, and he was admitted as a partner in July 1997 and retired in June 2020. During his years with PricewaterhouseCoopers Zhong Tian LLP from 1995 to 2020, Mr. Liu was a core member in the China assurance leadership team and a long-standing human capital partner in the assurance practice for over 10 years. During the same period, he also served as the Greater China automotive industry leader as well as Japanese business network leader of PricewaterhouseCoopers China.

Mr. Liu received his bachelor's degree in commerce from the University of Western Australia in Australia in April 1983. He has been a member of the Chartered Accountants Australia and New Zealand (previously the Institute of Chartered Accountants Australia) since March 1989, a fellow member of CPA Australia since April 2005, and a fellow member of the Hong Kong Institute of Certified Public Accountants since May 2010. He previously served as the president of CPA Australia North China Committee from 2005 to 2006, and is currently its council member.

Mr. Liu has been an independent non-executive director of Foran Energy Group Co., Ltd. (佛燃能源集团股份有限公司) a company listed on the Shenzhen Stock Exchange, stock code: 002911.SZ since November 2020; an independent non-executive director of Valuetronics Holdings Limited a company listed on the Singapore Stock Exchange, stock

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code: BN2.SI since August 2022; and an independent non-executive director of Guotai Junan International Holdings Limited (a company listed on the Main Board of the Stock Exchange, stock code: 1788) since October 2023.

Mr. Liu held the position of director of the following dissolved company incorporated in the British Virgin Islands. The relevant details are as follows:

Company name	Nature of business before dissolution	Reason for dissolution	Current status and date of dissolution
Prosperous Future Profits (BVI) Limited	Investment holding	Cessation of business operation	Struck-off in November 2012

Mr. Liu confirmed that (i) the company was solvent immediately prior to dissolution; (ii) there is no wrongful act on his part leading to the dissolution of the above company; (iii) he is not aware of any outstanding or potential claim that has been or will be made against him as a result of the dissolution of the above company; (iv) no misconduct or misfeasance had been involved in the dissolution of the above company; and (v) the above company he held directorship in was not involved in any non-compliance incidents and/or legal proceedings prior to its deregistration.

Ms. NIE Sijiang, aged 50, was appointed as our Independent Non-executive Director on 14 March 2025. She is mainly responsible for supervising and providing independent judgment to our Board.

Ms. Nie has approximately 26 years of experience in the healthcare industry, participating in drug development and supervising clinical trials. Ms. Nie worked at Guangzhou Novaken Pharmaceutical Co., Ltd* (廣州新濟藥業有限公司) as its vice president between December 2020 and March 2023, responsible for overseeing the management and business operations. She had also worked at Chengdu Kanghong Pharmaceutical Group Co., Ltd* (成都康弘藥業集團有限公司) from July 1998 to February 2020 with her last position as the district general manager of the market access department, where she was responsible for marketing and public affairs.

Ms. Nie has also held important roles in various associations, including the China Association of Traditional Chinese Medicine as the vice secretary of the Professional Committee on Pharmaco-economics* (中藥藥物經濟學專業委員會) from January 2013 to January 2017 and a member of the Professional Committee on Corporate and Hospital Pharmacy Management* (企業與醫院藥事管理專業委員會) from September 2014 to September 2018. She is currently a member of the management committee of the Heart-to-Heart Charity Fund for China Primary Health Care Foundation (中國初級衛生保健基金會) since February 2023, deputy director of the economic work committee of Chinese Peasants and Workers Democratic Party Guangzhou Committee* (中國農工民主黨廣州市委員會經濟工作委員會) since September 2021, and chief secretary and deputy director of the first council the CEIBS Alumni Healthcare Industry Association Guangdong-Hong Kong-Macau Greater Bay Area Branch* (中歐校友醫療健康產業協會粵港澳大灣區分會第一屆理事會) since August 2022.

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Ms. Nie obtained a master's degree in business administration from China Europe International Business School (中歐國際工商學院) in China in August 2021. She graduated from Beijing University of Chinese Medicine (北京中醫藥大學) with an undergraduate college diploma in Chinese medicine through night school in July 2005 and completed her postgraduate course of economic law at the School of Civil, Commercial and Economic Law in China University of Political Science and Law (中國政法大學) from October 2001 to October 2003. Ms. Nie also received her junior college diploma in pharmacy at West China University of Medical Sciences (華西醫科大學) (now known as West China Center of Medical Sciences of Sichuan University (四川大學華西醫學中心)) in China in June 2000.

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Our senior management is responsible for the day-to-day management of our daily business operations, implementation of our business strategies, risk management and internal control.

For details of **Dr. NI Jinsong**, **Mr. Van Son DINH** and **Dr. YANG Rong**, see “– Board of Directors” in this section.

Ms. CHAN Ching Chu, aged 57, is our chief financial officer since March 2022. She is primarily responsible for overseeing our Group's finance and operations, as well as formulating business plans of the Group for future development and maintaining financial position for sustainable growth. However, she has tendered her resignation on 3 May 2025 and will leave our Group starting 3 November 2025. Ms. Chan confirmed in writing that she has no claim against the Group and no disagreement with the Board.

Ms. Chan has extensive experience working at senior levels for international accounting firms and the Stock Exchange. Ms. Chan started her career in 1988 and was formerly a partner of Deloitte Touche Tohmatsu, KPMG and PricewaterhouseCoopers at different times of her career. She had led various capital market services group of these international accounting firms. Her experience in executing various types of capital market transactions spanned across various industries such as financial services, securities firms, consumer market, technology, media, conglomerate, property, services, energy, innovation and new economy sectors such as telecommunications, web advertising and biotech companies. She also served as the co-Head of the IPO team and Head of Accounting Affairs team of the Listing Division of The Stock Exchange of Hong Kong Limited.

Currently, Ms. Chan is a member of the Telecommunications Appeal Board of the HKSAR Government, Representative of Legal Services Consumers on the Costs Committee of the HKSAR Government, a member of the board of directors of the Hong Kong Academy for Gifted Education (HKAGE) and the chairperson of the Finance and General Affairs Committee of the HKAGE. Formerly she was a member of a number of governmental, professional and regulatory committees, including, among others, the Professional Services Advisory Committee of Hong Kong Trade Development Council, the Management Committee of Consumer Legal Action Fund and the Task Force on Alumni Engagement of Hang Seng University of Hong Kong Council, the Standing Committee on Legal Education and Training of the HKSAR Government, the Financial Reporting Advisory Panel of the Hong Kong Stock Exchange; the Dual Filing Advisory Group of the Securities and Futures

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Commission; the Policy Research Committee of the Financial Services Development Council; the Copyright Tribunal; the Hong Kong University of Science and Technology MBA Alumni Advisory Board; the Appeal Board on Closure Orders (Immediate Health Hazard); the Appeal Board Panel (Town Planning); the Mandatory Provident Fund Schemes Appeal Board; the Occupational Retirement Schemes Appeal Board; the Solicitors Disciplinary Tribunal Panel and various committees of the Hong Kong Institute of Certified Public Accountants including the Corporate Finance Committee, the Financial Accounting Standards Committee and the Professional Standard Monitoring Committee. She has been appointed as a member of the Asia Summit on Global Health 2025 Steering Committee.

Ms. Chan is a practising member of the Hong Kong Institute of Certified Public Accountants, and a fellow member of The Institute of Chartered Accountants in England and Wales. Ms. Chan obtained a master's degree in business administration from The Hong Kong University of Science and Technology.

Dr. Abu P ABRAHAM, aged 50, is our chief medical officer since June 2022. He is primarily responsible for the supervision and general management of clinical trials, employees, consultants and third parties providing clinical-related functions for our Group.

Dr. Abraham has approximately 15 years of pharmaceutical and clinical experience in ophthalmology and internal medicine. Prior to joining our Group, he joined Healthcare Communications Group as project manager in September 2009. He subsequently served as an independent contractor working in Amgen Inc. from April 2010 to October 2011 and in its global regulatory (affairs and safety) department from December 2011 until March 2012 when he joined AEROTEK SCIENTIFIC LLC and worked as a drug safety scientist (medical case evaluator) at Santen Inc. on a temporary basis until becoming an employee of Santen Inc. in September 2013, serving as a drug safety physician until June 2014. He became a director of global biomedical science from June 2014 to March 2016, and worked as the senior director and the head of global biomedical science at Santen Inc. from April 2016, where he was responsible for managing clinical science medical directors and overseeing the stages of clinical development for anterior segment, glaucoma, and retinal indications. He became the vice president for vitreous and retina therapeutic area Strategy at Santen Inc. in November 2018, where he managed teams of research scientists, clinical science intelligence director, translational research director and manager, and global development leaders and was responsible for the design and execution of global research and development strategy for retinal indications.

Dr. Abraham obtained his bachelor's degree in medicine and surgery from JJM Medical College, India in November 2004.

Ms. Elizabeth Sharon CAPAN, aged 43, is our chief patent officer and chief compliance officer since September 2022 and November 2023, respectively. She is primarily responsible for managing on our Group's patent portfolio, advising on intellectual property protection, and overseeing compliance matters of our Group, including reviewing and establishing compliance processes and procedures as well as investigating and monitoring identified non-compliance matters.

DIRECTORS AND SENIOR MANAGEMENT

Ms. Capan has over 16 years of experience in global intellectual property development and execution, as well as patent applications and prosecutions. Prior to joining our Group, she started her career in November 2007 as an U.S. patent examiner and was also an authorised PCT officer at the United States Patent and Trademark Office, where she was responsible for examining U.S. and PCT patent applications. From December 2008 to May 2009, she was a technical specialist at Hirshman Law Office. From 2010 to 2015, she served at 3M Company with last position as the intellectual property counsel, supporting business divisions globally. Thereafter, she worked in-house at corporations and handled intellectual properties matters, including having worked as an assistant chief patent counsel at Dynamics Inc. from March 2015 to December 2016, where she was responsible for patent applications, international prosecutions, as well as pitches and negotiations. In January 2017, she joined Fish & Richardson P.C. as an associate attorney, and has served in Minneapolis office in the United States, and Munich office in Germany until September 2019. From February 2020 to March 2021, she was a director and U.S. patent attorney at Advancing Innovation ESC AB, where she was responsible for providing U.S. legal services relating to intellectual property matters. From May 2021 to August 2022, she was the Patent Attorney at BASF, where she was responsible for supporting business units globally on intellectual property matters.

Ms. Capan was admitted to the United States Patent Bar in November 2009, and admitted as an attorney in Minnesota, the United States in May 2013.

Ms. Capan obtained her juris doctor degree (summa cum laude) at William Mitchell College of Law (now known as Mitchell Hamline School of Law), the United States in January 2013 and her bachelor's degrees in arts and science from the University of Pittsburgh, the United States in April 2004. Ms. Capan also obtained the certificate in compliance awarded by the International Compliance Association in November 2023.

Dr. FANG Wenkui Ken, aged 62, is our Chief Innovation Officer since September 2020. He is primarily responsible for developing pipelines, managing patent portfolio and assisting in fundraising, licensing activities.

Dr. Fang has over 20 years of experience in drug discovery. Prior to joining our Group, Dr. Fang worked at Allergan, Inc. from May 1998 to June 2015 as Scientist, Principle Chemistry, responsible for managing early drug discovery programs. Dr. Fang had been a major inventor of over 60 patents.

Dr. Fang obtained his doctor of philosophy degree (chemistry) from the University of Michigan, the United States in August 1997.

Directors' and Senior Management's Interests

Save as disclosed above, none of our Directors or senior management members has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this prospectus.

DIRECTORS AND SENIOR MANAGEMENT

Save as disclosed above, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors that needs to be brought to the attention of our Shareholders and there was no information relating to our Directors that is required to be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

As of the Latest Practicable Date, save for the interests in the Shares held by Dr. Ni, Mr. Dinh, Dr. Yang and Dr. Li, which are disclosed in “Statutory and General Information – C. Further Information about Directors and Substantial Shareholders” set out in Appendix IV to this prospectus, none of our Directors held any interest in the securities within the meaning of Part XV of the SFO.

As of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

JOINT COMPANY SECRETARIES

Mr. AU Thomas Tsz Ngai, is one of our joint company secretaries. He was appointed as our company secretary on 9 November 2023 and was re-designated as a joint company secretary on 14 March 2025, and is primarily responsible for the company secretarial matters of our Company. Mr. Au joined our Group in May 2023 as investment director. However, he has tendered his resignation on 26 March 2025 and will leave our Group with effect from 25 June 2025. Mr. Au confirmed that he has no claim against the Group and no disagreement with the Board. Ms. Fung Nga Fong will take over his duties in the capacity as our company secretary. For details of Ms. Fung Nga Fong, please refer to the paragraph below.

Mr. Au has over nine years of experience in auditing, accounting, financial management, corporate governance and internal control. Prior to joining our Group, from November 2013 to May 2023, Mr. Au worked at Ernst & Young in Hong Kong and in Shenzhen, with the last position held as a senior manager of the assurance department under Ernst & Young Hua Ming LLP Shenzhen Branch in the Greater Bay Area office.

Mr. Au obtained a bachelor’s degree in social science in economics from the University of New South Wales, Australia in December 2012. Mr. Au has been a member of the Hong Kong Institute of Certified Public Accountants since October 2021.

Ms. FUNG Nga Fong (馮雅芳) was appointed as a joint company secretary of our Company on 12 May 2025, and is primarily responsible for company secretarial matters of our Company. Ms. Fung joined our Group in April 2025 as financial controller, and is responsible for managing accounts and monitoring internal controls.

Ms. Fung has over 20 years of experience in audit, accounting, finance and company secretarial matters. Prior to joining our Group, Ms. Fung worked in audit roles in various private accounting firms, as well as in finance and/or company secretarial roles in various Hong Kong listed companies. Her last position was the company secretary of Xiwang Property Holdings Company Limited (stock code: 2088).

DIRECTORS AND SENIOR MANAGEMENT

Ms. Fung has been a member of the Hong Kong Institute of Certified Public Accountants since February 2008. Ms. Fung is a Chartered Secretary, a Chartered Governance Professional and an associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom.

KEY EMPLOYMENT TERMS

We normally enter into (i) an employment contract, and (ii) a confidentiality and non-disclosure agreement with our senior management members and other key personnel, and our staff is required to follow the corporate policies stated in our staff handbook. We normally enter into employment contract with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel, and the key policies in our staff handbook which our senior management and other key personnel are required to comply with.

Confidentiality

- *Scope of confidential information.* Confidential information includes but not limited to: information regarding patents, copyright, trade marks, software, domain names and all other intellectual property, trade secret information, documents, designs, sketches, drawings, models, methods, systems, prototypes, inventions, know-how, samples and properties thereof, biological and other materials, research, experimental work, pre-clinical and clinical testing information and results, data, engineering, contracts, customer and vendor lists, business forecasts, and other business and financial information, and include all copies, notes and records and all related information generated by the employee based on or arising out of any such confidential information during the course of his employment by the Company.
- *Confidential obligation.* The employee shall keep confidential information in confidence and shall not directly or indirectly (a) use the confidential information for any purpose other than performing his employment duties, or (b) reveal, report, publish, disclose or transfer any of the confidential information to any person or entity. The employee shall only disclose the confidential information to its directors, officers and employees solely on a need-to-know basis for the purpose of performing his employment duties.
- *Confidential period.* The confidentiality obligation shall continue to be in effect after the departure of the employee.

DIRECTORS AND SENIOR MANAGEMENT

Inventions

- *Acknowledgement.* The employee acknowledges that if he makes any invention whether patentable or not which relates to or is capable of being used in any business of the Company which the employee is or has been concerned to a material degree, employees must disclose to the Company without delay. All intellectual property rights in such invention shall vest absolutely in the Company which shall be entitled, so far as the law permits, to the exclusive use thereof.
- *Assignment of inventions.* The Company shall have all right, title, and interest in and for any and all of the copyright works or design originated, conceived, written or made by employees solely or with others during the period of their employment with the Company.

Non-competition clause

- *Non-competition obligation.* The employee shall not, without the prior written consent from the Company, directly or indirectly and whether alone or in conjunction with or on behalf of any other person and whether as principal, director, employee, agent, consultant, partner or otherwise during the term of his/her employment and within a reasonable period (no longer than one year) from the expiration or termination of relevant employment contract engage directly or indirectly in any work, employment, consulting or other services for remuneration of any kind for any other person or business entity whose products are with substantially similar indications as the existing products of the Company or its subsidiaries at the time of termination of the employment, or engage in any other activities which conflict with the obligations to the Company.

DIRECTORS' REMUNERATION

For the details of the service contracts that we have entered into with our Directors, see the section headed “Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 3. Particulars of service agreements and letters of appointment” set out in Appendix IV to this prospectus.

The aggregate amount of fees, salaries, wages and bonus, pension cost-defined contribution plan, other social security costs and housing benefits and share-based compensation expenses we paid to our Directors in respect of the years ended 31 December 2022, 2023 and 2024 were approximately US\$1.7 million, US\$11.6 million and US\$9.2 million, respectively. Further information on the remuneration of each Director during the Track Record Period is set out in Note 27 in the Accountant’s Report set out in Appendix I to this prospectus.

During the Track Record Period, no remuneration was paid to our Directors by our Group as an inducement to join or upon joining our Group. No compensation was paid or payable to our Directors, past Directors during the Track Record Period for the loss of office

DIRECTORS AND SENIOR MANAGEMENT

as director of any member of our Group or of any other office in connection with the management of the affairs of any member of our Group. None of our Directors waived any emoluments during the Track Record Period.

Under the arrangements currently in force, the aggregate amount of remuneration (including share-based payment and excluding any discretionary bonus which may be paid) payable by our Group to our Directors for the financial year ending 31 December 2025 is expected to be approximately US\$20.8 million.

For the years ended 31 December 2022, 2023 and 2024, the five highest paid individuals of our Group included three Directors, and the aggregate amount of fees, salaries, allowances and retirement benefits scheme contributions we paid to the highest paid individuals who are neither Directors nor chief executives of our Company were approximately US\$2.7 million, US\$5.2 million and US\$3.2 million, respectively.

During the Track Record Period, no remuneration was paid to the five highest paid individuals of our Company as an inducement to join or upon joining our Company. No compensation was paid or payable to such individuals during the Track Record Period for the loss of any office in connection with the management of the affairs of any member of our Company.

For the details of the RSUs, share awards or share options that we granted to our Directors, see the section headed “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus.

CORPORATE GOVERNANCE

We have established the following committees in our Board of Directors: an Audit Committee, a Remuneration Committee, and a Nomination Committee. The committees operate in accordance with terms of reference established by our Board of Directors.

Audit Committee

The Company has established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Code of Corporate Governance and Corporate Governance Report in Appendix C3 to the Listing Rules. The Audit Committee consists of three independent non-executive Directors, namely, Mr. Liu Chung Mun, Mr. Lai Hin Wing Henry Stephen and Ms. Nie Sijiang. Mr. Liu, being the chairman of the Audit Committee, holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the Audit Committee are to assist our Board of Directors by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Group, overseeing the audit process and performing other duties and responsibilities as assigned by our Board of Directors.

DIRECTORS AND SENIOR MANAGEMENT

Remuneration Committee

The Company has established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Code of Corporate Governance and Corporate Governance Report in Appendix C3 to the Listing Rules. The Remuneration Committee consists of three independent non-executive Directors, namely, Ms. Nie Sijiang, Mr. Lai Hin Wing Henry Stephen and Mr. Liu Chung Mun. Ms. Nie is the chairlady of the Remuneration Committee. The primary duties of the Remuneration Committee include, but are not limited to, the following: (i) making recommendations to the Board of Directors on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing the policy on such remuneration; (ii) determining the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by the Board of Directors from time to time.

Nomination Committee

The Company has established the Nomination Committee with written terms of reference in compliance with the Code of Corporate Governance and Corporate Governance Report in Appendix C3 to the Listing Rules. The Nomination Committee consists of three independent non-executive Directors, namely, Mr. Lai Hin Wing Henry Stephen, Mr. Liu Chung Mun and Ms. Nie Sijiang. Mr. Lai is the chairman of the Nomination Committee. The primary duties of the Nomination Committee include, without limitation, reviewing the structure, size and composition of the Board of Directors, assessing the independence of independent non-executive Directors and making recommendations to the Board of Directors on matters relating to the appointment of Directors.

Diversity

We are committed to promoting the culture of diversity in the Company. We have strived to promote diversity to the extent practicable by taking into consideration a number of factors in our corporate governance structure.

We have adopted the board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board in order to enhance the effectiveness of our Board. Pursuant to the board diversity policy, we seek to achieve Board diversity through the consideration of a number of factors, including but not limited to gender, age, race, language, cultural background, educational background, industry experience and professional experience. Our Directors have a balanced mix of knowledge and skills, including knowledge and experience in the areas of pharmaceutical and medical industry, business management, investment, finance, legal profession, auditing and accounting. They obtained degrees in various majors including biochemistry, biochemical engineering, business administration, medicine, commerce and law. Furthermore, the ages of our Board range from 41 to 66. We have also taken, and will continue to take steps to promote gender diversity at all levels of our Company, including but without limitation at the Board and the management levels. While we recognise that the gender diversity at the Board level can be improved given its current composition of predominantly male directors, we will continue to

DIRECTORS AND SENIOR MANAGEMENT

apply the principle of appointments based on merits with reference to our diversity policy as a whole. We aim to maintain the current gender ratio of our Board following Listing. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but not limited to at our Board and senior management levels. We will also ensure that there is gender diversity when recruiting staff at mid to senior level, as well as engage more resources in training more female staff with the aim of providing a pipeline of female senior management and potential successors to our Board going forward. It is our objective to maintain an appropriate balance of gender diversity with reference to the stakeholders' expectation and international and local recommended best practices.

Our Nomination Committee is delegated by our Board to be responsible for compliance with relevant codes governing board diversity under the Corporate Governance Code. After the Listing, our Nomination Committee will review the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy on an annual basis.

Corporate Governance Code

We aim to achieve high standards of corporate governance which are crucial to our development and safeguard the interests of our Shareholders. To accomplish this, we expect to comply with the Corporate Governance Code set out in Appendix C1 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules after the Listing.

Pursuant to code provision C.2.1 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between the chairman and the chief executive officer should be segregated and should not be performed by the same individual. We do not have a separate chairman and chief executive officer and Dr. Ni currently performs these two roles. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned above, Dr. Ni is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our chief executive officer. The Board also believes that vesting the roles of both chairman and chief executive officer in the same person has the benefit of (i) ensuring consistent leadership within our Group, (ii) enabling more effective and efficient overall strategic planning and execution of strategic initiatives of the Board, and (iii) facilitating the flow of information between the management and the Board for our Group. The Board considers that the balance of power and authority for the present arrangement will not be impaired and this structure will enable our Company to make and implement decisions promptly and effectively. Our Board will continue to review and consider splitting the roles of chairman of the Board and the chief executive officer of our Company at a time when it is appropriate by taking into account the circumstances of our Group as a whole.

DIRECTORS AND SENIOR MANAGEMENT

Compliance Adviser

We have appointed Fosun International Capital Limited as our Compliance Adviser pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including: (a) before the publication of any regulatory announcement, circular, or financial report; (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases; (c) where we propose to use the proceeds of the Global Offering in a manner different from that detailed in this prospectus or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this prospectus; and (d) where the Stock Exchange makes an inquiry to our Company under Rule 13.10 of the Listing Rules.

Pursuant to Rule 3A.24 of the Listing Rules, our Compliance Adviser will, on a timely basis, inform the Company of any amendment or supplement to the Listing Rules that are announced by the Stock Exchange. Our Compliance Adviser will also inform us of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of the appointment will commence on the Listing Date and is expected to end on the date on which our Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the Listing.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business and requires disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are neither our Single Largest Shareholders nor members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which they may hold directorships from time to time.

CONFIRMATION FROM OUR DIRECTORS

Rule 3.09D of the Listing Rules

Each of our Directors confirms that he or she (i) has obtained the legal advice referred to under Rule 3.09D of the Listing Rules in September, October, November 2023 or August 2024 (as the case may be), and (ii) understands his or her obligations as a director of a listed issuer under the Listing Rules.

DIRECTORS AND SENIOR MANAGEMENT

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) his or her independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) he or she has no past or present financial or other interest in the business of our Company or its subsidiaries or any connection with any core connected person of our Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect his or her independence at the time of his or her appointment.

RELATIONSHIP WITH SINGLE LARGEST SHAREHOLDERS

OVERVIEW

As of the Latest Practicable Date and immediately following the completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), our Company had and will have no controlling shareholder as defined under the Listing Rules. As of the Latest Practicable Date, Dr. Ni and Ms. Leng (spouse of Dr. Ni) were interested in an aggregate of 172,150,042 Ordinary Shares, representing approximately 22.18% of the total issued share capital of our Company. Dr. Ni and Ms. Leng's interest in our Company comprised: (i) 157,992,705 Ordinary Shares representing approximately 20.36% held through Water Lily Consultants; (ii) 3,900,219 Ordinary Shares representing approximately 0.50% held through Ni Legacy Trust; (iii) 5,288,139 Ordinary Shares representing approximately 0.68% held through Ice Tree LLC; (iv) 3,624,970 Ordinary Shares representing approximately 0.47% held through Ice Tree Consultants; and (v) 1,344,009 Ordinary Shares representing approximately 0.17% held through Leng Legacy Trust. Immediately following completion of the Share Conversion and Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), Dr. Ni and Ms. Leng will be interested in an aggregate of 172,150,042 Shares, representing approximately 20.52% of the enlarged share capital of our Company. Accordingly, Dr. Ni, Ms. Leng, Water Lily Consultants, Ni Legacy Trust, Ice Tree LLC, Ice Tree Consultants and Leng Legacy Trust are our Single Largest Shareholders upon Listing.

Confirmation

None of Dr. Ni, Ms. Leng and his/her close associates was, as of the Latest Practicable Date, interested in any business which competes, or is likely to compete, directly or indirectly, with the business of our Group.

INDEPENDENCE FROM OUR SINGLE LARGEST SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independent from our Single Largest Shareholders, after the Listing.

Management Independence

Our daily operational and management decisions are made collectively by our executive Directors and our senior management, with our Board having an overall supervision of our management. Our Board consists of three executive Directors, three non-executive Directors and three independent non-executive Directors. We believe that our Directors and senior management can independently perform their duties in our Company and we can operate independently from our Single Largest Shareholders, for the following reasons:

RELATIONSHIP WITH SINGLE LARGEST SHAREHOLDERS

- each of our Directors is aware of his/her fiduciary duties as a director of our Company which requires, among other things, that he/she acts for the benefit and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his/her personal interest;
- in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and Dr. Ni, Ms. Leng or his/her close associates, the interested Director(s) shall abstain from voting at the relevant Board meetings of our Company in respect of such transactions and shall not be counted in the quorum;
- our Board has a balanced composition of executive Directors and independent non-executive Directors which ensures the independence of our Board in making decisions affecting our Company. Specifically, (a) our independent non-executive Directors are not associated with Dr. Ni, Ms. Leng or his/her close associates; (b) our independent non-executive Directors account for one-third of the Board; and (c) our independent non-executive Directors individually and collectively possess the requisite knowledge and experience as independent directors of listed companies and will be able to provide professional and experienced advice to our Company. In conclusion, our Directors believe that our independent non-executive Directors are able to bring impartial and sound judgment to the decision-making process of our Board and protect the interest of our Company and our Shareholders as a whole; and
- we will establish corporate governance measures and adopt sufficient and effective control mechanisms to manage conflicts of interest, if any, between our Group and Dr. Ni, Ms. Leng and his/her close associates, which would support our independent management. For details, see “– Corporate Governance Measures” in this section.

Having considered the above factors, our Directors are satisfied that they are able to perform their managerial roles in our Company independently, and our Directors are of the view that we are capable of managing our business independently from Dr. Ni, Ms. Leng and his/her close associates after the Listing.

Operational Independence

Our Group holds all the relevant material intellectual property rights, licenses, qualifications and permits required for conducting our Group’s business. Our Group has sufficient capital, facilities and employees to operate our business independently from Dr. Ni, Ms. Leng and his/her close associates. We have our own accounting and financial department, human resources and administration department, internal control department and technology department. We have also established a set of internal control procedures and adopted corporate governance practices to facilitate the effective operation of our business.

RELATIONSHIP WITH SINGLE LARGEST SHAREHOLDERS

We believe that we are capable of carrying on our business independently of Dr. Ni, Ms. Leng and his/her close associates. Our Directors confirmed that our Group would be able to operate independently from Dr. Ni, Ms. Leng and his/her close associates after the Listing.

Financial Independence

Our Group has an independent internal control, accounting and financial management system as well as an independent finance department which makes financial decisions according to our Group's own business needs. Our Group's accounting and finance functions are independent of Dr. Ni, Ms. Leng and his/her close associates.

In addition, we have independent access to third party financing and our Group does not rely on Dr. Ni, Ms. Leng or his/her close associates for financial assistance. Our Directors confirm that, as of the Latest Practicable Date, there were no subsisting loans, guarantees or pledges provided by Dr. Ni, Ms. Leng or his/her close associates to our Group.

Based on the aforesaid, our Directors believe that we have the ability to conduct our business independently from Dr. Ni, Ms. Leng and his/her close associates from a financial perspective and are able to maintain financial independence from them.

CORPORATE GOVERNANCE MEASURES

Our Directors recognise the importance of good corporate governance to protect the interest of our Shareholders. We would adopt the following corporate governance measures to manage potential conflict of interests between our Group and Dr. Ni, Ms. Leng and his/her close associates:

- (a) where a Board meeting is held for the matters in which a Director has a material interest, such Director shall abstain from voting on the relevant resolutions and shall not be counted in the quorum for the voting;
- (b) in the event that our independent non-executive Directors are requested to review any conflict of interest between our Group and Dr. Ni, Ms. Leng and his/her close associates, Dr. Ni shall provide the independent non-executive Directors with all necessary information and our Company shall disclose the decisions of the independent non-executive Directors either in its annual reports or by way of announcements;
- (c) our Directors (including the independent non-executive Directors) will seek independent and professional opinions from external advisers at our Company's cost as and when appropriate in accordance with the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules;
- (d) any transactions between our Company and its connected persons shall be in compliance with the relevant requirements of Chapter 14A of the Listing Rules, including the announcement, annual reporting and independent shareholders' approval requirements (if applicable) under the Listing Rules;

RELATIONSHIP WITH SINGLE LARGEST SHAREHOLDERS

- (e) we have appointed Fosun International Capital Limited as our compliance adviser, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including various requirements relating to directors' duties and corporate governance.

Based on above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and Dr. Ni, Ms. Leng and his/her close associates and/or other Directors to protect minority Shareholders' rights after the Listing.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the Global Offering and assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements, the following persons will have interests and/or short positions (as applicable) in the Shares or underlying shares of our Company, which would be required to be disclosed to us and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO or will, directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at the general meetings of the Company or any other members of the Group:

Interests and/or short positions in the shares of our Company

Name of substantial shareholder	Nature of interest	Number of Shares interested as of the date of this prospectus	Approximate percentage of shareholding as of the date of this prospectus	Number of Shares interested upon completion of the Global Offering ⁽¹²⁾	Approximate percentage of shareholding upon completion of the Global Offering ⁽¹²⁾
Dr. Ni	Interest in a controlled corporation ⁽²⁾ , founder of a discretionary trust ⁽³⁾ , interest of spouse ⁽⁴⁾	245,235,661 Shares (L)	31.60%	245,235,661 Shares (L)	29.23%
Water Lily Consultants	Beneficial owner	221,149,197 Shares (L)	28.50%	221,149,197 Shares (L)	26.36%
Ms. Leng	Interest in a controlled corporation ⁽⁵⁾ , founder of a discretionary trust ⁽⁶⁾ , interest of spouse ⁽⁴⁾	245,235,661 Shares (L)	31.60%	245,235,661 Shares (L)	29.23%
Bright Future Pharmaceutical Laboratories Ltd.	Beneficial owner ⁽⁷⁾	95,489,794 Shares (L)	12.30%	95,489,794 Shares (L)	11.38%
Mr. Dinh	Interest in a controlled corporation ⁽⁸⁾ , founder of a discretionary trust ⁽⁹⁾	67,273,176 Shares (L)	8.67%	67,273,176 Shares (L)	8.02%
VD&TL	Beneficial owner	65,329,167 Shares (L)	8.42%	65,329,167 Shares (L)	7.79%

SUBSTANTIAL SHAREHOLDERS

Name of substantial shareholder	Nature of interest	Number of Shares interested as of the date of this prospectus	Approximate percentage of shareholding as of the date of this prospectus	Number of Shares interested upon completion of the Global Offering ⁽¹²⁾	Approximate percentage of shareholding upon completion of the Global Offering ⁽¹²⁾
Skketch Shine Limited	Beneficial owner ⁽¹⁰⁾	49,634,271 Shares (L)	6.40%	49,634,271 Shares (L)	5.92%
Yicun Holdings Limited	Beneficial owner ⁽¹¹⁾	46,881,393 Shares (L)	6.04%	46,881,393 Shares (L)	5.59%

Notes:

- (1) The letter “L” denotes a long position in the shareholder’s interest in the share capital of our Company.
- (2) Water Lily Consultants has a long position of 221,149,197 Shares. Water Lily Consultants is wholly-owned by Dr. Ni. Therefore, Water Lily Consultants is a controlled corporation of Dr. Ni, hence Dr. Ni is deemed to be interested in the same number of Shares that Water Lily Consultants is interested in under the SFO.

Water Lily Consultants is entitled to receive up to 63,156,492 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

- (3) Ni Legacy Trust has a long position of 3,900,219 Shares. Ni Legacy Trust is a discretionary family trust established by Dr. Ni for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Dr. Ni’s family members and charities independent of Dr. Ni. IconTrust, LLC is the trustee of Ni Legacy Trust. Therefore, Dr. Ni is interested in the same number of Shares that are held by IconTrust, LLC under Ni Legacy Trust under the SFO.
- (4) Ms. Leng is the spouse of Dr. Ni and is therefore deemed to be interested in the same number of Shares that Ms. Leng is interested in under the SFO.
- (5) Each of Ice Tree LLC and Ice Tree Consultants has a long position of 15,217,266 and 3,624,970 Shares, respectively. Each of Ice Tree LLC and Ice Tree Consultants is wholly-owned by Ms. Leng. Therefore, Ice Tree LLC and Ice Tree Consultants are controlled corporations of Ms. Leng, hence Ms. Leng is deemed to be interested in the same number of Shares that Ice Tree LLC and Ice Tree Consultants are interested in under the SFO.

Ice Tree LLC is entitled to receive up to 9,929,127 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

- (6) Leng Legacy Trust has a long position of 1,344,009 Shares. Leng Legacy Trust is a discretionary family trust established by Ms. Leng for estate planning and controlled by her by virtue of being settlor and protector. The beneficiaries are Ms. Leng’s family members and charities independent of Ms. Leng. IconTrust, LLC is the trustee of Leng Legacy Trust. Therefore, Ms. Leng is interested in the same number of Shares that are held by IconTrust, LLC under Leng Legacy Trust under the SFO.
- (7) Bright Future is owned as to 65% by Chan Chak Yeung and 35% by Wong Cheong Moon. Therefore Bright Future is a controlled corporation of Chan Chak Yeung, Wong Cheong Moon and Chan Chak Yeung and Wong Cheong Moon are deemed to be interested in the same number of Shares that Bright Future is interested in under the SFO.

SUBSTANTIAL SHAREHOLDERS

- (8) VD&TL has a long position of 65,329,167 Shares. VD&TL is wholly-owned by Mr. Dinh. Therefore, VD&TL is a controlled corporation of Mr. Dinh, hence Mr. Dinh is deemed to be interested in the same number of Shares that VD&TL is interested in under the SFO.

VD&TL is entitled to receive up to 9,929,127 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

- (9) Dinh Legacy Trust has a long position of 1,944,009 Shares. Dinh Legacy Trust is a discretionary family trust established by Mr. Dinh for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Mr. Dinh's family members and charities independent of Mr. Dinh. IconTrust, LLC is the trustee of Dinh Legacy Trust. Therefore, Mr. Dinh is interested in the same number of Shares that are held by IconTrust, LLC under Dinh Legacy Trust under the SFO.
- (10) Skketch Shine Limited is directly held by two private equity funds, both of which are managed by CDH Wealth Management Company Limited and have the same general partner, CDH China HF Holdings Company Limited.
- (11) Yicun Holdings Limited is controlled by Shanghai Xucun Enterprise Management Consulting Partnership (Limited Partnership)* (上海絮村企業管理諮詢合夥企業(有限合夥)), whose general partner is Jiangyin Huaxicun Investment Co., Ltd.* (江陰華西村投資有限公司), which is wholly-owned by Yicun Capital Co., Ltd.* (一村資本有限公司), which is in turn ultimately controlled by various local branches of the State-owned Assets Supervision and Administration Commission of the PRC.
- (12) Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), have interests or short positions in Shares or underlying Shares which would fall to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.

SHARE CAPITAL

AUTHORISED AND ISSUED SHARE CAPITAL

The following is a description of the authorised and issued share capital of our Company in issue and to be issued as fully paid prior to and immediately following the completion of the Global Offering.

As of the Latest Practicable Date, our authorised share capital was US\$100,000 divided into 1,000,000,000 shares, consisting of: (i) 358,205,597 Class A Ordinary Shares; (ii) 152,484,600 Class B Ordinary Shares; (iii) 183,646,804 Class C Ordinary Shares; (iv) 8,873,587 Series A Preferred Shares; (v) 81,707,570 Series B Preferred Shares; and (vi) 215,081,842 Series C Preferred Shares, with par value of US\$0.0001 each.

As of the Latest Practicable Date, our issued share capital consisted of: (i) 139,254,898 Class A Ordinary Shares; (ii) 152,484,600 Class B Ordinary Shares; (iii) 183,646,804 Class C Ordinary Shares; (iv) 8,873,587 Series A Preferred Shares; (v) 81,707,570 Series B Preferred Shares; and (vi) 210,118,415 Series C Preferred Shares, of par value of US\$0.0001 each.

Each of the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares will be converted into one Share on a 1:1 basis by way of re-designation and re-classification upon Listing.

Assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements, the share capital of our Company immediately after the Global Offering will be as follows:

Issued share capital		Aggregate par value (US\$)	Approximate % to total issued share capital
776,085,874	Shares in issue as at the date of this prospectus (assuming all Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares and Preferred Shares are converted into ordinary Shares on a 1:1 basis)	77,608.59	92.78%
2,225,000	Shares to be issued pursuant to RSUs that immediately become vested and issued as shares upon the Listing pursuant to the Equity Incentive Arrangements	2,225.00	0.27%
60,582,000	Shares to be issued under the Global Offering	6,058.20	7.22%
<u>838,892,874</u>	Total	<u>83,889.28</u>	<u>100%</u>

SHARE CAPITAL

ASSUMPTION

The above table assumes that the Global Offering becomes unconditional and the Shares are issued pursuant to the Global Offering. The above table does not take into account any Shares which may be further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme (except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), or any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase shares as described in “Statutory and General Information – A. Further Information about our Group – 4. Resolutions of the Shareholders of our Company dated 14 March 2025” set out in Appendix IV to this prospectus.

RANKING

The Offer Shares are ordinary shares in the share capital of our Company and will rank equally in all respects with all Shares in issue or to be issued as set forth in the above table, and will qualify and rank in full for all dividends or other distributions declared, made or paid after the date of this prospectus.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Our Company has only one class of Shares, namely ordinary Shares, each of which carries the same rights as the other Shares. Pursuant to the Cayman Companies Act and the terms of the Memorandum of Association and the Articles of Association, our Company may from time to time by ordinary resolution of Shareholders (i) increase its share capital; (ii) consolidate and divide its share capital into Shares of larger amount; (iii) sub-divide its Shares into shares of smaller amount; and (iv) cancel any shares which have not been taken. In addition, our Company may subject to the provisions of the Cayman Companies Act reduce its share capital or any undistributable reserve by its shareholders passing a special resolution. For more details, see “Summary of the Constitution of the Company and the Company Laws of the Cayman Islands – 2. Articles of Association – 2.1 Shares – (c) Alteration of Capital” set out in Appendix III to this prospectus.

GENERAL MANDATE TO ISSUE SHARES

Subject to the Global Offering becoming unconditional, our Directors have been granted general unconditional mandates to issue and repurchase our Shares.

For further details on this general mandate, see “Statutory and General Information – A. Further Information about our Group – 4. Resolutions of the Shareholders of our Company dated 14 March 2025” set out in Appendix IV to this prospectus.

EQUITY INCENTIVE ARRANGEMENTS

We have adopted the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, the principal terms of which are summarised in “Statutory and General Information – D. Equity Incentive Arrangements” set out in Appendix IV to this prospectus. Under the

SHARE CAPITAL

Equity Incentive Arrangements, an aggregate of 191,490,750 Shares have been reserved for grant (in whatever form). The number of Shares to be further issued under the Equity Incentive Arrangements shall not exceed 164,106,063 Shares, representing approximately 21.15% and 19.56% in the total issued Shares as of the Latest Practicable Date and upon Listing (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), respectively. The aggregate number of Shares underlying the Post-IPO Equity Incentive Plan will not exceed 10% of the total number of issued Shares as of the Listing Date (excluding any Shares which may be further issued pursuant to the Equity Incentive Arrangements, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements) without Shareholders' approval, being 83,889,287 Shares.

CORNERSTONE INVESTORS

THE CORNERSTONE PLACING

We have entered into cornerstone investment agreements (each a “**Cornerstone Investment Agreement**”, and together the “**Cornerstone Investment Agreements**”) with the cornerstone investors set out below (each a “**Cornerstone Investor**”, and together the “**Cornerstone Investors**”), pursuant to which the Cornerstone Investors have agreed to, subject to certain conditions, subscribe at the Offer Price for such number of Offer Shares (rounded down to the nearest whole board lot of 500 Shares) that may be subscribed for with an aggregate amount of US\$22.80 million (equivalent to approximately HK\$178.98 million) (the “**Cornerstone Placing**”).

At the Offer Price of HK\$10.10, the total number of Offer Shares to be subscribed by the Cornerstone Investors would be 17,720,000 Offer Shares, representing approximately 29.25% of the Offer Shares pursuant to the Global Offering and 2.11% of the number of issued Shares upon completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).

Our Company is of the view that, the Cornerstone Placing will help raise the profile of our Company and signify that such investors have confidence in our business and prospect. Our Company became acquainted with each of the Cornerstone Investors through introduction by one of our existing Shareholders or the Underwriters.

The Cornerstone Placing will form part of the International Offering and the Cornerstone Investors will not subscribe for any Offer Shares under the Global Offering (other than pursuant to the Cornerstone Investment Agreements). The Offer Shares to be subscribed by the Cornerstone Investors will carry the same rights in all respects with the fully paid Shares in issue upon completion of the Global Offering and will be counted towards the public float of the Company under Rule 8.08 of the Listing Rules and in compliance with the requirement under Rule 8.08 of the Listing Rules. Such Offer Shares will not be counted towards the public float of our Company for the purpose of Rule 18A.07 of the Listing Rules. Immediately following the completion of the Global Offering, (i) none of the Cornerstone Investors or their close associates will become a substantial shareholder of our Company; (ii) none of the Cornerstone Investors or their close associates will have any Board representation in our Company. Other than a guaranteed allocation of the relevant Offer Shares at the Offer Price, the Cornerstone Investors do not have any preferential rights in the Cornerstone Investment Agreements compared with other public Shareholders.

To the best knowledge of our Company after making reasonable enquiries, (i) each of the Cornerstone Investors is an Independent Third Party; (ii) none of the Cornerstone Investors is accustomed to take instructions from our Company, our Directors, chief executive of our Company, senior management of our Company, Single Largest Shareholders, existing Shareholders or any of their subsidiaries or their respective close associates in relation to the acquisition, disposal, voting, or other disposition of Offer Shares; and (iii) none of the subscription of the relevant Offer Shares by any of the Cornerstone Investors is financed by our Company, our Directors, chief executive of our Company, senior management of our Company, Single Largest Shareholders, substantial Shareholders, existing Shareholders or any of their subsidiaries or any of their respective close associates.

CORNERSTONE INVESTORS

As confirmed by each of the Cornerstone Investors, their subscription under the Cornerstone Placing would be financed by their own internal resources. Each of the Cornerstone Investors has confirmed that all necessary approvals have been obtained with respect to the Cornerstone Placing and that no specific approval from any stock exchange (if relevant) or its shareholders is required for the relevant cornerstone investment. There are no side arrangements or agreements between our Company and the Cornerstone Investors or any benefit, direct or indirect, conferred on the Cornerstone Investors by virtue of or in relation to the Listing, other than a guaranteed allocation of the relevant Offer Shares at the Offer Price.

The total number of Offer Shares to be subscribed by the Cornerstone Investors may be affected by reallocation of the Offer Shares between the International Offering and the Hong Kong Public Offering in the event of over-subscription under the Hong Kong Public Offering as described in the paragraph headed “Structure of the Global Offering – The Hong Kong Public Offering – Reallocation” in this prospectus. Details of the actual number of Offer Shares to be allocated to the Cornerstone Investors will be disclosed in the allotment results announcement of our Company to be published on or around 2 July 2025.

All of the Cornerstone Investors have confirmed that they have sufficient funds to settle the investment amounts and they will pay and settle in full for the relevant Offer Shares that they have subscribed before dealings in the Offer Shares commence on the Stock Exchange. There will be no delayed delivery of the Offer Shares and no deferred settlement of payment of the investment amounts for all of the Cornerstone Investors under the Cornerstone Investment Agreements.

THE CORNERSTONE INVESTORS

The information about our Cornerstone Investors set forth below has been provided by our Cornerstone Investors in connection with the Cornerstone Placing. None of the Cornerstone Investors is a listed company or a subsidiary of a listed company.

Wealth Strategy Holding Limited

Wealth Strategy Holding Limited (“WSH”) is an investment holding company incorporated in Hong Kong on 15 October 2014, which is indirectly wholly owned by Mr. Kung Hung Ka.

Mr. Kung is a highly reputable angel investor and entrepreneur with remarkable contributions and substantial experience in the areas of life sciences, healthcare and grand health as well as telecommunication industries in the PRC, including his investment in C-MER Eye Care Holdings Limited, a company listed on the Main Board of the Stock Exchange (stock code: 3309), in December 2022, and in QuantumPharm Inc., a company listed on the Main Board of the Stock Exchange (stock code: 2228), in June 2024. He and his family ranked 24th in Forbes’ China’s 100 Richest 2023. He is currently the chairman of the board of Vcanbio Cell & Gene Engineering Corp., Ltd., a company principally engaged in the preparation, detection and storage of stem cells, with its shares listed on Shanghai Stock Exchange (stock code: 600645.SH).

CORNERSTONE INVESTORS

We became acquainted with WSH through the introduction by one of our existing Shareholders. To the best knowledge of our Company, each of WSH and Mr. Kung is an Independent Third Party.

The Reynold Lemkins Group (Asia) Limited

The Reynold Lemkins Group (Asia) Limited (“**Reynold Lemkins**”) is an investment institution established in Hong Kong in 2020. Reynold Lemkins is principally engaged in investment activities in capital markets, and is committed to providing long-term value to and industrialisation of its invested companies from a long-term perspective. Reynold Lemkins is wholly owned by Mr. Liu Haoran (劉浩然). Mr. Liu is currently the President and Chief Investment Officer of Reynold Lemkins, responsible for strategic investments and risk management.

We became acquainted with Reynold Lemkins through the introduction by one of the Underwriters. To the best knowledge of our Company, each of Reynold Lemkins and Mr. Liu is an Independent Third Party.

The table below sets forth details of the Cornerstone Placing:

Based on the Offer Price of HK\$10.10

Cornerstone Investor	Total investment amount ⁽³⁾	Number of Offer Shares to be subscribed ⁽¹⁾⁽²⁾	% of total number of International Offer Shares	% of total number of Offer Shares	% of total number of issued Shares upon completion of the Global Offering
WSH	US\$20 million	15,544,000	28.51%	25.66%	1.85%
Reynold Lemkins	<u>US\$2.80 million</u>	<u>2,176,000</u>	<u>3.99%</u>	<u>3.59%</u>	<u>0.26%</u>
Total	<u>US\$22.80 million</u>	<u>17,720,000</u>	<u>32.50%</u>	<u>29.25%</u>	<u>2.11%</u>

Notes:

- (1) Calculated based on the exchange rate set out in the section headed “Information about this Prospectus and the Global Offering – Exchange Rate Conversion” in this prospectus for illustrative purpose. The actual number of Offer Shares to be subscribed may change due to the exchange rate to be used as prescribed in the relevant Cornerstone Investment Agreements.
- (2) Subject to rounding down to the nearest whole board lot of 500 Shares.
- (3) The total investment amount exclusive of brokerage, SFC transaction levy, Stock Exchange trading fee and AFRC transaction levy.

CORNERSTONE INVESTORS

CLOSING CONDITIONS

The obligation of the Cornerstone Investors to acquire the Offer Shares under the Cornerstone Investment Agreements is subject to, among other things, the following closing conditions:

- (a) the Underwriting Agreements being entered into and having become effective and unconditional (in accordance with their respective original terms or as subsequently waived or varied by agreement of the parties thereto) by no later than the time and date as specified in the Underwriting Agreements, and neither the Underwriting Agreements having been terminated;
- (b) the Offer Price having been agreed upon between our Company and the Overall Coordinators (for themselves and on behalf of the Underwriters);
- (c) the Listing Committee of the Stock Exchange having granted the approval for the listing of, and permission to deal in, the Shares (including the Shares under the Cornerstone Placing as well as other applicable waivers and consents) and such approval, permission, waivers or consents having not been revoked prior to the commencement of dealings in the Shares on the Stock Exchange;
- (d) no laws shall have been enacted or promulgated by any governmental authority which prohibits the consummation of the transactions contemplated in the Global Offering or the Cornerstone Investment Agreements, and there shall be no orders or injunctions from a court of competent jurisdiction in effect precluding or prohibiting consummation of such transactions; and
- (e) the respective representations, warranties, undertakings, confirmations and acknowledgements of the Cornerstone Investors under their respective Cornerstone Investment Agreements are (as of the date of the Cornerstone Investment Agreements) and will be (as of the date of closing of the Cornerstone Investment Agreements) accurate and true in all respects and not misleading and that there is no material breach of the Cornerstone Investment Agreements on the part of the Cornerstone Investors.

RESTRICTIONS ON THE CORNERSTONE INVESTORS

Each of the Cornerstone Investors has agreed that without the prior written consent of each of our Company, the Joint Sponsors, the Overall Coordinators and the Joint Global Coordinators, it will not, and will cause its affiliates not to, whether directly or indirectly, at any time during the period commencing from (and inclusive of) the Listing Date and ending on (and inclusive of) the date falling six months after the Listing Date (the “**Lock-up Period**”), directly or indirectly (i) dispose of, in any way, any of the Offer Shares it has subscribed for pursuant to the relevant Cornerstone Investment Agreement, including any securities convertible into or exchangeable or exercisable for or that represent the right to receive any of the forgoing securities; (ii) agree, enter into an agreement or publicly announce an intention to enter into such transaction described in (i); (iii) allow itself to undergo a change of control (as defined in the Takeovers Code) at the level of its ultimate

CORNERSTONE INVESTORS

beneficial owner; or (iv) enter into any transactions directly or indirectly with the same economic effect as any aforesaid transaction, save for certain limited circumstances, such as transfers to any of its wholly-owned subsidiaries which will be bound by the same obligations of such Cornerstone Investor, including the Lock-up Period restriction. In the event of a disposal of any Offer Shares it has subscribed for pursuant to the relevant Cornerstone Investment Agreement at any time after the Lock-up Period, the relevant Cornerstone Investor shall notify our Company, the Overall Coordinators and the Joint Sponsors in writing prior to the proposed disposal and shall ensure that (a) such disposal will comply with all applicable laws; and (b) the relevant Cornerstone Investor will use its best endeavours to ensure that the disposal will not create a disorderly and false market in the Shares.

FINANCIAL INFORMATION

You should read the following discussion in conjunction with the consolidated financial statements of our Group included in the Accountant's Report and the notes thereto included in Appendix I to this prospectus, and the selected historical financial information and operating data included elsewhere in this prospectus. The consolidated financial statements of our Group have been prepared in accordance with IFRS.

Our historical results do not necessarily indicate results expected for any future periods. The following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results may differ from those anticipated in these forward-looking statements as a result of any number of factors, including those set out in "Forward-looking Statements" and "Risk Factors" in this prospectus.

OVERVIEW

We are an innovation-driven clinical-stage ophthalmology biotechnology company dedicated to the development of novel and differentiated treatments. We are committed to the in-house discovery, development and commercialisation of first-in-class and best-in-class ophthalmic therapies to address global unmet medical needs.

We currently have no drugs approved for commercial sale and have not generated any revenue from drug sales. We only generated revenue from a one-time upfront payment of US\$10.0 million made by Santen to us under the Santen Licensing Agreement (see "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen" for details). We have never been profitable and have incurred operating losses in each year since our inception. Our operating losses were US\$23.0 million, US\$37.2 million and US\$36.6 million for the years ended 31 December 2022, 2023 and 2024, respectively. Substantially all of our operating losses are resulted from R&D expenses, and general and administrative expenses.

We expect to incur significant expenses and operating losses for at least the next several years as we further progress our pre-clinical R&D initiatives, continue the clinical development of, and seek regulatory approvals for, our drug candidates, commercialise our products if any of them receives regulatory approvals, and add personnel necessary to operate our business. Subsequent to the Listing, we also expect to incur costs associated with operating as a public company. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialisation of our drug candidates if they receive approvals.

BASIS OF PREPARATION

Immediately prior to the Group Restructuring, our Group's business was held by and mainly conducted through Cloudbreak USA and its subsidiaries. On 24 November 2021, our Company and Cloudbreak USA underwent the Share Swap as part of the Group Restructuring to establish our Company as the holding company of all Group companies, as a result of which the then shareholders of Cloudbreak USA would become shareholders of our Company. Upon completion of the Share Swap, Cloudbreak USA became directly wholly-owned by our Company. For details, see "History, Development and Corporate

FINANCIAL INFORMATION

Structure – Major Shareholding Changes of Our Group – 5. Our Company – (d) Share swap with Cloudbreak USA and allotment of shares in connection with the Series B Equity Incentive Arrangement” in this prospectus.

Our Company has not been involved in any other business prior to the Group Restructuring that met the definition of a business. The Group Restructuring is merely a recapitalisation of Cloudbreak USA, with no change in management and the ultimate owners of our Group remain the same. Accordingly, our Group resulting from the Group Restructuring is regarded as a continuation of the business held under Cloudbreak USA and, for the purpose of this prospectus, the historical financial information of our Group for the Track Record Period has been prepared and presented as a continuation of the consolidated financial statements of Cloudbreak USA, and its subsidiaries, with the assets and liabilities of our Group recognised and measured at the carrying amounts under the consolidated financial statements of Cloudbreak USA throughout the periods presented. Inter-company transactions, balances, and unrealised gains or losses on transactions between group companies are eliminated on consolidation.

The historical financial information has been prepared in accordance with all applicable IFRS issued by the International Accounting Standards Board, or IASB. The historical financial information has been prepared under the historical cost convention, as modified by the revaluation of convertible redeemable preferred shares, other financial liabilities at fair value through profit or loss and derivative financial instruments, which are carried at fair value. All IFRSs effective for the accounting period commencing from 1 January 2022, together with the relevant transitional provisions, have been adopted by us in the preparation of the historical financial information throughout the Track Record Period. The historical financial information has been prepared on a going concern basis. See Note 2.1 to the Accountant’s Report set out in Appendix I to this prospectus for further details.

FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our business, financial position and results of operations have been, or may expected to be in the future, significantly affected by a number of factors, many of which may be beyond our control. A discussion of certain of these key factors is set out below.

Regulatory Approvals and Commercialisation of our Drug Candidates

Our business and results of operations depend on our ability to commercialise our drug candidates. We had a pipeline of eight drug candidates as of the Latest Practicable Date, comprising four clinical-stage drug candidates and four pre-clinical stage drug candidates. Our two Core Products CBT-001 and CBT-009 are in more advanced clinical development stage, while other drug candidates are in relatively earlier stage. While we currently have no drugs approved for commercial sales and have not generated any revenue from drug sales, we expect to commercialise one or more of our drug candidates over the coming years as they move toward the final stages of development and if they receive the requisite regulatory approvals. See “Business – Our Pipeline of Drug Candidates” for details.

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The time required to obtain approvals from the FDA, the NMPA or other comparable regulatory authorities is unpredictable, but it typically take several years following the commencement of clinical trials. Any delays in the regulatory approvals of any of our drug candidates in major markets will delay our ability to generate revenue from those drug candidates in those markets and adversely affect our results of operations. See “Risk Factors – Risks Relating to the Development, Clinical Trials and Regulatory Approval of our Drug Candidates”, “Risk Factors – Risks Relating to the Commercialisation of our Drug Candidates”, and “Risk Factors – Risks Relating to Obtaining Regulatory Approvals, Commercialisation of Our Drug Candidates, and Doing Business Outside of China” for details of the risks in relation to obtaining regulatory approvals and commercialisation of our drug candidates.

R&D Expenditures

We believe that R&D is crucial to our future success and we have devoted significant resources to our drug development programmes. We capitalise our development expenditures as intangible assets only when they meet certain capitalisation criteria. See “– Critical Accounting Policies, Estimates and Judgements – R&D Expenditures” in this section for details. Development expenditures that do not meet the capitalisation criteria are expensed as incurred and are recognised as R&D costs. During the Track Record Period, our R&D expenditures incurred did not meet the capitalisation criteria for any products and were expensed as incurred. Our R&D expenses increased by 79.8% from US\$15.3 million in 2022 to US\$27.5 million in 2023, and increased by 38.0% from 2023 to US\$37.9 million in 2024, respectively, primarily due to the advancement of our clinical trials for clinical-stage drug candidates and the engagement of additional R&D personnel. Our R&D expenditures, as well as the portion of R&D expenditures being expensed, are affected by the stage of our existing drug candidates and any additional drug candidates to be developed. We expect to continue to increase our R&D expenditures to progress our drug development programmes.

Potential Competition Upon Commercialisation

The development and commercialisation of ophthalmic drugs is highly competitive. We face potential competition from different pharmaceutical and biopharmaceutical companies. Any drug candidates that we successfully develop and commercialise will compete with existing drugs and new drugs that may become available in the future. These entities are or may be seeking to develop drugs, therapies and approaches to treat our targeted diseases or their underlying causes. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialise drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than the drugs that we may develop or commercialise. See “Market Opportunity and Competition” under descriptions of each of our drug candidates in “Business” for details of our major competitors for each drug candidate and “Risk Factors – Risks Relating to the Commercialisation of Our Drug Candidates – If competing drugs are more effective, have fewer side effects, are more effectively marketed and cost less than our drugs or drug candidates, or receive regulatory approval or reach the market earlier, our drug candidates may not be approved, and our drugs or drug candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete” for details of the risks associated with potential competition.

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Cost Structure

During the Track Record Period, a substantial portion of our costs were in relation to R&D expenses, and general and administrative expenses. Our current R&D activities are mainly related to drug discovery, pre-clinical studies and clinical trials of our drug candidates. Our R&D expenses were US\$15.3 million, US\$27.5 million and US\$37.9 million for the years ended 31 December 2022, 2023 and 2024, respectively. Our general and administrative expenses primarily consist of employee benefit expenses for management and administrative personnel, and legal and professional fees. Our general and administrative expenses were US\$8.9 million, US\$11.3 million and US\$9.5 million for the years ended 31 December 2022, 2023 and 2024, respectively. We expect our general and administrative expenses which were recurring from ordinary operations to increase in the future to support the development of our drug candidates and the expansion of our operational scale in general. We also expect to start incurring selling and distribution expenses after the commercialisation of our drug candidates.

We expect our cost structure to evolve as we move our drug candidates currently at earlier clinical stage into more advanced clinical development stages and advance pre-clinical programmes into clinical trials, and progress our drug candidates to commercialisation.

Milestone Payments and Royalties

We expect to generate additional income from commercialisation collaboration of certain of our drug candidates in the future. Our ability to achieve the relevant milestone events of the clinical development of our drug candidates will affect the timing and amount of milestone payments, and the future sales of these drug candidates will affect the amount of royalties we receive, all of which have an effect on our profitability and cash flow.

On 13 April 2020, we entered into a commercialisation licensing arrangement with Grand Pharma (the “**Licensing Agreement**”), pursuant to which we granted Grand Pharma an exclusive, sublicensable, royalty-bearing licence to manufacture and commercialise CBT-001 in all human use in mainland China, Hong Kong, Macau and Taiwan. Subject to the terms and conditions of the Licensing Agreement, we are entitled to receive a one-time upfront payment, a one-time right of first refusal payment, milestone payment, and tiered royalty payments which is based on total sales of CBT-001. The one-time upfront payment and one-time right of first refusal payment had been made in full by Grand Pharma to us in the year of 2020. See “Business – Our Pipeline of Drug Candidates – Clinical Stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 2. Commercialisation plan in China, through Licensing Arrangement with Grand Pharma” for details.

On 6 August 2024, we entered into a license agreement with Santen, pursuant to which we granted Santen an exclusive, fee-based, milestone and royalty-bearing license to (a) develop, manufacture, and commercialise any pharmaceutical product that contains Nintedanib as a sole or one of the APIs (including without limitation CBT-001) (the “**Product**”) and/or Nintedanib in the topical therapeutic treatment of sign and/or symptom of ophthalmic disease related to pterygium, pinguecula and any other indication(s) to be

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mutually agreed by Santen and us in writing (the “**Field**”) in Japan, Korea, Vietnam, Thailand, Malaysia, Singapore, the Philippines and Indonesia (the “**Territory**”); and (b) to develop and manufacture Nintedanib outside the Territory but solely for the commercialisation of the Product in the Field in the Territory. The one-time upfront payment of US\$10.0 million had been made in full by Santen to us in two batches in September 2024 and November 2024, respectively. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan - 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” for details.

Financing for Our Operations

During the Track Record Period, we funded our cash requirements primarily through proceeds from Pre-IPO Investments, capital contribution from our shareholders and government grants. We expect our expenses will continue to increase in connection with our ongoing R&D activities, particularly as we advance the clinical development of our clinical-stage drug candidates. Accordingly, we will likely need to use cash to fund our continuing operations. If we are required to obtain substantial additional funding and are unable to raise capital when needed, or on acceptable terms or at all, we could be forced to delay, reduce or terminate our drug development programmes or any future commercialisation efforts, which could adversely impact our ability to generate revenue and achieve profitability. See “Risk Factors – Risks Relating to Our Financial Prospects and Need for Additional Capital” for details.

General Factors Affecting the Ophthalmology Industry in which We Operate

Our business and operating results are affected by general factors affecting the ophthalmology industry in which we operate, including but not limited to relevant laws and regulations, governmental policies and initiatives, as well as the public medical insurance programmes affecting the ophthalmic pharmaceutical market in the United States and the PRC, the growth and competition environment of the global ophthalmic pharmaceutical market, political, economic and social instability of different local markets in which we are conducting or plan to conduct clinical trials and/or commercialisation activities.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND JUDGEMENTS

The discussion and analysis of our financial position and results of operations are based on the consolidated financial statements of our Group prepared in accordance with the material accounting policies set out in the Accountant’s Report included in Appendix I to this prospectus. The preparation of our financial information requires us to make estimates and judgements in applying certain critical accounting policies which may have a significant impact on our results of operations. We base our estimates on historical experience and other assumptions which our management believes to be reasonable under the circumstances. Results may differ from these estimates under different assumptions and conditions. The following discussion provides supplemental information on our material accounting policies, certain of which require estimates and assumptions from our Directors.

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R&D Expenditures

The R&D expenditures incurred on our R&D activities, including conducting clinical trials and other activities related to regulatory filings for our drug candidates, are capitalised as intangible assets only when the capitalisation criteria is met. Expenditures that do not meet these capitalisation principles are recognised as R&D expenses. During the Track Record Period, our R&D expenditures did not meet these capitalisation principles for any drug candidates and were all expensed as incurred.

Measure of Financial Liabilities at Fair Value through Profit or Loss

We designated the convertible redeemable preferred shares as financial liabilities at fair value through profit or loss. They are initially recognised at fair value. Subsequent to initial recognition, our convertible redeemable preferred shares are carried at fair value with changes in fair value recognised in the profit or loss, except for the gains or losses arising from our own credit risk which are presented in other comprehensive income with no subsequent reclassification to the profit or loss. The fair values of the convertible redeemable preferred shares, which are not traded in an active market, are determined by using valuation techniques. Significant judgements and assumptions are exercised by our management in selecting valuation models and unobservable inputs at the end of each reporting periods. Changing the key assumptions used by our management could materially affect the fair values of these financial liabilities and as a result affect our financial position and results of operation.

Impairment of Financial Assets

We assess on a forward-looking basis the expected credit loss associated with our debt instruments carried at amortised cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For cash and cash equivalents and short-term bank deposits, the expected credit loss risk is considered immaterial.

Impairment on other receivables from third parties and related parties are measured as either 12-month expected credit losses or lifetime expected credit losses, depending on whether there has been a significant increase in credit risk since initial recognition. If no significant increase in credit risk of a receivable has occurred since initial recognition, then impairment is measured as 12-month expected credit losses. For other receivables during the Track Record Period, our management considers that the expected credit loss for other financial assets at amortised cost to be immaterial.

Impairment of Non-financial Assets

Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the carrying amount of the asset exceeds its recoverable amount. The recoverable amount is the higher of the fair value of an asset less costs of disposal and value in use. For the purposes of assessing impairment, assets are

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grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (i.e. cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

Financial Instruments Issued to Investors

Financial instruments issued to investors consist of convertible redeemable preferred shares and other financial liabilities of fair value through profit or loss. During the Track Record Period, we entered into a series of share purchase agreements with investors and issued Series A, Series B and Series C Preferred Shares, respectively.

The Preferred Shares are redeemable upon occurrence of certain future events. Those instruments can be converted into ordinary shares of our Company at any time at the option of the holders or automatically converted into ordinary shares upon occurrence of an initial public offering of our Company or at any time after the date of issuance of such shares as set out in Note 24 to the Accountant's Report in Appendix I to this prospectus.

We designated the Preferred Shares as financial liabilities at fair value through profit or loss. They are initially recognised at fair value. Subsequent to initial recognition, the Preferred Shares are carried at fair value with changes in fair value recognised in the profit or loss, except for the gains or losses arising from our own credit risk which are presented in other comprehensive income with no subsequent reclassification to the profit or loss.

Financial Instruments Measured within Level 3 Fair Value Measurement

Fair Value of Financial Assets

The fair value of financial assets that are not traded in an active market is determined by using valuation techniques. We use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period. Changes in these assumptions and estimates could materially affect the respective fair value of these investments.

Fair Value of Redeemable Convertible Preferred Shares

The convertible redeemable preferred shares issued by our Company are not traded in an active market and the respective fair value is determined by using various applicable valuation techniques. Our Directors have applied the discounted cash flow method to determine the underlying equity value of our Company and adopted equity allocation model to determine the fair value of the convertible redeemable preferred shares.

Our policy is to recognise transfers into and transfers out of fair value hierarchy levels as at the end of the reporting period:

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- Level 1: the fair value of financial instruments traded in active markets (such as publicly traded derivatives, and equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by our Group is the current bid price;
- Level 2: the fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques which maximise the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2; and
- Level 3: if one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

During the Track Record Period, we had certain financial liabilities categorised within level 3 fair value measurement, which included the convertible redeemable preferred shares measured at fair value through profit or loss. There were no transfers between level 1, 2 and 3 of fair value hierarchy classifications during the Track Record Period. See Note 3.3, Note 24 and Note 25 to the Accountant's Report set out in Appendix I to this prospectus for more details on the fair value estimation.

In relation to the valuation of the Level 3 financial liabilities, with reference to the "Guidance note on directors' duties in the context of valuations in corporate transactions" issued by the SFC, our Directors have adopted the following procedures, including (i) reviewed the relevant agreements; (ii) carefully considered all information, especially non-market related information, that requires management's assessment and estimate; and (iii) reviewed the valuation report prepared by the external valuer at each reporting date, with analysis of changes in fair value measurement. Based on the above procedures, our Directors are of the view that the valuation analysis performed by the valuer is fair and reasonable.

The Joint Sponsors have conducted relevant due diligence work in relation to the level 3 fair value measurement, including:

- (i) reviewed the terms of the relevant agreements and documents in respect of the financial instruments measured within level 3 fair value measurement ("**Level 3 Financial Instruments**"), including the relevant investment agreements of the Company;
- (ii) reviewed the valuation report prepared by the external valuer engaged by the Company;
- (iii) discussed with the external valuer to understand the basis for determining the valuation methodologies applied, including but not limited to the major assumptions and key parameters adopted in the valuation process;

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- (iv) discussed with the management of the Company to understand the valuation methodology of the Level 3 Financial Instruments, judgement of the management and the internal policies associated with the valuation of Level 3 Financial Instruments;
- (v) reviewed the relevant notes in the Accountant's Report set out in Appendix I to this prospectus; and
- (vi) discussed with the Reporting Accountant to understand the work performed by the Reporting Accountant in relation to the valuation of the Level 3 Financial Instruments for the purpose of reporting on our Group's historical financial information as a whole.

Based upon the due diligence work conducted as stated above, nothing came to the Joint Sponsors' attention that would cause them to question the valuation performed by the valuer and the Company in relation to the Level 3 Financial Instruments.

The Reporting Accountant's opinion on the historical financial information of our Group for the Track Record Period as a whole in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 "Accountants' Reports on Historical Financial Information in Investment Circulars" issued by the Hong Kong Institute of Certified Public Accountants is set out on pages I-1 to I-3 of Appendix I to this prospectus.

Fair Value of Share-based Payment Transactions

The awarded shares granted to employees under the Equity Incentive Arrangements less amount paid by employees is recognised as an employee benefits expense over the relevant service period, being the vesting period of the shares, and the credit is recognised in equity in the share-based payment reserves. The fair value of the shares is measured at the grant date. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted including any market performance conditions and the impact of any non-vesting conditions, and excluding the impact of any service and non-market performance vesting conditions (for example, the requirement for employees to serve).

The total expense is recognised over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each reporting period, we reassess our estimates of the number of shares that are expected to vest based on the service conditions. We recognise the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

Where there is any modification of terms and conditions which increases the fair value of the equity instruments granted, we include the incremental fair value granted in the measurement of the amount recognised for the services received over the remainder of the vesting period. The incremental fair value is the difference between the fair value of the modified equity instrument and that of the original equity instrument, both estimated as at the date of the modification. An expense based on the incremental fair value is recognised over the period from the modification date to the date when the modified equity instruments vest in addition to any amount in respect of the original instrument, which should continue

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to be recognised over the remainder of the original vesting period. Where shares are forfeited due to a failure by the employee to satisfy the service conditions, any expenses previously recognised in relation to such shares are reversed effective at the date of the forfeiture.

RESULTS OF OPERATIONS

The following table sets forth a summary of our consolidated statements of comprehensive income set out in the Accountant's Report included in Appendix I to this prospectus:

	For the year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Revenue	–	–	10,000
Other income	471	880	214
Other gains, net	718	674	645
General and administrative expenses	(8,912)	(11,277)	(9,489)
Research and development expenses	(15,290)	(27,492)	(37,946)
Operating loss	(23,013)	(37,215)	(36,576)
Finance income	1,602	3,872	2,029
Finance costs	(31)	(275)	(27)
Finance income, net	1,571	3,597	2,002
Change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments	(45,314)	(95,777)	(63,723)
Loss before income tax	(66,756)	(129,395)	(98,297)
Income tax expenses	(82)	(23)	(833)
Loss for the year	(66,838)	(129,418)	(99,130)
Other comprehensive losses			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Currency translation difference	(1,815)	(801)	(877)
<i>Items that will not be reclassified subsequently to profit or loss:</i>			
Change in fair value of convertible redeemable preferred shares due to own credit risk	(2,476)	(982)	(13)
Change in fair value of other financial liabilities due to own credit risk	(1,824)	–	–
Other comprehensive losses for the year	(6,115)	(1,783)	(890)
Total comprehensive loss for the year	(72,953)	(131,201)	(100,020)

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DESCRIPTION OF SELECTED COMPONENTS OF CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Revenue

We are a clinical-stage ophthalmology biotechnology company. We did not generate any revenue from the sale of pharmaceutical products during the Track Record Period. We only generated revenue from a one-time upfront payment of US\$10.0 million made by Santen to us under the Santen Licensing Agreement (see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” for details).

Other Income

Our other income amounted to US\$0.5 million, US\$0.9 million and US\$0.2 million in the years ended 31 December 2022, 2023 and 2024, respectively. Our other income during the Track Record Period consisted of government grants.

Our government grants during the Track Record Period related to (i) subsidies from U.S. National Institutes of Health in 2022 for our R&D activities on our most advanced drug candidate, CBT-001, and (ii) government grants in 2023 and 2024 granted by Suzhou government (a) in connection with our development undertakings and activities in Cloudbreak Suzhou, and (b) under a technological innovation incentive program. There are no unfulfilled conditions or other contingencies attaching to these grants and we recognise these grants as other income upon receipt.

Other Gains, Net

Our other gains during the Track Record Period primarily consisted of net foreign exchange gains, insurance compensation and gains on financial assets at fair value through profit or loss. Our other losses during the Track Record Period primarily consisted of net foreign exchange losses and net losses on disposal of property, plant and equipment. The following table sets forth a breakdown of our other gains and losses, by amount and as a percentage of our total gains, for the years indicated:

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	For the year ended 31 December					
	2022		2023		2024	
	US\$'000	%	US\$'000	%	US\$'000	%
Change in fair value on financial assets at fair value through profit or loss	55	7.7	–	–	–	–
Net losses on disposal of property, plant and equipment	(4)	(0.6)	–	–	–	–
Foreign exchange gains, net	623	86.8	662	98.2	647	100.3
Others	44	6.1	12	1.8	(2)	(0.3)
Total	718	100.0	674	100.0	645	100.0

Our change in fair value on financial assets at fair value through profit or loss related to our purchase of an investment product offered by a major PRC commercial bank in 2021 with expected rates of return ranged from 2.3% to 2.4% per annum which was fully redeemed by us in 2022. The fair values were determined based on the expected rate of return according to our management's judgement. Going forward, we expect to hold our surplus cash primarily in time deposits to achieve our capital preservation objective.

We incurred foreign exchange gains during the Track Record Period due to several reasons. In the year ended 31 December 2024, we had foreign exchange gains of US\$0.6 million when the remaining amount in our account for saving the registered capital injection funds (which were being utilised by us) received by Cloudbreak Suzhou and Cloudbreak Yixing denominated in U.S. Dollars was translated to RMB, as the RMB depreciated against U.S. Dollars.

In the year ended 31 December 2023, we had foreign exchange gains of US\$0.7 million (i) when the registered capital injection received by Cloudbreak Suzhou in April 2023 denominated in U.S. Dollars was translated to RMB, as a result of the depreciation of RMB against U.S. Dollars in first half of 2023, and (ii) when we repaid Hong Kong Dollars-denominated bank borrowings with our deposited cash denominated in U.S. Dollars due to the depreciation of Hong Kong Dollars against U.S. Dollars.

In the year ended 31 December 2022, we had foreign exchange gains of US\$0.6 million, primarily when the registered capital injection received by Cloudbreak Suzhou in December 2021 denominated in U.S. Dollars was translated to RMB, as the RMB depreciated against U.S. Dollars.

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General and Administrative Expenses

Our general and administrative expenses during the Track Record Period primarily consisted of (i) employee benefit expenses, consisting of staff costs including salaries, bonuses, pension, and benefits, and share-based compensation for our management and administrative personnel, (ii) legal and professional fee paid to counsels and other professional agencies, (iii) listing expenses in connection with the proposed Listing, (iv) depreciation of our property, plant and equipment and right-of-use assets, (v) expenses relating to short-term leases, (vi) insurance expenses, and (vii) others. The following table sets forth a breakdown of our general and administrative expenses, by amount and as a percentage of our total general and administrative expenses, for the years indicated:

	For the year ended 31 December					
	2022		2023		2024	
	US\$'000	%	US\$'000	%	US\$'000	%
Legal and professional fee	5,076	57.0	1,738	15.4	2,443	25.7
Employee benefit expenses	3,119	35.0	5,969	52.9	3,784	39.9
– Staff costs	1,774	19.9	4,224	37.5	3,364	35.5
– Share-based compensation	1,345	15.1	1,745	15.5	420	4.4
Depreciation	221	2.5	394	3.5	438	4.6
Expenses relating to short-term leases	155	1.7	179	1.6	111	1.2
Insurance expenses	58	0.7	112	1.0	82	0.9
Listing expenses	–	–	2,118	18.8	1,478	15.6
Auditor's remunerations						
– audit services	3	–	3	–	6	–
Others	280	3.1	764	6.8	1,147	12.1
Total	8,912	100.0	11,277	100.0	9,489	100.0

R&D Expenses

Our R&D expenses during the Track Record Period primarily consisted of (i) clinical research expenses, which primarily consisted of service fees paid for clinical research expenses to CROs and CDMOs for our clinical trials, expenses for raw materials and consumables used in clinical trials, and other miscellaneous expenses such as IP registration fees and maintenance fees, (ii) employee benefit expenses, consisting of staff costs including salaries and pension, and share-based compensation for our R&D personnel (for details of the share-based Share-based compensation for R&D personnel, see “Share-based Payment – Equity-settled Sharebased Payment Transactions - (a) Share Awards Scheme” under Note 10 in Appendix I and “Statutory and General Information – D. Equity Incentive Arrangements – 2. Series C Equity Incentive Arrangement” in Appendix IV to this prospectus), and (iii)

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depreciation of our property, plant and equipment related to R&D. The following table sets forth a breakdown of our R&D expenses, by amount and as a percentage of our total R&D expenses, for the years indicated:

	For the year ended 31 December					
	2022		2023		2024	
	US\$'000	%	US\$'000	%	US\$'000	%
Clinical research expenses	11,711	76.6	11,212	40.8	22,014	58.0
Employee benefit expenses	3,471	22.7	15,845	57.6	15,138	39.9
– Staff costs	3,471	22.7	4,019	14.6	4,290	11.3
– Share-based compensation	–	–	11,826	43.0	10,848	28.6
Depreciation	108	0.7	435	1.6	794	2.1
Total	15,290	100.0	27,492	100.0	37,946	100.0

The following table sets forth a breakdown of our clinical research expenses by Core Products and other drug candidates and as a percentage of our total clinical research expenses, for the years indicated:

	For the year ended 31 December					
	2022		2023		2024	
	US\$'000	%	US\$'000	%	US\$'000	%
Core Products						
– CBT-001	6,612	56.5	7,430	66.3	19,409	88.2
– CBT-009	944	8.0	1,463	13.0	397	1.8
Other drug candidates	4,155	35.5	2,319	20.7	2,208	10.0
Total	11,711	100.0	11,212	100.0	22,014	100.0

Finance Income

Our finance income during the Track Record Period consisted of interest income from time deposit. Our finance income for the years ended 31 December 2022, 2023 and 2024 were US\$1.6 million, US\$3.9 million and US\$2.0 million, respectively.

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Finance Costs

Our finance cost during the Track Record Period consisted of (i) interest expense on lease liabilities of our leased properties, including the laboratories and offices, and (ii) interest paid on bank borrowings in 2023 and 2024, which were fully repaid prior to 31 December 2024. Our finance costs for the years ended 31 December 2022, 2023 and 2024 were US\$31,000, US\$0.3 million and US\$27,000, respectively.

Change in Fair Value of Financial Liabilities at Fair Value through Profit or Loss and Derivative Financial Instruments

Our change in fair value of financial liabilities through profit or loss and derivative financial instruments during the Track Record Period related to the change in fair value of the convertible redeemable preferred shares, derivative financial instruments in connection with the Preferred Shares we issued to our Pre-IPO Investors, other financial liabilities of the fair value through profit or loss in connection with warrants granted in connection with the Pre-IPO Investment and derivative financial instruments.

Our change in fair value of financial liabilities through profit or loss and derivative financial instruments were losses of US\$45.3 million, US\$95.8 million and US\$63.7 million for the years ended 31 December 2022, 2023 and 2024, respectively. The relatively higher amount was recognised for the changes in fair value in Preferred Shares in 2023, as compared to that in 2024, was primarily due to the higher increase in the Company's valuation as a result of the Company's milestone developments of the product candidates in 2023. For example, for CBT-009, we completed phase 1/2 clinical trial in Australia in January 2023, submitted pre-IND application to the FDA in July 2023, and received no objection letter from the FDA in September 2023. The fair values of our convertible redeemable preferred shares, other financial liabilities of fair value through profit or loss and derivative financial instruments which are not traded in an active market, are determined by using valuation techniques. See Note 24 and Note 25 to the Accountant's Report as set out in Appendix I to this prospectus for details.

Income Tax Expenses

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of our Group are domiciled and operate.

Our income tax expenses during the Track Record Period primarily consisted of tax charged on our revenue from a one-time payment made by Santen under the Santen Licensing Agreement (See "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen" for details), on interest income from time deposits, and on unrealised foreign exchange gains. Our income tax expenses for the years ended 31 December 2022, 2023 and 2024 were US\$82,000, US\$23,000 and US\$0.8 million, respectively.

During the Track Record Period, we did not generate any revenue from the sale of pharmaceutical products and incurred operating losses. During the Track Record Period and up to the Latest Practicable Date, we had paid all taxes in accordance with tax regulations and did not have any disputes or unresolved tax issues with the relevant tax authorities.

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Cayman Islands

Under the current laws of Cayman Islands, our Company and Cloudbreak Pharmaceutical Inc. are not subject to tax on income or capital gains. In addition, upon payments of dividends by our Company to its shareholders, no Cayman Islands withholding tax is imposed.

British Virgin Islands (“BVI”)

Under the current laws of the BVI, the subsidiary incorporated in the BVI is exempted from income tax on their foreign-derived income in the BVI. There are no withholding taxes in the BVI.

Hong Kong

Hong Kong profits tax rate is 16.5% during the Track Record Period. No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax during the Track Record Period.

The United States

The federal income tax, California income tax and Delaware income tax in the United States have been provided for at the statutory rate of 21%, 8.84% and 8.7%, respectively, on the estimated taxable profits of the subsidiaries incorporated in the United States during the Track Record Period.

The PRC

Provision for PRC corporate income tax is calculated at the statutory rate of 25% on the assessable income of our Group’s subsidiaries incorporated and operated in the PRC during the Track Record Period. In addition, based on applicable national tax regulations, Cloudbreak Suzhou and Cloudbreak Guangzhou were eligible for preferential tax treatment during the Track Record Period, under which eligible R&D expenses at 75% to 100% could be deducted from our income tax expenditures if we had income tax obligations. For risks relating to preferential tax treatment, see “Risk Factors – Risks Relating to Our Financial Prospects and Need for Additional Capital – The discontinuation of any of the government grants or preferential tax treatment currently available to us could adversely affect our financial position, results of operations, cash flows and prospects.”

Other Foreign Countries

Taxes on profits in other foreign countries, including Germany and Australia, have been calculated at the rates of tax prevailing in the jurisdictions in which our Group operates, based on existing legislation, interpretations and practices in respect thereof. No income tax for other foreign countries was provided for as there was no estimated assessable profit that was subject to the income tax for other foreign countries during the Track Record Period.

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REVIEW OF HISTORICAL RESULTS OF OPERATIONS

Year Ended 31 December 2023 Compared to Year Ended 31 December 2024

Revenue

Our revenue increased from nil in 2023 to US\$10.0 million in 2024, upon the receipt of one-time upfront payment of US\$10.0 million made by Santen to us under the Santen Licensing Agreement (see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” for details).

Other Income

Our other income decreased by US\$0.7 million, or 75.7%, from US\$0.9 million in 2023 to US\$0.2 million in 2024, because we received less government grants granted by Suzhou government in 2024 as compared to those in 2023.

Other Gains, Net

Our other gains decreased by US\$29,000, or 4.3%, from US\$0.7 million in 2023 to US\$0.6 million in 2024, primarily due to a US\$15,000 decrease in foreign exchange gains as (i) we had been utilising the proceeds in our account for the capital injection denominated in U.S. Dollars received by Cloudbreak Suzhou and Cloudbreak Yixing for our R&D activities and daily operations, so the principal amount to generate foreign exchange gains had been decreasing, and (ii) the depreciation of RMB against U.S. Dollars in 2024.

General and Administrative Expenses

Our general and administrative expenses decreased by US\$1.8 million, or 15.9%, from US\$11.3 million in 2023 to US\$9.5 million in 2024, primarily as a result of (i) a US\$2.2 million decrease in employee benefit expenses, which is primarily led by a US\$0.9 million decrease in staff costs mainly resulting from less bonus paid to our employees as compared to that in 2023, and a US\$1.3 million decrease in share-based compensation under the Series C Equity Incentive Arrangement which was issued pursuant to the schedule, and (ii) a US\$0.6 million decrease in listing expenses in relation to the preparation of our proposed Listing, reflecting the progress made by each professional party, partially offset by a US\$0.7 million increase in legal and professional fees paid to counsels and other professional agencies in relation to our financing and business development activities.

R&D Expenses

Our R&D expenses increased by US\$10.5 million, or 38.0%, from US\$27.5 million in 2023 to US\$37.9 million in 2024, primarily as a result of a US\$10.8 million increase in clinical research expenses primarily because we are conducting phase 3 MRCT for CBT-001,

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partially offset by a US\$0.7 million decrease in employee benefit expenses, primarily led by a US\$1.0 million decrease in relation to the share-based compensation under the Series C Equity Incentive Arrangement which was issued pursuant to the schedule.

Finance Income

Our finance income decreased by US\$1.8 million, or 47.6%, from US\$3.9 million in 2023 to US\$2.0 million in 2024, primarily because our interest income from our time deposits decreased as a result of (i) the decreased amount of our deposits with banks as we have been utilising the proceeds in our deposit accounts for our R&D activities and daily operations, and (ii) the decreased interest rate for time deposits in 2024.

Finance Costs

Our finance cost decreased by US\$0.2 million, or 90.2%, from US\$0.3 million in 2023 to US\$27,000 in 2024, primarily as a result of the decrease in our interest expenses, as we have fully repaid our bank borrowings prior to 31 December 2024.

Income Tax Expenses

Our income tax expenses increased by US\$0.8 million, or 3,521.7%, from US\$23,000 in 2023, to US\$0.8 million in 2024, primarily as a result of the assessable income arising from the revenue generated from one-time upfront payment of US\$10.0 million as stipulated in the Santen Licensing Agreement (see “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001 – Commercialisation Plan – 3. Commercialisation plan in other selected regions in Asia, through Licensing Agreement with Santen” for details) and R&D services in relation to CBT-009 provided by ADS USA to Cloudbreak Suzhou.

Net Loss for the Period

As a result of the foregoing, our net loss decreased by US\$30.3 million, or 23.4%, from US\$129.4 million in 2023 to US\$99.1 million in 2024.

Year Ended 31 December 2022 Compared to Year Ended 31 December 2023

Other Income

Our other income increased by US\$0.4 million, or 86.8%, from US\$0.5 million in 2022 to US\$0.9 million in 2023, mainly because of the increase in the government grants we received in 2023 granted by Suzhou government (a) in connection with our development undertakings and activities in Cloudbreak Suzhou, and (b) under a technological innovation incentive program.

Other Gains, Net

Our other gains remained relatively stable at US\$0.7 million and US\$0.7 million in 2022 and 2023, respectively.

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General and Administrative Expenses

Our general and administrative expenses increased by US\$2.4 million, or 26.5%, from US\$8.9 million in 2022 to US\$11.3 million in 2023, primarily as a result of (i) a US\$2.9 million increase in employee benefit expenses, consisting of a US\$2.5 million increase in staff costs as we recruited additional employees, including senior officers, to support our business expansion and increased compensation level for existing employees, and a US\$0.4 million increase in share-based compensation under the Series C Equity Incentive Arrangement, and (ii) a US\$2.1 million increase in listing expenses in relation to the preparation of our proposed Listing, partially offset by a US\$3.3 million decrease in legal and professional fees paid to counsels and other professional agencies.

R&D Expenses

Our R&D expenses increased by US\$12.2 million, or 79.8%, from US\$15.3 million in 2022 to US\$27.5 million in 2023, primarily as a result of a US\$12.4 million increase in employee benefit expenses, consisting of (a) a US\$11.8 million increase mainly in relation to the share-based compensation under the Series C Equity Incentive Arrangement, and (b) a US\$0.5 million increase in staff costs due to the increased compensation level for our R&D personnel in 2023 as we recruited additional R&D staff to support the clinical development of our drug candidates.

Finance Income

Our finance income increased by US\$2.3 million, or 141.7%, from US\$1.6 million in 2022 to US\$3.9 million in 2023, primarily as a result of our increased interest income from our time deposits.

Finance Costs

Our finance cost increased by US\$0.2 million, or 787.1%, from US\$31,000 in 2022 to US\$0.3 million in 2023, primarily as a result of the interest paid on interest-bearing bank borrowings for general business operating purposes in 2023. We fully settled such bank borrowings prior to 31 December 2023.

Income Tax Expenses

Our income tax expenses decreased by US\$59,000, from US\$82,000 in 2022 to US\$23,000 in 2023, primarily as a result of the decrease in taxable income in 2023. The taxable income in both 2022 and 2023 was influenced by the net foreign exchange gains in the relevant year.

Net Loss for the Year

As a result of the foregoing, our net loss increased by US\$62.6 million, or 93.6%, from US\$66.8 million in 2022 to US\$129.4 million in 2023.

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DISCUSSION OF SELECTED BALANCE SHEET ITEMS

The following table sets forth a summary of our balance sheet items as of 31 December 2022, 2023 and 2024, derived from our consolidated statements of financial position set out in the Accountant's Report in Appendix I to this prospectus:

	As of 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Assets			
Non-current assets			
Property, plant and equipment	363	1,106	375
Right-of-use assets	807	2,161	2,051
Prepayments and other receivables	<u>808</u>	<u>97</u>	<u>74</u>
	<u>1,978</u>	<u>3,364</u>	<u>2,500</u>
Current assets			
Prepayments and other receivables	869	1,263	2,325
Current income tax receivables	129	50	322
Short-term bank deposits	63,194	7,500	–
Cash and cash equivalents	<u>15,917</u>	<u>52,654</u>	<u>34,862</u>
	<u>80,109</u>	<u>61,467</u>	<u>37,509</u>
Total assets	<u><u>82,087</u></u>	<u><u>64,831</u></u>	<u><u>40,009</u></u>
Equity			
Share capital	48	48	48
Other reserves	(29,508)	(17,720)	(7,342)
Accumulated losses	<u>(115,704)</u>	<u>(245,122)</u>	<u>(344,252)</u>
Total deficit	<u>(145,164)</u>	<u>(262,794)</u>	<u>(351,546)</u>

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	As of 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Liabilities			
Non-current liability			
Lease liability	<u>548</u>	<u>228</u>	<u>209</u>
Current liabilities			
Trade and other payables	30,711	4,599	4,766
Convertible redeemable preferred shares	109,957	322,459	386,195
Other financial liabilities at fair value through profit or loss	73,960	–	–
Derivative financial instruments	11,783	–	–
Lease liabilities	292	317	302
Current income tax liabilities	<u>–</u>	<u>22</u>	<u>83</u>
	<u>226,703</u>	<u>327,397</u>	<u>391,346</u>
Total liabilities	<u><u>227,251</u></u>	<u><u>327,625</u></u>	<u><u>391,555</u></u>
Total deficit and liabilities	<u><u>82,087</u></u>	<u><u>64,831</u></u>	<u><u>40,009</u></u>

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Net Current Liabilities

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of 31 December			As of
	2022	2023	2024	30 April
	US\$'000	US\$'000	USD'000	2025
				US\$'000
				(unaudited)
Current assets				
Prepayments and other				
receivables	869	1,263	2,325	2,392
Current income tax				
receivables	129	50	322	322
Short-term bank deposits	63,194	7,500	–	3,038
Cash and cash				
equivalents	15,917	52,654	34,862	22,340
	<u>80,109</u>	<u>61,467</u>	<u>37,509</u>	<u>28,092</u>
Current liabilities				
Trade and other payables	30,711	4,599	4,766	4,023
Convertible redeemable				
preferred shares	109,957	322,459	386,195	386,195
Other financial liabilities				
at fair value through				
profit or loss	73,960	–	–	–
Derivative financial				
instruments	11,783	–	–	–
Lease liabilities	292	317	302	239
Current income tax				
liabilities	–	22	83	89
	<u>226,703</u>	<u>327,397</u>	<u>391,346</u>	<u>390,546</u>
Net Current Liabilities	<u>(146,594)</u>	<u>(265,930)</u>	<u>(353,837)</u>	<u>(362,454)</u>

Our net current liabilities increased from US\$353.8 million as of 31 December 2024 to US\$362.5 million as of 30 April 2025, primarily due to a US\$12.5 million decrease in cash and cash equivalents as we have been utilising proceeds in our bank accounts to support our R&D activities and daily operation, and partially offset by a US\$3.0 million increase in short-term bank deposits.

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Our net current liabilities increased from US\$265.9 million as of 31 December 2023 to US\$353.8 million as of 31 December 2024, primarily due to (i) a US\$63.7 million increase in the fair value of the Preferred Shares we issued, (ii) a US\$17.8 million decrease in cash and cash equivalents as we have been utilising proceeds in our bank accounts to support our R&D activities and daily operation, and (iii) a US\$7.5 million decrease in short-term bank deposits as the proceeds are gradually utilised.

Our net current liabilities increased from US\$146.6 million as of 31 December 2022 to US\$265.9 million as of 31 December 2023, primarily due to a US\$212.5 million increase in convertible redeemable preferred shares in connection with the issuance of Series C Preferred Shares in Series C Financing and the fair value changes in the Preferred Shares we issued, partially offset by (i) a US\$74.0 million decrease in other financial liabilities at fair value through profit or loss as the Series C Warrants were fully exercised by the relevant Pre-IPO Investors in January 2023, (ii) a US\$26.1 million decrease in trade and other payables primarily due to a US\$27.2 million decrease in receipt in advance from an investor in 2023, as the first tranche of investment amounts we received from a Series C Investor in December 2021 (as such Series C Investor and us had separately agreed that its consideration may be paid in two tranches in order to facilitate settlement) were initially recognised as trade and other payables, and (iii) a US\$11.8 million decrease in derivative financial instruments upon the settlement of Series C Financing.

We seek to improve our liquidity and net current liabilities as well as ensure our working capital sufficiency going forward by driving our operating cash flow and improving our net current liabilities position through (i) the sales of future commercialised products by optimising the marketing plans of our drug candidates, (ii) adopting comprehensive measures to effectively control our cost and operating expense, for example, establishing, maintaining and executing guidelines designed for cost-effective pre-clinical studies and clinical trials procedures, and to ensure that the capacity of all employees (including R&D staff and other staff responsible for financial, HR and administrative matters, etc.) are fully utilised, (iii) optimising our manufacturing capability and efficiency by operating the pilot production facility in Suzhou, and preparing for building a commercial production facility in Suzhou to fulfill our future later-stage clinical trials and commercialisation manufacturing needs, as well as entering into more favourable terms with our CROs and CDMOs, so that the costs of engaging qualified CROs and CDMOs can be saved to a certain extent (if not all), and (iv) successfully launching the Global Offering to obtain the proceeds. Along with the expected reclassification of Preferred Shares from liabilities to equity upon their automatic conversion into ordinary shares upon Listing, we will also turn into net assets position. We will closely monitor the level of our working capital, particularly in view of our strategy to scale up our organisation to build an international platform.

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Property, Plant and Equipment

Our property, plant and equipment primarily consists of office and laboratory equipment, computer equipment, furniture and fixture, and leasehold improvements. Our property, plant and equipment amounted to US\$0.4 million, US\$1.1 million and US\$0.4 million as of 31 December 2022, 2023 and 2024, respectively. The increase in the balance of our property, plant and equipment from 31 December 2022 to 31 December 2023 was due to our purchases of various equipment, furnitures and other leasehold fixtures, which were in line with our business expansion. The decrease in the balance of our property, plant and equipment from 31 December 2023 to 31 December 2024 was primarily due to the depreciation of our existing property, plant and equipment pursuant to the accounting policies on depreciation we adopted.

As of 31 December 2022, 2023 and 2024, our management performed an assessment on the recoverable amount of the cash generating units. Based on the results of the assessments, our Directors concluded that the recoverable amounts of the cash generating units were higher than their carrying amounts and no impairment was required as of 31 December 2022, 2023 and 2024.

Prepayments and Other Receivables

Our prepayments and other receivables primarily consisted of (i) prepayments for property, plant and equipment which represented the rental fees of our laboratories, facilities and office space that we leased for R&D and office uses, (ii) other receivables which mainly consisted of value-added tax receivables and interest receivables, (iii) prepayments to CROs and CDMOs in connection with our clinical trials, (iv) prepayments to professional agencies in relation to the proposed Listing, and (v) the rental deposits we pay to the landlord for the properties and facilities we lease as we expand our operation and engage additional staff.

The following table sets forth the balances of our prepayments and other receivables as of the balance sheet dates indicated:

	As of 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Non-current assets			
Prepayments for property, plant and equipment	687	–	–
Rental deposits	<u>121</u>	<u>97</u>	<u>74</u>
	<u>808</u>	<u>97</u>	<u>74</u>
Current assets			
Prepayments	180	170	49
Deferred listing expenses	–	287	307

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	As of 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Prepayments for listing expenses	–	48	145
Rental deposits	5	34	60
Other receivables	684	724	1,764
	<u>869</u>	<u>1,263</u>	<u>2,325</u>
Total prepayments and other receivables	<u>1,677</u>	<u>1,360</u>	<u>2,399</u>

Our prepayments and other receivables increased from US\$1.4 million as of 31 December 2023 to US\$2.4 million as of 31 December 2024. The increase was primarily attributable to a US\$1.0 million increase in other receivables in relation to a refundable deposit paid by us to Zhejiang government as guarantee for our cooperation with Zhejiang government in respect of new drug development, as well as the recoverable tax payment paid in advance to U.S. tax department by ADS USA for its income from R&D services in relation to CBT-009 from Cloudbreak Suzhou.

Our prepayments and other receivables decreased from US\$1.7 million as of 31 December 2022 to US\$1.4 million as of 31 December 2023. The decrease was primarily attributable to a US\$0.7 million decrease in prepayments for property, plant and equipment, and partially offset by a US\$0.3 million increase in deferred listing expenses in connection with the preparation of the Listing.

Convertible Redeemable Preferred Shares

Our convertible redeemable preferred shares consisted of the Preferred Shares issued by us. We designated the Preferred Shares as financial liabilities at fair value through profit or loss, as certain Pre-IPO Investors holding the convertible redeemable preferred shares were granted the right to require us to redeem the Preferred Shares they hold if the proposed Listing is not consummated within a certain period. As of the Latest Practicable Date, we had not received any redemption notice from Series C Investors and a majority of Series C Investors have indicated to us that they have no intention to exercise the redemption rights for at least 12 months from 31 December 2024. See Note 2.1 to the Accountant's Report set out in Appendix I to this prospectus for details. Our convertible redeemable preferred shares had fair value of US\$110.0 million as of 31 December 2022, US\$322.5 million as of 31 December 2023, and US\$386.2 million as of 31 December 2024, primarily due to the increase in fair value of our Preferred Shares. See "History, Development and Corporate Structure – Pre-IPO Investment" in this prospectus for details of our Preferred Shares in the Pre-IPO Investment. The fair value changes of convertible redeemable preferred shares affected our financial performance in the Track Record Period, and will continue to affect our financial performance subsequent to the Track Record Period until the conversion of Preferred Shares into ordinary shares upon Listing. After the reclassification of our

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convertible redeemable preferred shares into the share capital upon the Listing, we do not expect to recognise any further loss or gain on fair value changes from Preferred Shares in the future.

Trade and Other Payables

Our trade and other payables primarily consist of (i) trade payables mainly in connection with our R&D activities, including fees payable to CROs and CDMOs, (ii) receipt in advance from an investor, (iii) payables to a convertible redeemable preferred shareholder in connection with the redeemable Preferred Shares issued pursuant to the Pre-IPO Investments, (iv) accrued legal and professional fee in connection with the service fees paid to counsels and professional agencies, (v) accrued staff costs, (vi) accrued listing expenses, and (vii) other accruals and payables mainly consisted of payables on purchase of software and office facilities, and accruals and payables on other miscellaneous fees. The following table sets forth the balances of our trade and other payables as of the balance sheet dates indicated:

	As of 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Trade payables	1,225	2,102	1,760
Receipt in advance from an investor	27,200	–	–
Payable to a convertible redeemable preferred shareholder	435	–	–
Accrued legal and professional expenses	675	426	128
Accrued staff costs	856	825	1,301
Accrued listing expenses	–	781	947
Other accruals and payables	320	465	630
	<u>30,711</u>	<u>4,599</u>	<u>4,766</u>

Our trade and other payables increased from US\$4.6 million as of 31 December 2023 to US\$4.8 million as of 31 December 2024, mainly due to a US\$0.5 million increase in accrued staff costs, and partially offset by a US\$0.3 million decrease in trade payables primarily for R&D expenses, as we mainly focused on the phase 3 clinical trial of CBT-001 in 2024, which led to fewer associated invoices and a quicker settlement process. In contrast, in 2023, we were concurrently engaged in a number of R&D projects, leading to several suppliers issuing invoices which consequently resulted in a slower payment process.

Our trade and other payables decreased from US\$30.7 million as of 31 December 2022 to US\$4.6 million as of 31 December 2023, primarily due to (i) a US\$27.2 million decrease in receipt in advance from an investor in 2023, as the first tranche of investment amounts we received from a Series C Investor in December 2021 (as such Series C Investor and us had separately agreed that its consideration may be paid in two tranches in order to facilitate settlement) were initially recognised as trade and other payables. The amounts were later recognised as convertible redeemable Preferred Shares when the full investment amounts were received in 2023 (see note (8) to the table under “History, Development and Corporate

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Structure – Pre-IPO Investment – Series C Financing” in this prospectus for reference), partially offset by (i) a US\$0.9 million increase in trade payables as one of our major suppliers issued an invoice to us in late December which was not due as of 31 December 2023, and (ii) a US\$0.8 million increase in accrued listing expenses.

As of the Latest Practicable Date, US\$1.8 million, or 100.0% of our trade payables as of 31 December 2024 had been subsequently settled.

LIQUIDITY AND CAPITAL RESOURCES

Our use of cash during the Track Record Period was primarily related to our R&D activities and general and administrative costs associated with our operations. During the Track Record Period, we funded our cash requirements principally through proceeds from Pre-IPO Investments, capital contribution from our shareholders and government grants.

Although we recorded net current liabilities and net liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including general, administrative and operating costs as well as R&D costs, for at least 12 months from the date of publication of this prospectus by using our cash and cash equivalents amounted to US\$34.9 million as of 31 December 2024, consisting of deposits with banks, cash at banks and cash on hand, and the estimated net proceeds from the Global Offering. As of 30 April 2025 and the Latest Practicable Date, we had unutilised banking facilities of US\$45.0 million and US\$45.0 million, respectively, and none of which were restricted. We do not anticipate any changes to the availability of bank financing to finance our operations in the future and net proceeds from the Global Offering. We estimate that we will receive net proceeds from the Global Offering of approximately HK\$522.2 million after deducting professional fees, underwriting commissions and other fees incurred in connection with the Global Offering at the Offer Price of HK\$10.10 per Offer Share.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, including R&D expenses, (ii) capital expenditures, and (iii) lease payments. As of 31 December 2024, we had cash and cash equivalents of US\$34.9 million. Assuming an average cash burn rate going forward of 1.4 times of the level in the 12 months ended 31 December 2024, which is primarily based on the prospective monthly cash burn rate in the 12 months ending 31 December 2025, we estimate that our cash and cash equivalents as of 31 December 2024 will be able to maintain our financial viability for approximately 11 months, or, if we also take into account the estimated net proceeds (based on the Offer Price of HK\$10.10) from the Global Offering, for approximately 32 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

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Cash Operating Costs

The following table sets out the components of our cash operating cost for the years indicated:

	For the year ended		
	31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
R&D costs			
<i>R&D costs for Core Products</i>			
CDMO fees	926	83	494
CRO fees	6,130	7,538	16,353
Staff costs	1,523	1,762	2,062
Consulting fees	364	565	2,688
Others ⁽¹⁾	136	707	205
<i>R&D costs for other drug candidates</i>			
CDMO fees	1,177	335	218
CRO fees	1,703	1,149	1,178
Staff costs	1,948	2,257	2,228
Consulting fees	419	485	688
Others ⁽¹⁾	<u>856</u>	<u>350</u>	<u>190</u>
Total R&D costs	<u>15,182</u>	<u>15,231</u>	<u>26,304</u>
Workforce employment⁽²⁾	1,774	4,224	3,364

Note:

- (1) Others include equipment costs, raw material and consumables costs, and other miscellaneous fees incurred for the clinical trials for our drug candidates.
- (2) Workforce employment costs represent non-R&D staff costs mainly including salaries, bonuses, pension and benefits.

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Cash Flows

The following table sets forth a summary of our consolidated statements of cash flows for the years indicated:

	For the year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Cash flows from operating activities			
Cash used in operation	(19,835)	(22,586)	(25,480)
Income tax (paid)/refund	(215)	80	(1,042)
Net cash used in operating activities	<u>(20,050)</u>	<u>(22,506)</u>	<u>(26,522)</u>
Cash flows from investing activities			
Purchase of property, plant and equipment	(778)	(556)	(155)
Purchase of land use rights	–	(1,655)	–
Proceeds from disposal of financial assets at fair value through profit or loss	32,552	–	–
Placement of short-term bank deposits	(326,848)	(74,713)	–
Repayment of short-term bank deposits	263,654	130,407	7,500
Interest received	1,602	3,872	2,029
Net cash (used in)/generated from investing activities	<u>(29,818)</u>	<u>57,355</u>	<u>9,374</u>
Cash flows from financing activities			
Repayment to a director	(89)	–	–
Proceeds from issuance of preferred shares	–	2,800	–
Proceeds from issuance of warrants and related financial liabilities	15,975	–	–
Proceeds from bank borrowings	–	284,930	14,000
Repayment of bank borrowings	–	(284,930)	(14,000)
Interest paid on bank borrowings	–	(240)	(4)
Payment for listing expenses	–	(173)	(102)
Payments for acquisition of Cloudbreak USA	(30,000)	–	–
Payment for lease liabilities, principal portion	(192)	(300)	(328)
Payment for lease liabilities, interest portion	(31)	(35)	(23)
Net cash (used in)/generated from financing activities	<u>(14,337)</u>	<u>2,052</u>	<u>(457)</u>
Net (decrease)/increase in cash and cash equivalents	<u>(64,205)</u>	<u>36,901</u>	<u>(17,605)</u>
Cash and cash equivalents at beginning of the year	80,604	15,917	52,654
Exchange differences on cash and cash equivalents	(482)	(164)	(187)
Cash and cash equivalents at the end of the year	<u>15,917</u>	<u>52,654</u>	<u>34,862</u>

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Net Cash Used in Operating Activities

We have incurred negative cash flows from our operations during the Track Record Period. Our net cash used in operating activities mainly consisted of R&D expenses, and general and administrative expenses.

In the year ended 31 December 2024, our net cash used in operating activities was US\$26.5 million, consisting of US\$25.5 million of cash used in operations primarily for our R&D activities and business expansion.

In the year ended 31 December 2023, our net cash used in operating activities was US\$22.5 million, consisting of US\$22.6 million of cash used in operations primarily for our R&D activities and business expansion.

In the year ended 31 December 2022, our net cash used in operating activities was US\$20.1 million, consisting of US\$19.8 million of cash used in operations primarily for our R&D activities and business expansion, and US\$0.2 million of income tax paid primarily consisted of current corporate income tax on unrealised exchange gains.

We target to achieve positive operating cash flow in the future as we continue to enhance our R&D capabilities, improve cost efficiency, and accelerate clinical development of our drug candidates, and to pursue diversified and tailored commercialisation strategies for our drug candidates. Before our future products are commercialised and start to generate revenue, we will mainly focus on controlling and managing the cash outflow, measures of which include accurately tracing and frequently reviewing the budget and then adjust the budget goals based on actual spending as necessary, carefully managing the payment throughout the year, and reviewing the costs and expenses in a more frequent way so that they can match our budget goals.

Net Cash (Used in)/ Generated from Investing Activities

During the Track Record Period, our cash flows used in investing activities primarily related to our short-term bank deposits after we received payment from Series C Investors in 2022, our payment for financial assets at fair value through profit or loss relating to our purchase of an investment product offered by a major PRC commercial bank in 2021, our purchase of property, plant and equipment, and our purchase of land use rights. Our cash flows generated from investing activities primarily consisted of the principal and interest amounts from maturities of the above-mentioned short-term bank deposits, and the proceeds from disposal of fair value through profit or loss when we fully redeemed the above-mentioned investment product in 2022.

In the year ended 31 December 2024, our net cash generated from investing activities was US\$9.4 million, primarily consisting of the principal and interest amounts from maturities of short-term bank deposits.

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In the year ended 31 December 2023, our net cash generated from investing activities was US\$57.4 million, primarily consisting of proceeds from maturities of short-term bank deposits of US\$130.4 million, partially offset by placement in short-term bank deposits of US\$74.7 million and purchase of land use rights of US\$1.7 million in Suzhou.

In the year ended 31 December 2022, our net cash used in investing activities was US\$29.8 million, which primarily consisted of placement of short-term bank deposits of US\$326.8 million after (a) we received payment from Series C Investors and (b) proceeds from maturities of short-term bank deposits in 2022, partially offset by (i) proceeds from maturities of short-term bank deposits of US\$263.7 million, and (ii) proceeds from disposal of financial assets at fair value through profit or loss of US\$32.6 million when we fully redeemed the investment product we purchased from a major PRC commercial bank.

Net Cash (Used in)/ Generated from Financing Activities

During the Track Record Period, our cash flows generated from financing activities primarily reflected proceeds from warrant holders and proceeds from issue of Preferred Shares in connection with the Pre-IPO Investments. Our cash flows used in financing activities primarily reflected our repayments to the then shareholders of Cloudbreak USA under the Share Swap under part of the Group Restructuring and our repayment of bank borrowings.

In the year ended 31 December 2024, our net cash used in financing activities was US\$0.5 million, primarily consisting of (i) the principal and interest amounts we paid for our lease liabilities, and (ii) the payment for listing expenses in relation to the preparation of our proposed Listing.

In the year ended 31 December 2023, our net cash generated from financing activities was US\$2.1 million, primarily consisting of proceeds from issuance of Preferred Shares in connection with Series C Financing as part of the Pre-IPO Investments.

In the year ended 31 December 2022, our net cash used in financing activities was US\$14.3 million, which primarily consisted of the payments for acquisition of Cloudbreak USA of US\$30.0 million, partially offset by the proceeds from warrant holders of US\$16.0 million.

FINANCIAL INFORMATION

INDEBTEDNESS

The following table sets forth the breakdown of our indebtedness as of the dates indicated:

	As of 31 December			As of
	2022	2023	2024	30 April
	US\$'000	US\$'000	US\$'000	2025
				US\$'000
				(unaudited)
Non-Current liability				
Lease liability	548	228	209	149
Current liabilities				
Convertible redeemable preferred shares	109,957	322,459	386,195	386,195
Other financial liabilities at fair value through profit or loss	73,960	–	–	–
Derivative financial instruments	11,783	–	–	–
Lease liabilities	<u>292</u>	<u>317</u>	<u>302</u>	<u>239</u>
Total	<u><u>196,540</u></u>	<u><u>323,004</u></u>	<u><u>386,706</u></u>	<u><u>386,583</u></u>

Bank Borrowings

We did not have any outstanding bank borrowings as of 31 December 2022, 2023 and 2024. As of 30 April 2025 and the Latest Practicable Date, we had unutilised banking facilities of US\$45.0 million and US\$45.0 million, respectively, and none of which were restricted. We do not anticipate any changes to the availability of bank financing to finance our operations in the future. However, we cannot guarantee that we will be able to access bank financing on favorable terms, or at all.

FINANCIAL INFORMATION

Convertible Redeemable Preferred Shares

Our convertible redeemable preferred shares consisted of the Preferred Shares issued by us. Our convertible redeemable preferred shares had fair value of US\$110.0 million, US\$322.5 million, US\$386.2 million and US\$386.2 million as of 31 December 2022, 2023, 2024, and 30 April 2025, respectively, primarily due to the increase in fair value of our Preferred Shares. See “History, Development and Corporate Structure – Pre-IPO Investments” in this prospectus for details of our Preferred Shares in the Pre-IPO Investments.

We designated the Preferred Shares as financial liabilities at fair value through profit or loss, as certain Pre-IPO Investors holding the convertible redeemable preferred shares were granted the right to require us to redeem the Preferred Shares they hold if the proposed Listing is not consummated within a certain period. As of the Latest Practicable Date, we had not received any redemption notice from Series C Investors and a majority of Series C Investors have indicated to us that they have no intention to exercise the redemption rights for at least 12 months from 31 December 2024. See Note 2.1 to the Accountant’s Report set out in Appendix I to this prospectus for details. The Preferred Shares are initially recognised at fair value. Subsequent to initial recognition, the Preferred Shares are carried at fair value with changes in fair value recognised in the profit or loss. See “– Critical Accounting Policies, Estimates and Judgements – Financial Instruments Issued to Investors” above for details.

Our Group has early adopted amendments to Presentation of Financial Statements (“IAS 1”) for accounting period beginning on or after 1 January 2022. As such, all the convertible redeemable preferred shares of US\$110.0 million, US\$322.5 million and US\$386.2 million have been classified as current liabilities in our Group’s consolidated statements of financial position for accounting period as at 31 December 2022, 2023 and 2024.

Other Financial Liabilities at Fair Value through Profit or Loss

Our other financial liabilities at fair value through profit or loss amounted to US\$74.0 million, nil and nil as of 31 December 2022, 2023 and 2024, respectively. The fair value of other financial liabilities in 2022 represented our obligation to Pre-IPO Investors with respect to the Series C Warrants they held as of the respective year ends. Our other financial liabilities at fair value through profit or loss as of 31 December 2023 and 2024 were nil as the relevant warrants were fully exercised by such Pre-IPO Investors in January 2023. See “History, Development and Corporate Structure – Pre-IPO Investments” for details of the Preferred Shares and the warrants.

Derivative Financial Instruments

The derivative financial instruments reflect the outstanding warrants we granted in connection with the Pre-IPO Investment which were converted to Preferred Shares upon the exercise of conversion rights by Pre-IPO Investors. See Note 25 to the Accountant’s Report

FINANCIAL INFORMATION

set out in Appendix I to this prospectus for details. Our derivative financial instruments amounted to US\$11.8 million, nil and nil as of 31 December 2022, 2023, and 2024, respectively.

Lease Liabilities

Our lease liabilities amounted to US\$0.8 million, US\$0.5 million, US\$0.5 million and US\$0.4 million as of 31 December 2022, 2023, 2024, and 30 April 2025, respectively. During the Track Record Period, our lease liabilities were mainly related to our leased properties primarily used for administrative and R&D functions, and leased corporate housing for several employees. See “Business – Land and Properties” in this prospectus for details.

Except as disclosed above, and apart from intra-group liabilities, we did not have, as of 30 April 2025, being our indebtedness statement date, any other debt securities issued and outstanding or authorised or otherwise created but unissued, bank overdrafts, loans or other similar indebtedness, liabilities under acceptances or acceptance credits, debentures, mortgages, charges, hire purchases commitments, guarantees or other material contingent liabilities. We currently do not have any plans for material external debt financing. Our Directors confirm that as of the Latest Practicable Date, there was no material covenant on any of our outstanding debt, and there was no breach of any covenant during the Track Record Period and up to the Latest Practicable Date. Our Directors confirm that our Group did not experience any difficulty in obtaining bank loans and other borrowings, default in payment of bank loans and other borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date. After due and careful consideration, our Directors further confirm that there had been no material change in our indebtedness since 30 April 2025 and up to the date of this prospectus.

CAPITAL EXPENDITURES

Our capital expenditure during the Track Record Period represented payment for our land use rights and purchase of property, plant and equipment. In the years ended 31 December 2022, 2023 and 2024, our capital expenditures amounted to US\$0.8 million, US\$2.2 million and US\$0.2 million respectively.

We have historically funded our capital expenditures primarily through proceeds from Pre-IPO Investments. Going forward, we expect our capital expenditures will continue to consist primarily of payment of purchase of property, plant and equipment, as we continue to progress the development of our product candidates. We expect to finance our capital expenditures primarily through the net proceeds from the Global Offering. We may adjust our capital expenditures for any given period according to our ongoing business needs.

COMMITMENTS

We had capital commitments of US\$241,000, nil and nil as of 31 December 2022, 2023, and 2024, respectively, primarily in connection with the capital expenditures for the purchase of property, plant and equipment, which had not been incurred as at the respective year ends.

FINANCIAL INFORMATION

CONTINGENT LIABILITIES

We did not have any material contingent liabilities during the Track Record Period and up to the Latest Practicable Date.

RELATED PARTY TRANSACTIONS

We had no material related party transactions during the Track Record Period. See Note 26 to the Accountant's Report set out in Appendix I to this prospectus for details on compensation paid or payable to senior management (including Directors) during the Track Record Period classified as related party transactions.

KEY FINANCIAL RATIO

The following table sets forth our key financial ratio as of the balance sheet dates indicated:

	As of 31 December		
	2022	2023	2024
Current ratio <i>(note)</i>	0.35	0.19	0.10

Note: current ratio represents current assets divided by current liabilities as of the same date.

See “– Net Current Liabilities” in this section for details of changes in our current assets and current liabilities over the Track Record Period.

FINANCIAL RISKS

We are exposed to various types of financial and market risks, including foreign exchange risk, cash flow and fair value interest rate risk, credit risk and liquidity risk. Our Directors review and agree financial management policies and practices for managing each of these risks.

Market Risks

Foreign Exchange risk

Foreign currency risk refers to the risk of loss resulting from changes in foreign currency exchange rates. Foreign exchange risk arises when future commercial transactions or recognised assets and liabilities are denominated in a currency that is not the respective group entities' functional currency.

We are exposed to foreign exchange risk arising from various currency exposures. The functional currency of our Group is U.S. dollars, but most of our foreign exchange transactions were denominated in RMB.

FINANCIAL INFORMATION

RMB is not freely convertible into foreign currencies for capital account transactions. The value of U.S. dollar against RMB is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amounts available to us. If RMB strengthened/weakened by 5% against the U.S. dollar as of 31 December 2022, 2023 and 2024, with all other variables held constant, loss before income tax for the years ended 31 December 2022, 2023 and 2024 would have been US\$0.5 million, US\$1.7 million and US\$0.9 million lower/higher. See Note 3.1.1(a) to Accountant's Report set out in Appendix I to this prospectus for details.

We do not believe that we currently have any significant direct foreign exchange risk and did not hedge against any fluctuation in foreign currencies during the Track Record Period. We seek to limit our exposure to foreign currency risk by minimising our net foreign currency position.

Cash flow and Fair Value Interest Rate Risk

Other than interest-bearing short-term bank deposit, we do not have any other significant interest-bearing assets. We do not anticipate there is any significant impact to interest-bearing assets resulted from the changes in interest rates, because the interest rates of short-term bank deposit are not expected to change significantly.

Credit Risk

Credit risk refers to the risk that the counterparty to a financial instrument would fail to discharge its obligation under the terms of the financial instrument and cause a financial loss to us. The carrying amounts of other receivables, short-term bank deposits and cash and cash equivalents represent our Group's maximum exposure to credit risk in relation to financial assets.

During the Track Record Period, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by us. We do not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables was recognised.

We expect that there is no significant credit risk associated with short-term bank deposits and cash and cash equivalents since they are substantially deposited at state-owned banks or reputable commercial banks which are high-credit-quality financial institutions. We do not expect that there will be any significant losses from non-performance by these counterparties.

FINANCIAL INFORMATION

Liquidity risk

We finance our working capital requirements through the issue of preferred shares and convertible preferred shares. Our management monitors rolling forecasts of our liquidity reserve on the basis of expected cash flow.

Prudent liquidity risk management includes maintaining sufficient cash and cash equivalents and the ability to apply for credit facilities if necessary. We are able to meet our financial obligations and fund our R&D activities through our cash on hand and consecutive capital raising activities.

See Note 3.1 to the Accountant's Report set out in Appendix I to this prospectus for details of our foreign exchange risk, cash flow and fair value interest rate risk, credit risk and liquidity risk.

DIVIDEND

We have not declared or paid any dividend during the Track Record Period. We do not currently have any dividend policy or fixed dividend payout ratio or intention to declare or pay any dividend in the near future. Any amount of dividends we pay will be at the discretion of our Directors and will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by our Company from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Directors. Any declaration and payment as well as the amount of dividends will also be subject to our constitutional documents and the relevant laws. See "Summary of the Constitution of the Company and the Cayman Companies Act" set out in Appendix III to this prospectus for details. As advised by our legal advisers as to Cayman Islands laws, although we experienced net loss during the Track Record Period, we will still be able to declare dividends out of our profits after all our historically accumulated losses have been made up for and the allocation of sufficient net profit to our statutory common reserve fund as described above. No dividend shall be declared or payable except out of our profits or share premium account lawfully available for distribution.

DISTRIBUTABLE RESERVES

As of 31 December 2024, we did not have any distributable reserves.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, there were no circumstances that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FINANCIAL INFORMATION

LISTING EXPENSES

Listing expenses represent professional fees, underwriting commissions and other fees incurred in connection with the Global Offering. At the Offer Price of HK\$10.10 per Offer Share, the listing expenses which are payable by us are estimated to amount in aggregate to be approximately US\$11.4 million (equivalent to approximately HK\$89.7 million), accounting for approximately 14.7% of the gross proceeds from the Global Offering.

The total listing expenses consist of (i) approximately US\$4.1 million underwriting fees (including underwriting commission, incentive fee, SFC transaction levy, Stock Exchange trading fee and AFRC transaction levy) and (ii) approximately US\$7.3 million non-underwriting fees mainly comprising (a) fees paid to legal adviser(s) and accountant(s) of approximately US\$4.4 million, and (b) other fees and expenses and fees paid to other professional parties of approximately US\$2.9 million. Among the total listing expenses, US\$2.1 million and US\$1.5 million was charged to our consolidated statements of comprehensive income for the year ended 31 December 2023 and 2024, respectively, and approximately US\$3.3 million is expected to be charged to profit or loss, and approximately US\$4.5 million directly attributable to the issue of the Shares is expected to be deducted from equity upon the completion of the Global Offering. Our total listing expenses are estimated to account for 14.7% of the gross proceeds of the Global Offering. The listing expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED PRO FORMA ADJUSTED NET TANGIBLE ASSETS

See “Unaudited Pro Forma Financial Information” in Appendix II to this prospectus for further details of our unaudited pro forma statement of adjusted consolidated net tangible assets.

OFF-BALANCE SHEET ARRANGEMENTS

During the Track Record Period and as of the Latest Practicable Date, we had no off-balance sheet arrangements.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, having performed reasonable due diligence on our Group, there has been no material adverse change in our financial or trading position or prospects since 31 December 2024 and up to the date of this prospectus.

FUTURE PLANS AND USE OF PROCEEDS

FUTURE PLANS

See “Business – Our Strategies” for a detailed description of our future plans and strategies.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the Global Offering of approximately HK\$522.2 million after deducting professional fees, underwriting commissions and other fees incurred in connection with the Global Offering at the Offer Price of HK\$10.10 per Offer Share. We intend to use the net proceeds we receive from the Global Offering as follows:

- Approximately 62.4%, or HK\$325.9 million, will be used to fund the continuing clinical R&D activities including costs and expenses of our R&D staff and R&D activities as well as registration filings and post-approval studies of our Core Product, CBT-001:
 - approximately 46.4%, or HK\$242.3 million, will be used for advancing our phase 3 MRCT clinical trials in the United States and China, as well as additional clinical trials in other regions as part of the global phase 3 MRCT, including the payment to CROs and CDMOs, and costs for raw materials and consumables to be used in our ongoing clinical trials. The phase 3 MRCT in the United States and China was commenced in June 2022 and September 2023, respectively. We target to complete phase 3 MRCT in the United States and in China in June 2026, respectively. We have also commenced additional clinical trials in New Zealand, Australia and India to continue to assess the efficacy of CBT-001 as part of the global phase 3 MRCT. See “Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-001” for details;
 - approximately 7.7%, or HK\$40.2 million, will be devoted to improving our chemistry, manufacture and control (“CMC”) process. We plan to improve (i) our manufacturing capabilities in the view to complying with applicable GMP standards, (ii) clinical supply capabilities to support the phase 3 MRCT, and (iii) quality assurance system including validating trial methods, conducting drug testing, and ensuring stability for drug products to support the CMC process, which would in turn support the ongoing clinical trials and anticipated commercialisation plan of CBT-001;
 - approximately 6.5%, or HK\$34.0 million, will be used to fund the registration procedures of CBT-001, such as the NDA submission to the FDA;
 - approximately 1.8%, or HK\$9.4 million, will be devoted to R&D staff costs and non-clinical matters of CBT-001 in connection with its registration filing procedures.

FUTURE PLANS AND USE OF PROCEEDS

- Approximately 27.6%, or HK\$144.1 million, will be used to fund the continuing clinical R&D activities including costs and expenses of our R&D staff and R&D activities as well as registration filings of our Core Product, CBT-009:
 - approximately 21.8%, or HK\$113.8 million, will be used for CBT-009's proposed phase 3 MRCT in the United States and China. In September 2023, the FDA approved us to proceed with the phase 3 clinical trial under the 505(b)(2) pathway in the United States utilising the phase 1/2 clinical results in Australia. We submitted the IND application to the FDA in July 2024 after we completed the six-month ocular toxicity study to support phase 3 clinical trial, and received an approval letter from the FDA in September 2024 stating that it had no objection to us proceeding with phase 3 clinical trial. We have commenced the toxicity study on juvenile animals in China in February 2025 to support our plan of including China as part of CBT-009's phase 3 MRCT. See "Business – Our Pipeline of Drug Candidates – Clinical-stage Drug Candidates – Our Core Product – CBT-009" for details;
 - o approximately 13.6%, or HK\$71.0 million, will be used for PIs and patient enrolment for phase 3 clinical trial of CBT-009 in the United States and China;
 - o approximately 7.2%, or HK\$37.6 million, will be used for the payment to CROs and CDMOs for phase 3 clinical trial of CBT-009 in the United States and China;
 - o approximately 1.0%, or HK\$5.2 million, will be used for other miscellaneous expenses for phase 3 clinical trial of CBT-009 in the United States and China, such as the IRB review procedures and costs for raw materials and consumables to be used in our ongoing clinical trials;
 - approximately 5.3%, or HK\$27.7 million, will be devoted to improving our CMC process, which would in turn support the planned phase 3 clinical trial for CBT-009;
 - approximately 0.4%, or HK\$2.1 million, will be devoted to R&D staff costs and non-clinical matters of CBT-009 in connection with its registration filing procedures;
 - approximately 0.1%, or HK\$0.5 million, will be used to fund the registration procedures of CBT-009, such as the IND amendment procedures and the maintenance fees.
- Approximately 5.5%, or HK\$28.7 million, will be used for funding the manufacturing facilities and commercialisation activities. We have built a pilot production facility located in Suzhou New District, which was designed and built with a view to complying with GMP standards in the United States, China and EU, and we plan to use the net proceeds to purchase manufacturing equipment

FUTURE PLANS AND USE OF PROCEEDS

and analytical equipment for quality control (“QC”) release testing, in order to support our global clinical trials and global commercialisation of our future products. In addition, we plan to build a sizeable commercial production facility in Suzhou, Jiangsu, the PRC, based on our clinical development progress and commercialisation needs, that meets various quality standards set by relevant regulatory authorities globally, including GMP, to prepare for the anticipated commercialisation of our drug candidates or our drug candidates. The phase 1 construction of our commercial production facility has commenced in December 2024, and the phase 2 and phase 3 construction is expected to be completed in 2028 and 2033, respectively. See “Business – Manufacturing – Our Production Facility in Suzhou” for details.

- Approximately 4.5%, or HK\$23.5 million, will be used for working capital and other general corporate purposes.

Compared to the R&D expenses incurred for the clinical development of our Core Products during the Track Record Period, the use of proceeds to be allocated to our Core Products after Listing is higher, because (i) both CBT-001 and CBT-009 are/ will be in phase 3 clinical trial stage, the costs of which are significantly higher than phase 2 and earlier stage clinical trials we conducted during the Track Record Period, taking into consideration the substantial increase in the number of patients enrolled and the duration of the clinical trial; (ii) ongoing Phase 3 MRCTs are being conducted for CBT-001 in multiple jurisdictions, and we also plan to conduct MRCTs for CBT-009 in the United States and China in the following few years. Therefore, the ongoing and future engagements of local CROs and CDMOs and the communications and filings with relevant local authorities would potentially incur additional expenses; (iii) part of the clinical development costs for the Core Products will be devoted to the costly process of NDA submission, in particular in the United States. In addition, there are additional non-clinical studies required before for the NDA submission for each of CBT-001 and CBT-009; and (iv) the use of proceeds will be allocated to the clinical development of CBT-001 and CBT-009 for a period longer than the Track Record Period.

To the extent that the net proceeds of the Global Offering are not immediately required for the above purposes or if we are unable to put into effect any part of our development plan as intended, we may hold such funds in short-term interest-bearing accounts at licensed commercial banks and/or other authorised financial institutions (as defined under the SFO or applicable laws and regulations in other jurisdictions). In such event, we will comply with the appropriate disclosure requirements under the Listing Rules.

We currently have no specific plans as to how the net proceeds from this Global Offering will be allocated beyond the uses specified above, and therefore management will retain discretion to allocate the remainder of the net proceeds of this Global Offering among these uses.

This expected use of the net proceeds from this Global Offering represents our intentions based upon our current plans and business conditions. As of the Latest Practicable Date, we could not predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this Global Offering or the amounts that we will actually

FUTURE PLANS AND USE OF PROCEEDS

spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our drug development programmes, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our drug candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this Global Offering and may change the allocation of use of these proceeds among the uses described above. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

We will issue an appropriate announcement if there is any material change in the above-mentioned use of proceeds.

UNDERWRITING

HONG KONG UNDERWRITERS

(in alphabetic order with respective to (i) the Joint Sponsors, and (ii) the other Hong Kong Underwriters, respectively)

CCB International Capital Limited

Huatai Financial Holdings (Hong Kong) Limited

BOCI Asia Limited

BOCOM International Securities Limited

China Galaxy International Securities (Hong Kong) Co., Limited

China Industrial Securities International Capital Limited

CMBC Securities Company Limited

CMB International Capital Limited

First Shanghai Securities Limited

Fosun International Securities Limited

Huafu International Securities Limited

ICBC International Securities Limited

Livermore Holdings Limited

Patrons Securities Limited

Quam Securities Limited

Ruibang Securities Limited

Soliton Securities Limited

SPDB International Capital Limited

uSMART Securities Limited

UNDERWRITING

This prospectus is published solely in connection with the Hong Kong Public Offering. The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters on a conditional basis. The International Offering is expected to be fully underwritten by the

UNDERWRITING

International Underwriters. If, for any reason, the Offer Price is not agreed between the Overall Coordinators (for themselves and on behalf of the Underwriters) and our Company, the Global Offering will not proceed and will lapse.

The Global Offering comprises the Hong Kong Public Offering of initially 6,058,500 Hong Kong Offer Shares and the International Offering of initially 54,523,500 International Offer Shares, subject, in each case, to reallocation on the basis described in “Structure of the Global Offering” in this prospectus.

UNDERWRITING ARRANGEMENTS AND EXPENSES

Hong Kong Public Offering

Hong Kong Underwriting Agreement

The Hong Kong Underwriting Agreement was entered into on or around Monday, 23 June 2025. Pursuant to the Hong Kong Underwriting Agreement, we are offering initially 6,058,500 Hong Kong Offer Shares for subscription by the public in Hong Kong on the terms and conditions set out in this prospectus and the Hong Kong Underwriting Agreement at the Offer Price.

Subject to (i) the Stock Exchange granting approval for the listing of, and permission to deal in, the Shares in issue and to be issued pursuant to the Global Offering (including the Shares to be issued pursuant to the Equity Incentive Arrangements and Post-IPO Equity Incentive Scheme) on the Main Board of the Stock Exchange and such approval not subsequently having been revoked or withdrawn prior to the commencement of trading of the Shares on the Stock Exchange and (ii) certain other conditions set out in the Hong Kong Underwriting Agreement, the Hong Kong Underwriters have agreed severally but not jointly to subscribe or procure subscribers for their respective applicable proportions of the Hong Kong Offer Shares now being offered which are not taken up under the Hong Kong Public Offering on the terms and conditions set out in this prospectus and the Hong Kong Underwriting Agreement.

The Hong Kong Underwriting Agreement is conditional on, among other things, the International Underwriting Agreement having been executed and becoming unconditional and not having been terminated in accordance with its terms.

If there is any change to the offer size due to change in the number of Offer Shares initially offered in the Global Offering (other than pursuant to the reallocation mechanism as disclosed in this prospectus), or change to the Offer Price, or if our Company becomes aware that there has been a significant adverse change affecting any matter contained in this prospectus or a significant new matter has arisen, the inclusion of information in respect of which would have been required to be in this prospectus if it had arisen before this prospectus was issued, after the issue of this prospectus and before the commencement of dealings in our Shares as prescribed under Rule 11.13 of the Listing Rules, we are required to cancel the Global Offering and relaunch the offer and issue a supplemental prospectus or a new prospectus in FINI.

UNDERWRITING

Grounds for Termination

If any of the events set out below shall occur at any time prior to 8:00 a.m. on the Listing Date, the Overall Coordinators (for themselves and on behalf of the Hong Kong Underwriters) shall in their absolute discretion, be entitled by giving notice (in writing) to our Company to terminate the Hong Kong Underwriting Agreement with immediate effect:

- (a) there shall develop, occur, exist or come into effect:
 - (i) any event, or series of events, or circumstance in the nature of force majeure (including, without limitation, any acts of government, declaration of a national, regional or international emergency or war, calamity, crisis, epidemic, pandemic, outbreak, escalation, mutation or aggravation of diseases (including, without limitation, COVID-19, Severe Acute Respiratory Syndrome (SARS), swine or avian flu, H5N1, H1N1, H7N9, Ebola virus, Middle East respiratory syndrome and such related/ mutated forms and the escalation of such disease), economic sanctions, strikes, labour disputes, lock-outs, other industrial actions, fire, explosion, flooding, tsunami, earthquake, volcanic eruption, civil commotion, riots, rebellion, public disorder, acts of war, outbreak or escalation of hostilities (whether or not war is declared), acts of God or acts of terrorism (whether or not responsibility has been claimed), paralysis in government operations, interruptions or delays in transportation in or affecting Hong Kong, the Cayman Islands, the British Virgin Islands, the PRC, the United States, Australia, Hong Kong, Germany or any other jurisdiction relevant to the Group (each a “**Relevant Jurisdiction**” and collectively, the “**Relevant Jurisdictions**”); or
 - (ii) any change or development involving a prospective change, or any event or circumstances likely to result in any change or development involving a prospective change, in any local, national, regional or international financial, economic, political, military, industrial, legal, fiscal, regulatory, currency, credit or market conditions (including, without limitation, conditions in the stock and bond markets, money and foreign exchange markets, the interbank markets and credit markets) in or affecting any of the Relevant Jurisdictions; or
 - (iii) any moratorium, suspension or restriction (including, without limitation, any imposition of or requirement for any minimum or maximum price limit or price range) in or on trading in securities generally on the Stock Exchange, the New York Stock Exchange, the NASDAQ Global Market, the London Stock Exchange, the Shanghai Stock Exchange or the Shenzhen Stock Exchange; or
 - (iv) any general moratorium on commercial banking activities in any of the Relevant Jurisdictions (declared by the relevant competent authority), or any disruption in commercial banking or foreign exchange trading or securities settlement or clearance services, procedures or matters in or affecting any of the Relevant Jurisdictions; or
 - (v) any new laws, or any change or development involving a prospective change or any event or circumstance likely to result in a change or a development involving a prospective change in (or in the interpretation or application by any court or other competent authority of) existing laws, in each case, in or affecting any of the Relevant Jurisdictions; or

UNDERWRITING

- (vi) the imposition of economic sanctions, in whatever form, directly or indirectly, by, or for, any of the Relevant Jurisdictions or any other jurisdiction relevant to any member of the Group; or
- (vii) a change or development involving a prospective change or amendment in or affecting taxation or foreign exchange control, currency exchange rates or foreign investment regulations (including, without limitation, a material devaluation of the United States dollar, the Hong Kong dollar, the Renminbi or Euro against any foreign currencies, a change in the system under which the value of the Hong Kong dollar is linked to that of the United States dollar or the Renminbi is linked to any foreign currency or currencies), or the implementation of any exchange control, in any of the Relevant Jurisdictions or affecting an investment in the Offer Shares; or
- (viii) any litigation or claim of any third party, regulatory or administrative or investigative action being threatened, instigated or announced against any member of the Group or any Director which will have a Material Adverse Effect (as defined in the Hong Kong Underwriting Agreement); or
- (ix) any Director or member of the senior management of the Company is being charged with an indictable offence or prohibited by operation of law or otherwise disqualified from taking part in the management of a company or there is the commencement by any governmental, political or regulatory body of any investigation or other action against any Director or member of the senior management of the Company in his or her capacity as such or an announcement by any governmental, political or regulatory body that it intends to commence any such investigation or take any such action; or
- (x) the chairman, chief executive officer, any Director or any other member of senior management of the Company vacating his or her office; or
- (xi) an authority or a political body or organisation in any Relevant Jurisdiction commencing any investigation or other action, or announcing an intention to investigate or take other action, against any Director; or
- (xii) a contravention by any member of the Group or any Director of the Listing Rules or applicable laws which will have a Material Adverse Effect; or
- (xiii) a prohibition on the Company for whatever reason from offering, allotting, issuing or selling any of the Offer Shares pursuant to the terms of the Global Offering; or
- (xiv) any non-compliance of this prospectus (or any other documents used in connection with the contemplated offer and sale of the Offer Shares), the CSRC Filings (as defined in the Hong Kong Underwriting Agreement) or any aspect of the Global Offering with the Listing Rules, the CSRC Rules (as defined in the Hong Kong Underwriting Agreement) or any other applicable laws, which will have a Material Adverse Effect; or
- (xv) the issue or requirement to issue by the Company of any supplement or amendment to this prospectus, the CSRC Filings (or to any other documents used in connection with the contemplated offer and sale of the Offer Shares) pursuant to the Companies Ordinance or the Companies (Winding Up and Miscellaneous Provisions) Ordinance or the Listing Rules or the CSRC Rules or upon any requirement or request of the Stock Exchange, the SFC and/or the CSRC; or

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(xvi) an order or petition for the winding up of any member of the Group or any composition or arrangement made by any member of the Group with its creditors or a scheme of arrangement entered into by any member of the Group or any resolution for the winding-up of any member of the Group or the appointment of a provisional liquidator, receiver or manager over all or part of the material assets or undertaking of any member of the Group or anything analogous thereto occurring in respect of any member of the Group,

which, individually or in the aggregate, in the sole opinion of the Joint Sponsors and the Overall Coordinators (for themselves and on behalf of the Hong Kong Underwriters):

- (1) has or will have or may have a material adverse effect on the assets, liabilities, business, general affairs, management, prospects, shareholders' equity, profits, losses, results of operations, position or condition, financial or otherwise, or performance of the Group as a whole or to any present or prospective shareholder of the Company in its capacity as such; or
 - (2) has or will have or may have a material adverse effect on the success of the Global Offering or the level of applications of the Offer Shares under the Hong Kong Public Offering or the level of interest under the International Offering; or
 - (3) makes or will make or may make it inadvisable, inexpedient or impracticable for the Global Offering to proceed or to market the Global Offering or the delivery or distribution of the Offer Shares on the terms and in the manner contemplated by the Offering Documents (as defined in the Hong Kong Underwriting Agreement); or
 - (4) has or will have or may have the effect of making any part of the Hong Kong Underwriting Agreement (including underwriting) incapable of performance in accordance with its terms or preventing the processing of applications and/or payments pursuant to the Global Offering or pursuant to the underwriting thereof; or
- (b) there has come to the notice of the Joint Sponsors and the Overall Coordinators (for themselves and on behalf of the Hong Kong Underwriters):
- (i) any statement contained in this prospectus and/or in any notices, announcements, advertisements, communications or other documents issued or used by or on behalf of the Company in connection with the Hong Kong Public Offering (including any supplement or amendment thereto) was, when it was issued, or has become, untrue, incorrect, inaccurate, incomplete in any material respects, deceptive or misleading in any respect, or that any forecast, estimate, expression of opinion, intention or expectation contained in any of this prospectus and/or any notices, announcements, advertisements, communications or other documents issued or used by or on behalf of the Company in connection with the Hong Kong Public Offering (including any supplement or amendment thereto) is not fair and honest and based on reasonable grounds or reasonable assumptions; or

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- (ii) any of the CSRC Filings relating to or in connection with the Global Offering, or any amendments or supplements thereto (in each case, whether or not approved by the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters and the Capital Market Intermediaries, or any of them) containing any untrue, incorrect or inaccurate or alleged untrue, incorrect or inaccurate statement of a material fact, or omitting or being alleged to have omitted a fact necessary to make any statement therein, in the light of the circumstances under which it was made, misleading, or not containing, or being alleged not to contain, all information in the context of the Global Offering or otherwise required to be contained thereto or being or alleged to be defamatory of any person or any jurisdiction;
- (iii) any matter has arisen or has been discovered which would, had it arisen or been discovered immediately before the date of this prospectus, constitute a material omission from, or material misstatement in, any of the Offering Documents and/or in any notices, announcements, advertisements, communications or other documents issued or used by or on behalf of the Company in connection with the Hong Kong Public Offering (including any supplement or amendment thereto) and the CSRC Filings; or
- (iv) any breach of any of the obligations imposed upon any party to the Hong Kong Underwriting Agreement or the International Underwriting Agreement (other than upon any of the Hong Kong Underwriters or the International Underwriters), as applicable; or
- (v) any event, act or omission which gives or is likely to give rise to any liability of any of the Indemnifying Parties (as defined in the Hong Kong Underwriting Agreement) set out in the Hong Kong Underwriting Agreement; or
- (vi) any material adverse change, or any development involving a prospective material adverse change, in the assets, liabilities, business, general affairs, management, prospects, shareholders' equity, profits, losses, results of operations, position or condition, financial or otherwise, or performance of the Group as a whole; or
- (vii) any breach of, or any event or circumstance rendering untrue or incorrect or misleading in any respect, any of the Warranties (as defined in the Hong Kong Underwriting Agreement); or
- (viii) any Material Adverse Change (as defined in the Hong Kong Underwriting Agreement);
- (ix) that approval by the Listing Committee of the listing of, and permission to deal in, the Shares to be issued or sold under the Global Offering is refused or not granted, other than subject to customary conditions, on or before the Listing Date, or if granted, the approval is subsequently withdrawn, cancelled, qualified (other than by customary conditions), revoked or withheld; or

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- (x) any person (other than any of the Joint Sponsors), whose consent is required for the issue of this prospectus with the inclusion of its reports, letters or opinions and references to its name included in the form and context in which it respectively appears, has withdrawn its consent to the issue of this prospectus with the inclusion of its reports, letter and/or legal opinions (as the case may be) and references to its name included in the form and context in which it respectively appears;
- (xi) the Company withdraws this prospectus (and/or any other documents issued or used in connection with the Global Offering) or the Global Offering; or
- (xii) a material portion of the orders placed or confirmed in the bookbuilding process, or of the investment commitments made by any cornerstone investors under agreements signed with such cornerstone investors, have been withdrawn, terminated or cancelled, or any Cornerstone Investment Agreement is terminated.

Undertakings to the Stock Exchange pursuant to the Listing Rules

Undertakings by our Company

Pursuant to Rule 10.08 of the Listing Rules, our Company has undertaken to the Stock Exchange that it will not, at any time within six months from the Listing Date, issue any shares or other securities convertible into equity securities of our Company (whether or not of a class already listed) or enter into any agreement or arrangement to issue any shares or such other securities (whether or not such issue of the shares or such other securities will be completed within six months from the Listing Date, except (i) pursuant to the Global Offering or any exercise of the options which may be granted under the Post-IPO Equity Incentive Scheme, or (ii) under any of the circumstances provided under Rule 10.08 of the Listing Rules.

Undertakings by the Single Largest Shareholders

Each of our Single Largest Shareholders has voluntarily undertaken to our Company that, except pursuant to (i) the Global Offering, or (ii) the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, or as permitted under the Listing Rules, they shall not and shall procure that the relevant registered holder(s) will not, in the period commencing on the date by reference to which disclosure of their shareholding in our Company is made in this prospectus and ending on the date which is six months from the Listing Date (the “**First Six-month Period**”), dispose of, nor enter into any agreement to dispose of or otherwise create any options, rights, interests or encumbrances in respect of, any of the securities of our Company in respect of which they are shown by this prospectus to be the beneficial owners.

Our Single Largest Shareholders have irrevocably and unconditionally undertaken to our Company that, within the period commencing on the date by reference to which disclosure of their shareholding in our Company is made in this prospectus and ending on the date which is 12 months from the date on which dealings in the Shares commence on the Stock Exchange, they will and will procure that the relevant registered holder(s) will:

- (a) when they pledge or charge any securities of our Company beneficially owned by him in favour of an authorised institution (as defined in the Banking Ordinance (Chapter 155 of the Laws of Hong Kong)) for a bona fide commercial loan, immediately inform our Company of such pledge or charge together with the number of the securities so pledged or charged; and

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- (b) when they receive indications, either verbal or written, from the pledgee or chargee that any of the pledged or charged securities will be disposed of, immediately inform our Company of such indications.

Our Company will inform the Stock Exchange as soon as it has been informed of the matters referred to in paragraph (a) and (b) above (if any) by our Single Largest Shareholders and subject to the then requirements of the Listing Rules disclose such matters by way of an announcement which is published in accordance with Rule 2.07C of the Listing Rules as soon as possible.

Undertakings pursuant to the Hong Kong Underwriting Agreement

Undertakings by our Company

Our Company has undertaken to each of the Hong Kong Underwriters, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers and the Joint Sponsors not to and to procure each other member of the Group not to, without the prior written consent of the Joint Sponsors and the Overall Coordinators (for themselves and on behalf of the Hong Kong Underwriters) and unless in compliance with the requirements of the Listing Rules, at any time during the period commencing on the date of the Hong Kong Underwriting Agreement and ending on, and including, the date that is six months after the Listing Date (the “**First Six-Month Period**”):

- (a) allot, issue, sell, accept subscription for, offer to allot, issue or sell, contract or agree to allot, issue or sell, mortgage, charge, pledge, hypothecate, lend, grant or sell any option, warrant, contract or right to subscribe for or purchase, grant or purchase any option, warrant, contract or right to allot, issue or sell, or otherwise transfer or dispose of or create an encumbrance over, or agree to transfer or dispose of or create an encumbrance over, either directly or indirectly, conditionally or unconditionally, any Shares or other securities of the Company or any shares or other securities of such other member of the Group, as applicable, or any interest in any of the foregoing (including, without limitation, any securities convertible into or exchangeable or exercisable for or that represent the right to receive, or any warrants or other rights to purchase, any Shares or any shares of such other member of the Group, as applicable), or deposit any Shares or other securities of the Company or any shares or other securities of such other member of the Group, as applicable, with a depositary in connection with the issue of depositary receipts; or
- (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Shares or other securities of the Company or any shares or other securities of such other member of the Group, as applicable, or any interest in any of the foregoing (including, without limitation, any securities convertible into or exchangeable or exercisable for or that represent the right to receive, or any warrants or other rights to purchase, any Shares or any shares of such other member of the Group, as applicable); or
- (c) enter into any transaction with the same economic effect as any transaction specified in paragraphs (a) or (b) above; or

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- (d) offer to or agree to or announce any intention to effect any transaction specified in paragraphs (a), (b) or (c) above,

In the event that, during the period of six months commencing on the date on which the First Six-Month Period expires (the “**Second Six-Month Period**”), our Company enters into any such transactions specified in paragraphs (a), (b) or (c) above or offers or agrees or contracts to, or announces, or publicly discloses, any intention to, enter into any such transactions, our Company shall take all reasonable steps to ensure that it will not create a disorderly or false market in the securities of our Company.

Undertakings by the Single Largest Shareholders

The Single Largest Shareholders have undertaken to our Company, the Overall Coordinators, the Joint Global Coordinators, the Joint Sponsors and the Hong Kong Underwriters that, without the prior written consent of the Joint Sponsors and the Overall Coordinators (for themselves and on behalf of the Hong Kong Underwriters) and unless in compliance with the requirements of the Listing Rules:

- (a) they will not, at any time during the First Six-Month Period, (i) sell, offer to sell, contract or agree to sell, mortgage, charge, pledge, hypothecate, lend, grant or sell any option, warrant, contract or right to purchase, grant or purchase any option, warrant, contract or right to sell, or otherwise transfer or dispose of or create an encumbrance over, or agree to transfer or dispose of or create an encumbrance over, either directly or indirectly, conditionally or unconditionally, any Shares or other securities of the Company or any interest therein (including, without limitation, any securities convertible into or exchangeable or exercisable for or that represent the right to receive, or any warrants or other rights to purchase, any Shares), or deposit any Shares or other securities of the Company with a depositary in connection with the issue of depositary receipts, or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any Shares or other securities of the Company or any interest therein (including, without limitation, any securities convertible into or exchangeable or exercisable for or that represent the right to receive, or any warrants or other rights to purchase, any Shares), or (iii) enter into any transaction with the same economic effect as any transaction specified in (i) or (ii) above, or (iv) offer to or agree to or announce any intention to effect any transaction specified in (i), (ii) or (iii) above, in each case, whether any of the transactions specified in (i), (ii) or (iii) above is to be settled by delivery of Shares or other securities of the Company or in cash or otherwise (whether or not the issue of such Shares or other securities will be completed within the First Six-Month Period);
- (b) they will not, during the Second Six-Month Period, enter into any of the transactions specified in (a)(i), (ii) or (iii) above or offer to or agree to or announce any intention to effect any such transaction if, immediately following any sale, transfer or disposal or upon the exercise or enforcement of any option, right, interest or encumbrance pursuant to such transaction, they will cease to be the Single Largest Shareholders of the Company; and

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- (c) until the expiry of the Second Six-Month period, in the event that they enter into any of the transactions specified in (a)(i), (ii) or (iii) above or offer to or agrees to or announce any intention to effect any such transaction, they will take all reasonable steps to ensure that they will not create a disorderly or false market in the securities of the Company.

The Single Largest Shareholders have further undertaken to our Company, the Overall Coordinators, the Joint Global Coordinators, the Joint Sponsors and the Hong Kong Underwriters that they will, at any time within the period commencing on the date of the Hong Kong Underwriting Agreement and ending on the date which is 12 months after the Listing Date:

- (a) upon any pledge or charge in favour of an authorised institution (as defined in the Banking Ordinance (Chapter 155 of the Laws of Hong Kong)) of any Shares or securities or interests in the Shares or securities of our Company beneficially owned by them for a bona fide commercial loan, immediately inform our Company, the Overall Coordinators, the Joint Global Coordinators and the Joint Sponsors in writing of such pledge or charge together with the number of Shares or securities so pledged or charged; and
- (b) upon any indication received by them, either verbal or written, from any pledgee or chargee that any of the pledged or charged Shares or securities or interests in the Shares or securities of our Company will be disposed of, immediately inform our Company, the Overall Coordinators, the Joint Global Coordinators and the Joint Sponsors in writing of such indications.

Our Company has agreed and undertaken to the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators and each of the Hong Kong Underwriters, that, upon receiving such information in writing from the Single Largest Shareholders, it shall, as soon as practicable, notify the Stock Exchange and make an announcement in accordance with the Listing Rules.

Undertakings by certain of our existing Shareholders

Each of VD&TL, Dinh Legacy Trust, YDD Consulting, Dr. Li, Bright Future, Skketch Shine, Yicun Holdings, Gaotejia, Whitcup Life, Grand Diamond, Design Time, De Hong Xin, Brillimedical, Ms. Chan Ching Chu, Saier Holdings, Hainan Efung, K. RUI, Yunxin Holdings, Shanghai Tianyi, Chuangdongfang Changhui, Zhongyin Health, Renfu Zhou Ltd., Yingke Zhi De Pu Ze, Yunwen, Jiangmen Efung, Jinhua Jinkai, Shanghai Yiyue and Dr. John Hovanesian (collectively, the “**Relevant Existing Shareholders**”), has entered into a lock-up undertaking letter (the “**Lock-up Undertakings**”) in favor of the Company and the Joint Sponsors (for themselves and on behalf of the Underwriters). Pursuant to the Lock-up Undertakings, the Relevant Existing Shareholders are subject to a lock-up undertaking for a period commencing on the date of this prospectus and ending on the last day of six (6) months from the Listing Date.

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Hong Kong Underwriters' interests in our Company

Save for their respective obligations under the Hong Kong Underwriting Agreement and/or the International Underwriting Agreement, as of the Latest Practicable Date, none of the Hong Kong Underwriters was interested, legally or beneficially, directly or indirectly, in any Shares or other securities of our Company or any other member of the Group or had any right or option (whether legally enforceable or not) to subscribe for or purchase, or to nominate persons to subscribe for or purchase, any Shares or other securities of our Company or any other member of the Group.

Following the completion of the Global Offering, the Hong Kong Underwriters and their affiliated companies may hold a certain portion of the Shares as a result of fulfilling their respective obligations under the Hong Kong Underwriting Agreement and/or the International Underwriting Agreement. See “Structure of the Global Offering” for details.

International Offering

International Underwriting Agreement

In connection with the International Offering, our Company and the Single Largest Shareholders expect to enter into the International Underwriting Agreement with the International Underwriters. Under the International Underwriting Agreement, the International Underwriters would, subject to certain conditions set out therein, agree severally but not jointly to procure purchasers for, or themselves purchase, their respective proportions of the International Offer Shares being offered pursuant to the International Offering. See “Structure of the Global Offering-The International Offering” for details. It is expected that the International Underwriting Agreement may be terminated in similar grounds as the Hong Kong Underwriting Agreement. Potential investors should note that in the event that the International Underwriting Agreement is not entered into, the Global Offering will not proceed. See “Structure of the Global Offering” for details.

Commissions and expenses

The Underwriters will receive an underwriting commission of 3.0% of the aggregate Offer Price of all the Offer Shares for both the Hong Kong Public Offering and the International Offering, out of which they will pay any sub-underwriting commission and other fees. Our Company may pay the Underwriters an incentive fee up to 3.0% of the aggregate Offer Price of all the Offer Shares for both the Hong Kong Public Offering and International Offering to be awarded at our Company's discretion. For any unsubscribed Hong Kong Offer Shares reallocated to the International Offering, we will pay the underwriting commission for such Offer Shares to the International Underwriters (but not the Hong Kong Underwriters).

The aggregate underwriting commissions and fees payable to the Underwriters, together with the Stock Exchange listing fees, the SFC transaction levy, the AFRC transaction levy and the Stock Exchange trading fee, legal and other professional fees and printing and all other expenses in relation to the Global Offering are estimated to be approximately HK\$89.7 million (assuming no Shares are further issued pursuant to the Equity Incentive

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Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements, and based on the Offer Price of HK\$10.10 per Offer Share and the full payment of the discretionary incentive fee) in total and are payable by our Company.

Indemnity

Each of our Company and the Single Largest Shareholders have agreed to indemnify the Hong Kong Underwriters for certain losses which they may suffer or incur, including losses arising from their performance of their obligations under the Hong Kong Underwriting Agreement and any breach by our Company of the Hong Kong Underwriting Agreement.

INDEPENDENCE OF THE JOINT SPONSORS

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

ACTIVITIES BY SYNDICATE MEMBERS

The underwriters of the Hong Kong Public Offering and the International Offering (together, the “**Syndicate Members**”) and their affiliates may each individually undertake a variety of activities (as further described below) which do not form part of the underwriting or stabilising process.

The Syndicate Members and their affiliates are diversified financial institutions with relationships in countries around the world. These entities engage in a wide range of commercial and investment banking, brokerage, funds management, trading, hedging, investing and other activities for their own account and for the account of others. In the ordinary course of their various business activities, the Syndicate Members and their respective affiliates may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers. Such investment and trading activities may involve or relate to assets, securities and/or instruments of our Company and/or persons and entities with relationships with our Company and may also include swaps and other financial instruments entered into for hedging purposes in connection with our Group’s loans and other debt.

In relation to the Shares, the activities of the Syndicate Members and their affiliates could include acting as agent for buyers and sellers of the Shares, entering into transactions with those buyers and sellers in a principal capacity, including as a lender to initial purchasers of the Shares (which financing may be secured by the Shares) in the Global Offering, proprietary trading in the Shares, and entering into over the counter or listed derivative transactions or listed or unlisted securities transactions (including issuing securities such as derivative warrants listed on a stock exchange) which have as their underlying assets, assets including the Shares. Such transactions may be carried out as bilateral agreements or trades with selected counterparties. Those activities may require hedging activity by those entities involving, directly or indirectly, the buying and selling of

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the Shares, which may have a negative impact on the trading price of the Shares. All such activities could occur in Hong Kong and elsewhere in the world and may result in the Syndicate Members and their affiliates holding long and/or short positions in the Shares, in baskets of securities or indices including the Shares, in units of funds that may purchase the Shares, or in derivatives related to any of the foregoing.

In relation to issues by Syndicate Members or their affiliates of any listed securities having the Shares as their underlying securities, whether on the Stock Exchange or on any other stock exchange, the rules of the stock exchange may require the issuer of those securities (or one of its affiliates or agents) to act as a market maker or liquidity provider in the security, and this will also result in hedging activity in the Shares in most cases.

All such activities may occur both during and after the end of the stabilising period. See “Structure of the Global Offering” for details. Such activities may affect the market price or value of the Shares, the liquidity or trading volume in the Shares and the volatility of the price of the Shares, and the extent to which this occurs from day to day cannot be estimated.

It should be noted that when engaging in any of these activities, the Syndicate Members will be subject to certain restrictions, including the following:

- (a) the Syndicate Members (other than any person acting for it) must not, in connection with the distribution of the Offer Shares, effect any transactions (including issuing or entering into any option or other derivative transactions relating to the Offer Shares), whether in the open market or otherwise, with a view to stabilising or maintaining the market price of any of the Offer Shares at levels other than those which might otherwise prevail in the open market; and
- (b) the Syndicate Members must comply with all applicable laws and regulations, including the market misconduct provisions of the SFO, including the provisions prohibiting insider dealing, false trading, price rigging and stock market manipulation.

Certain of the Syndicate Members or their respective affiliates have provided from time to time, and expect to provide in the future, investment banking and other services to our Company and our Company’s affiliates for which such Syndicate Members or their respective affiliates have received or will receive customary fees and commissions.

In addition, the Syndicate Members or their respective affiliates may provide financing to investors to finance their subscriptions of Offer Shares in the Global Offering.

STRUCTURE OF THE GLOBAL OFFERING

THE GLOBAL OFFERING

This prospectus is published in connection with the Hong Kong Public Offering as part of the Global Offering. CCB International Capital Limited and Huatai Financial Holdings (Hong Kong) Limited are the Overall Coordinators and Joint Global Coordinators of the Global Offering.

The listing of the Shares on the Stock Exchange is sponsored by the Joint Sponsors. The Joint Sponsors have made an application on behalf of our Company to the Stock Exchange for the listing of, and permission to deal in, the Shares in issue and to be issued as mentioned in this prospectus.

60,582,000 Offer Shares will initially be made available under the Global Offering comprising:

- (i) the Hong Kong Public Offering of initially 6,058,500 Shares (subject to reallocation) in Hong Kong as described in “– The Hong Kong Public Offering” in this prospectus; and
- (ii) the International Offering of initially 54,523,500 Shares (subject to reallocation) to be offered outside the United States (including to professional and institutional investors within Hong Kong) in offshore transactions in accordance with Regulation S as described in “– The International Offering” in this prospectus.

Investors may either:

- (i) apply for Hong Kong Offer Shares under the Hong Kong Public Offering; or
- (ii) apply for or indicate an interest for International Offer Shares under the International Offering,

but may not do both.

The Offer Shares will represent approximately 7.2% of the issued share capital of our Company immediately following the completion of the Global Offering, assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements.

The number of Offer Shares to be offered under the Hong Kong Public Offering and the International Offering may be subject to reallocation as described in “– The Hong Kong Public Offering – Reallocation” in this prospectus.

References in this prospectus to applications, application monies or the procedure for applications relate solely to the Hong Kong Public Offering.

STRUCTURE OF THE GLOBAL OFFERING

THE HONG KONG PUBLIC OFFERING

Number of Offer Shares Initially Offered

We are initially offering 6,058,500 Shares (subject to reallocation) for subscription by the public in Hong Kong at the Offer Price, representing approximately 10.0% of the total number of Offer Shares initially available under the Global Offering. The Hong Kong Offer Shares initially offered under the Hong Kong Public Offering, subject to any reallocation of Offer Shares between the International Offering and the Hong Kong Public Offering, will represent approximately 0.72% of the total issued share capital of our Company immediately following the completion of the Global Offering assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements.

The Hong Kong Public Offering is open to members of the public in Hong Kong as well as to institutional and professional investors. Professional investors generally include brokers, dealers, companies (including fund managers) whose ordinary business involves dealing in shares and other securities and corporate entities that regularly invest in shares and other securities.

Completion of the Hong Kong Public Offering is subject to the conditions set out in “– Conditions of the Global Offering” in this prospectus.

Allocation

Allocation of Offer Shares to investors under the Hong Kong Public Offering will be based solely on the level of valid applications received under the Hong Kong Public Offering. The basis of allocation may vary, depending on the number of Hong Kong Offer Shares validly applied for by applicants. Such allocation could, where appropriate, consist of balloting, which could mean that some applicants may receive a higher allocation than others who have applied for the same number of Hong Kong Offer Shares, and those applicants who are not successful in the ballot may not receive any Hong Kong Offer Shares.

For allocation purposes only, the total number of Hong Kong Offer Shares available under the Hong Kong Public Offering (after taking into account any reallocation referred to below) will be divided equally (to the nearest board lot) into two pools (with any odd lots being allocated to pool A): pool A and pool B. The Hong Kong Offer Shares in pool A will be allocated on an equitable basis to applicants who have applied for Hong Kong Offer Shares with an aggregate subscription price of HK\$5 million (excluding the brokerage, the SFC transaction levy, the AFRC transaction levy and the Stock Exchange trading fee payable) or less. The Hong Kong Offer Shares in pool B will be allocated on an equitable basis to applicants who have applied for Hong Kong Offer Shares with an aggregate subscription price of more than HK\$5 million (excluding the brokerage, the SFC transaction levy, the AFRC transaction levy and the Stock Exchange trading fee payable) and up to the total value in pool B.

STRUCTURE OF THE GLOBAL OFFERING

Investors should be aware that applications in pool A and applications in pool B may receive different allocation ratios. If any Hong Kong Offer Shares in one (but not both) of the pools are undersubscribed, such undersubscribed Hong Kong Offer Shares will be transferred to the other pool to satisfy demand in that other pool and be allocated accordingly. For the purpose of the immediately preceding paragraph only, the “price” for Hong Kong Offer Shares means the price payable on application therefor (without regard to the Offer Price as finally determined). Applicants can only receive an allocation of Hong Kong Offer Shares from either pool A or pool B and not from both pools. Multiple or suspected multiple applications under the Hong Kong Public Offering and any application for more than 3,029,000 Hong Kong Offer Shares are liable to be rejected.

Reallocation

The allocation of Offer Shares between the Hong Kong Public Offering and the International Offering is subject to reallocation. Paragraph 4.2 of Practice Note 18 of the Listing Rules requires a clawback mechanism to be put in place which would have the effect of increasing the number of Offer Shares under the Hong Kong Public Offering to a certain percentage of the total number of Offer Shares offered under the Global Offering if the International Offering is fully subscribed or oversubscribed and certain prescribed total demand levels are reached as further described below:

- if the number of Offer Shares validly applied for under the Hong Kong Public Offering represents 15 times or more but less than 50 times the number of Offer Shares initially available for subscription under the Hong Kong Public Offering, then Offer Shares will be reallocated to the Hong Kong Public Offering from the International Offering so that the total number of Offer Shares available under the Hong Kong Public Offering will be 18,175,000 Offer Shares, representing approximately 30% of the Offer Shares initially available under the Global Offering;
- if the number of Offer Shares validly applied for under the Hong Kong Public Offering represents 50 times or more but less than 100 times the number of Offer Shares initially available for subscription under the Hong Kong Public Offering, then the number of Offer Shares to be reallocated to the Hong Kong Public Offering from the International Offering will be increased so that the total number of Offer Shares available under the Hong Kong Public Offering will be 24,233,000 Offer Shares, representing approximately 40% of the Offer Shares initially available under the Global Offering; and
- if the number of Offer Shares validly applied for under the Hong Kong Public Offering represents 100 times or more the number of Offer Shares initially available for subscription under the Hong Kong Public Offering, then the number of Offer Shares to be reallocated to the Hong Kong Public Offering from the International Offering will be increased so that the total number of Offer Shares available under the Hong Kong Public Offering will be 30,291,000 Offer Shares, representing 50% of the Offer Shares initially available under the Global Offering.

In addition, the Offer Shares to be offered in the Hong Kong Public Offering and the International Offering may, in certain circumstances, be reallocated as between these offerings at the discretion of the Overall Coordinators. If the Hong Kong Public Offering is not fully subscribed for, the Overall Coordinators (for themselves and on behalf of the other Underwriters) will have the authority (but shall not be under any obligation) to reallocate all or any unsubscribed Hong Kong Offer Shares to the International Offering, in such proportions as the Overall Coordinators deem appropriate. In addition, the Overall

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Coordinators may in their discretion reallocate Offer Shares from the International Offering to the Hong Kong Public Offering to satisfy valid applications under the Hong Kong Public Offering. In particular, if (i) the International Offering is not fully subscribed and the Hong Kong Public Offering is fully subscribed or oversubscribed irrespective of the number of times; or (ii) the International Offering is fully subscribed or oversubscribed and the Hong Kong Public Offering is fully subscribed or oversubscribed with the number of Offer Shares validly applied for in the Hong Kong Public Offering representing less than 15 times of the number of Offer Shares initially available for subscription under the Hong Kong Public Offering, the Overall Coordinators have the authority to reallocate International Offer Shares originally included in the International Offering to the Hong Kong Public Offering in such number as they deem appropriate. In accordance with Chapter 4.14 of the Guide, if such reallocation is done other than pursuant to Practice Note 18 of the Listing Rules, the number of International Offer Shares reallocated to the Hong Kong Public Offering should not exceed 6,058,500 Offer Shares, representing approximately 10% of the Offer Shares initially available under the Global Offering, increasing the total number of Offer Shares available under the Hong Kong Public Offering to 12,117,000 Offer Shares, representing two times of the initial allocation to the Hong Kong Public Offering.

In each case, the additional Offer Shares reallocated to the Hong Kong Public Offering will be allocated between Pool A and Pool B in equal proportion and the number of Offer Shares allocated to the International Offering will be correspondingly reduced in such manner as the Joint Global Coordinators in their discretion consider appropriate.

In the event that both the Hong Kong Public Offering and International Offering are undersubscribed, the Global Offering will not proceed unless the Underwriters would subscribe or procure subscribers for their respective applicable proportions of the Offer Shares being offered which are not taken up under the Global Offering on the terms and conditions of this prospectus and the Underwriting Agreements.

Applications

Each applicant under the Hong Kong Public Offering will be required to give an undertaking and confirmation in the application submitted by him/her/it that he/she/it and any person(s) for whose benefit he/she/it is making the application has not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any International Offer Shares under the International Offering. Such applicant's application is liable to be rejected if such undertaking and/ or confirmation is breached and/ or untrue (as the case may be) or if it has been or will be placed or allocated International Offer Shares under the International Offering.

Multiple or suspected multiple applications and any application for more than approximately 50% of the 6,058,500 Shares initially comprised in the Hong Kong Public Offering (that is 3,029,000 Hong Kong Offer Shares) will be rejected.

The listing of the Shares on the Stock Exchange is sponsored by the Joint Sponsors. Applicants under the Hong Kong Public Offering may be required to pay, on application (subject to application channels), the Offer Price of HK\$10.10 per Offer Share in addition to the brokerage, the SFC transaction levy, the AFRC transaction levy and the Stock Exchange trading fee payable on each Offer Share, amounting to a total of HK\$5,100.94 for one board lot of 500 Shares. See "How to Apply for Hong Kong Offer Shares" in this prospectus for details.

References in this prospectus to applications, application monies or the procedure for application relate solely to the Hong Kong Public Offering.

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THE INTERNATIONAL OFFERING

Number of International Offer Shares Initially Offered

Subject to reallocation as described above, the International Offering will consist of an offering of initially 54,523,500 Shares, representing approximately 90% of the total number of Offer Shares initially available under the Global Offering. Subject to the reallocation of Offer Shares between the International Offering and the Hong Kong Public Offering, the International Offer Shares will represent approximately 6.50% of our Company's enlarged issued share capital immediately after completion of the Global Offering assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements.

Allocation

The International Offering will include selective marketing of Offer Shares to institutional and professional investors and other investors anticipated to have a sizeable demand for such Offer Shares in Hong Kong and other jurisdictions outside the United States in reliance on Regulation S. The International Offering is subject to the Hong Kong Public Offering being unconditional. Professional investors generally include brokers, dealers, companies (including fund managers) whose ordinary business involves dealing in shares and other securities and corporate entities that regularly invest in shares and other securities. Allocation of Offer Shares pursuant to the International Offering will be effected in accordance with the "book-building" process described in "– Pricing of the Global Offering" in this section and based on a number of factors, including the level and timing of demand, the total size of the relevant investor's invested assets or equity assets in the relevant sector and whether or not it is expected that the relevant investor is likely to buy further Offer Shares, and/ or hold or sell its Offer Shares, after the Listing. Such allocation is intended to result in a distribution of the Offer Shares on a basis which would lead to the establishment of a solid professional and institutional shareholder base to the benefit of our Company and the Shareholders as a whole.

The Overall Coordinators (for themselves and on behalf of the International Underwriters) may require any investor who has been offered Offer Shares under the International Offering and who has made an application under the Hong Kong Public Offering to provide sufficient information to the Overall Coordinators so as to allow them to identify the relevant applications under the Hong Kong Public Offering and to ensure that they are excluded from any application of Offer Shares under the Hong Kong Public Offering.

Reallocation

The total number of Offer Shares to be issued or sold pursuant to the International Offering may change as a result of the clawback arrangement described in "– The Hong Kong Public Offering – Reallocation" in this section, and/ or any reallocation of unsubscribed Offer Shares originally included in the Hong Kong Public Offering to the International Offering.

STRUCTURE OF THE GLOBAL OFFERING

PRICING AND ALLOCATION

The Offer Price will be HK\$10.10 per Offer Share unless otherwise announced, as further explained below. Applicants under the Hong Kong Public Offering may be required to pay, on application (subject to application channels), the Offer Price of HK\$10.10 per Offer Share plus brokerage, SFC transaction levy, the AFRC transaction levy and Stock Exchange trading fee, amounting to a total of HK\$5,100.94 for one board lot of 500 Shares.

The International Underwriters will be soliciting from prospective investors indications of interest in acquiring Offer Shares in the International Offering. Prospective professional and institutional investors will be required to specify the number of Offer Shares under the International Offering they would be prepared to acquire either at different prices or at a particular price. This process, known as “book-building”, is expected to continue up to, and to cease on or around, the last day for lodging applications under the Hong Kong Public Offering.

The Overall Coordinators, on behalf of the Underwriters, may, where they deem appropriate, based on the level of interest expressed by prospective investors during the book-building process in respect of the International Offering, and with the consent of the Company, reduce the number of Offer Shares offered and /or the Offer Price below that stated in this prospectus at any time on or prior to the morning of the last day for lodging applications under the Hong Kong Public Offering. In such a case, we will, as soon as practicable following the decision to make such reduction, and in any event not later than the morning of the last day for lodging applications under the Hong Kong Public Offering, publish an announcement or supplemental prospectus on the websites of our Company and the Stock Exchange at www.cloudbreakpharma.com and www.hkexnews.hk, respectively. Upon the issue of such announcement or supplemental prospectus, the revised number of Offer Shares and/ or the Offer Price will be final and conclusive and the Offer Price, if agreed upon by the Overall Coordinators (for themselves and on behalf of the Underwriters) and us, will be fixed within such revised Offer Price.

Before submitting applications for the Hong Kong Offer Shares, applicants should have regard to the possibility that any announcement of a reduction in the number of Offer Shares and/ or the Offer Price may not be made until the last day for lodging applications under the Hong Kong Public Offering. Such announcement or supplemental prospectus will also include confirmation or revision, as appropriate, of the working capital statement, the use of proceeds and the Global Offering statistics as currently set out in this prospectus, and any other financial information which may change as a result of any such reduction. In the absence of any such announcement or supplemental prospectus so published, the number of Offer Shares will not be reduced and/ or the Offer Price, if agreed upon by the Overall Coordinators (for themselves and on behalf of the Underwriters) and us, will under no circumstances be set outside the Offer Price as stated in this prospectus.

If there is any change to the offer size due to change in the number of Offer Shares initially offered under the Global Offering (other than pursuant to the reallocation mechanism as disclosed in this prospectus), or if our Company becomes aware that there has been a significant change affecting any matter contained in this prospectus or a significant new matter has arisen, the inclusion of information in respect of which would have been required to be in this prospectus if it had arisen before this prospectus was issued, after the issue of this prospectus and before the commencement of dealings in our Shares as prescribed under Rule 11.13 of the Listing Rules, we are required to cancel the Global Offering and relaunch the offering on FINI and issue a supplemental or new prospectus.

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In the event of a reduction in the number of Offer Shares, the Overall Coordinators (for themselves and on behalf of the Underwriters) may, at their discretion, reallocate the number of Offer Shares to be offered in the Hong Kong Public Offering and International Offering, provided that the number of Offer Shares comprised in the Hong Kong Public Offering shall not be less than 10% of the total number of Offer Shares available under the Global Offering.

The final Offer Price, the level of indications of interest in the International Offering, the level of applications in the Hong Kong Public Offering, the basis of allocation of the Hong Kong Offer Shares and the results of allocations in the Hong Kong Public Offering are expected to be made available through a variety of channels in the manner described in “How to Apply for Hong Kong Offer Shares – B. Publication of Results” in this prospectus.

UNDERWRITING

The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters under the terms and conditions of the Hong Kong Underwriting Agreement and is conditional upon the International Underwriting Agreement being signed and becoming unconditional and is subject to our Company and the Overall Coordinators (for themselves and on behalf of the Underwriters) agreeing on the Offer Price.

We expect to enter into the International Underwriting Agreement relating to the International Offering on or around Monday, 30 June 2025.

These underwriting arrangements, including the Underwriting Agreements, are summarised in “Underwriting” in this prospectus.

CONDITIONS OF THE GLOBAL OFFERING

Acceptance of all applications for Offer Shares will be conditional on:

- (i) the Stock Exchange granting approval for the listing of, and permission to deal in, the Shares in issue and to be issued pursuant to the Global Offering on the Main Board of the Stock Exchange (including the additional Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme), and such listing and permission not subsequently having been revoked prior to the commencement of dealings in the Shares on the Stock Exchange;
- (ii) the execution and delivery of the International Underwriting Agreement on or around Monday, 30 2025; and
- (iii) the obligations of the Underwriters under each of the Hong Kong Underwriting Agreement and the International Underwriting Agreement becoming and remaining unconditional and not having been terminated in accordance with the terms of the respective agreements, in each case on or before the dates and times specified in the respective Underwriting Agreements.

STRUCTURE OF THE GLOBAL OFFERING

(unless and to the extent such conditions are validly waived on or before such dates and times).

The consummation of each of the Hong Kong Public Offering and the International Offering is conditional upon, amongst others, the other offering becoming unconditional and not having been terminated in accordance with its terms.

If the above conditions are not fulfilled or waived prior to the dates and times specified, the Global Offering will lapse and the Stock Exchange will be notified immediately. Notice of the lapse of the Hong Kong Public Offering will be published by our Company on the websites of the Stock Exchange at www.hkexnews.hk and our Company at www.cloudbreakpharma.com on the next day following such lapse. In such a situation, all application monies will be returned, without interest, on the terms set out in “How to Apply for Hong Kong Offer Shares – D. Despatch/Collection of Share Certificates and Refund of Application Monies” in this prospectus. In the meantime, all application monies will be held in separate bank account(s) with the receiving bank or other bank(s) in Hong Kong licensed under the Banking Ordinance (Chapter 155 of the Laws of Hong Kong).

Share certificates for the Offer Shares will only become valid at 8:00 a.m. on Thursday, 3 July 2025, the date of commencement of the dealing in our Shares, provided that the Global Offering has become unconditional in all respects and the right of termination described in “Underwriting” in this prospectus has not been exercised. Investors who trade Shares prior to the receipt of Share certificates or prior to the Share certificates bearing valid certificates of title do so entirely at their own risk.

DEALING

Assuming that the Hong Kong Public Offering becomes unconditional at or before 8:00 a.m. in Hong Kong on Thursday, 3 July 2025, it is expected that dealings in the Shares on the Stock Exchange will commence at 9:00 a.m. on Thursday, 3 July 2025.

The Shares will be traded in board lots of 500 Shares each and the stock code of the Shares will be 2592.

HOW TO APPLY FOR HONG KONG OFFER SHARES

IMPORTANT NOTICE TO INVESTORS OF HONG KONG OFFER SHARES

FULLY ELECTRONIC APPLICATION PROCESS

We have adopted a fully electronic application process for the Hong Kong Public Offering and below are the procedures for application.

This prospectus is available at the website of the Stock Exchange at www.hkexnews.hk under the “HKEXnews > New Listings > New Listing Information” section, and our website at www.cloudbreakpharma.com.

The contents of this prospectus are identical to the prospectus as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

A. APPLICATION FOR HONG KONG OFFER SHARES

1. Who Can Apply

You can apply for Hong Kong Offer Shares if you or the person(s) for whose benefit you are applying for:

- are 18 years of age or older; and
- have a Hong Kong address (*for the **HK eIPO White Form** service only*).

Unless permitted by the Listing Rules or a waiver and/or consent has been granted by the Stock Exchange to us, you cannot apply for any Hong Kong Offer Shares if you or the person(s) for whose benefit you are applying for:

- are an existing Shareholder or close associates; or
- are a Director or any of his/her close associates.

2. Application Channels

The Hong Kong Public Offering period will begin at 9:00 a.m. on Tuesday, 24 June 2025 and end at 12:00 noon on Friday, 27 June 2025 (Hong Kong time).

To apply for Hong Kong Offer Shares, you may use one of the following application channels:

HOW TO APPLY FOR HONG KONG OFFER SHARES

Application Channel	Platform	Target Investors	Application Time
HK eIPO White Form service	www.hkeipo.hk	<p>Investors who would like to receive a physical Share certificate.</p> <p><i>Hong Kong Offer Shares successfully applied for will be allotted and issued in your own name.</i></p>	<p>From 9:00 a.m. on Tuesday, 24 June 2025 to 11:30 a.m. on Friday, 27 June 2025, Hong Kong time.</p> <p>The latest time for completing full payment of application monies will be 12:00 noon on Friday, 27 June 2025, Hong Kong time.</p>
HKSCC EIPO channel	Your broker or custodian who is a HKSCC Participant will submit an EIPO application on your behalf through HKSCC's FINI system in accordance with your instruction	<p>Investors who would <u>not</u> like to receive a physical Share certificate.</p> <p><i>Hong Kong Offer Shares successfully applied for will be allotted and issued in the name of HKSCC Nominees, deposited directly into CCASS and credited to your designated HKSCC Participant's stock account.</i></p>	Contact your broker or custodian for the earliest and latest time for giving such instructions, as this may vary by broker or custodian.

The **HK eIPO White Form** service and the HKSCC EIPO channel are facilities subject to capacity limitations and potential service interruptions and you are advised not to wait until the last day of the application period to apply for Hong Kong Offer Shares.

For those applying through the **HK eIPO White Form** service, once you complete payment in respect of any application instructions given by you or for your benefit through the **HK eIPO White Form** service to make an application for Hong Kong Offer Shares, an actual application shall be deemed to have been made. If you are a person for whose benefit the electronic application instructions are given, you shall be deemed to have declared that only one set of electronic application instructions has been given for your benefit. If you are an agent for another person, you shall be deemed to have declared that you have only given one set of electronic application instructions for the benefit of the person for whom you are an agent and that you are duly authorised to give those instructions as an agent.

For the avoidance of doubt, giving an application instruction under the **HK eIPO White Form** service more than once and obtaining different payment reference numbers without effecting full payment in respect of a particular reference number will not constitute an actual application.

HOW TO APPLY FOR HONG KONG OFFER SHARES

If you apply through the **HK eIPO White Form** service, you are deemed to have authorised the **HK eIPO White Form** Service Provider to apply on the terms and conditions in this prospectus, as supplemented and amended by the terms and conditions of the **HK eIPO White Form** service.

By instructing your broker or custodian to apply for the Hong Kong Offer Shares on your behalf through the HKSCC EIPO Channel, you (and, if you are joint applicants, each of you jointly and severally) are deemed to have instructed and authorised HKSCC to cause HKSCC Nominees (acting as nominee for the relevant HKSCC Participants) to apply for Hong Kong Offer Shares on your behalf and to do on your behalf all the things stated in this prospectus and any supplement to it.

For those applying through HKSCC EIPO channel, an actual application will be deemed to have been made for any application instructions given by you or for your benefit to HKSCC (in which case an application will be made by HKSCC Nominees on your behalf) provided such application instruction has not been withdrawn or otherwise invalidated before the closing time of the Hong Kong Public Offering.

HKSCC Nominees will only be acting as a nominee for you and neither HKSCC nor HKSCC Nominees shall be liable to you or any other person in respect of any actions taken by HKSCC or HKSCC Nominees on your behalf to apply for Hong Kong Offer Shares or for any breach of the terms and conditions of this prospectus.

3. Information Required to Apply

You must provide the following information with your application:

For Individual Applicants	For Corporate Applicants
<ul style="list-style-type: none">● Full name(s)² as shown on your identity document● Identity document's issuing country or jurisdiction● Identity document type, with order of priority:<ul style="list-style-type: none">i. HKID card; orii. National identification document; oriii. Passport; and● Identity document number	<ul style="list-style-type: none">● Full name(s)² as shown on your identity document● Identity document's issuing country or jurisdiction● Identity document type, with order of priority:<ul style="list-style-type: none">i. LEI registration document; orii. Certificate of incorporation; oriii. Business registration certificate; oriv. Other equivalent document; and● Identity document number

HOW TO APPLY FOR HONG KONG OFFER SHARES

For Individual Applicants	For Corporate Applicants
<p><i>Notes:</i></p> <ol style="list-style-type: none"> If you are applying through the HK eIPO White Form service, you are required to provide a valid e-mail address, a contact telephone number and a Hong Kong address. You are also required to declare that the identity information provided by you follows the requirements as described in note 2 below. In particular, where you cannot provide a HKID number, you must confirm that you do not hold a HKID card. The number of joint applicants may not exceed four. If you are a firm, the applicant must be in the individual members' names. The applicant's full name as shown on their identity document must be used and the surname, given name, middle and other names (if any) must be input in the same as shown on the identity document. If an applicant's identity document contains both an English and Chinese name, both English and Chinese names must be used. Otherwise, either English or Chinese names will be accepted. The order of priority of the applicant's identity document type must be strictly followed and where an individual applicant has a valid HKID card (including both Hong Kong Residents and Hong Kong Permanent Residents), the HKID number must be used when making an application to subscribe for shares in a public offer. Similarly for corporate applicants, a LEI number must be used if an entity has a LEI certificate. If the applicant is a trustee, the client identification data ("CID") of the trustee, as set out above, will be required. If the applicant is an investment fund (i.e. a collective investment scheme, or CIS), the CID of the asset management company or the individual fund, as appropriate, which has opened a trading account with the broker will be required, as above. The maximum number of joint account holders on FINI is capped at four in accordance with market practice. If you are applying as a nominee, you must provide: (i) the full name (as shown on the identity document), the identity document's issuing country or jurisdiction, the identity document type; and (ii), the identity document number, for each of the beneficial owners or, in the case(s) of joint beneficial owners, for each joint beneficial owner. If you do not include this information, the application will be treated as being made for your benefit. If you are applying as an unlisted company and (i) the principal business of that company is dealing in securities; and (ii) you exercise statutory control over that company, then the application will be treated as being for your benefit and you should provide the required information in your application as stated above. <p>"Unlisted company" means a company with no equity securities listed on the Stock Exchange or any other stock exchange.</p> <p>"Statutory control" means you:</p> <ul style="list-style-type: none"> control the composition of the board of directors of the company; control more than half of the voting power of the company; or hold more than half of the issued share capital of the company (not counting any part of it which carries no right to participate beyond a specified amount in a distribution of either profits or capital). 	

For those applying through HKSCC EIPO channel, and making an application under a power of attorney, we and the Overall Coordinators, as our agent, have discretion to consider whether to accept it on any conditions we think fit, including evidence of the attorney's authority.

HOW TO APPLY FOR HONG KONG OFFER SHARES

Failing to provide any required information may result in your application being rejected.

4. Permitted Number of Hong Kong Offer Shares for Application

Board lot size : 500

Permitted number of Hong Kong Offer Shares for application and amount payable on application/successful allotment : Hong Kong Offer Shares are available for application in specified board lot sizes only. Please refer to the amount payable associated with each specified board lot size in the table below.

The Offer Price is HK\$10.10 per Share.

If you are applying through the HKSCC EIPO channel, you are required to prefund your application based on the amount specified by your broker or custodian, as determined based on the applicable laws and regulations in Hong Kong.

By instructing your broker or custodian to apply for the Hong Kong Offer Shares on your behalf through the HKSCC EIPO Channel, you (and, if you are joint applicants, each of you jointly and severally) are deemed to have instructed and authorised HKSCC to cause HKSCC Nominees (acting as nominee for the relevant HKSCC Participants) to arrange payment of the final Offer Price, brokerage, SFC transaction levy, the Stock Exchange trading fee and the AFRC transaction levy by debiting the relevant nominee bank account at the designated bank for your broker or custodian.

If you are applying through the **HK eIPO White Form** service, you may refer to the table below for the amount payable for the number of Shares you have selected. You must pay the respective maximum amount payable on application in full upon application for Hong Kong Offer Shares.

HOW TO APPLY FOR HONG KONG OFFER SHARES

No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment	No. of Hong Kong Offer Shares applied for	Amount payable ⁽²⁾ on application/successful allotment
	HK\$		HK\$		HK\$		HK\$
500	5,100.94	7,000	71,413.01	50,000	510,092.93	700,000	7,141,300.96
1,000	10,201.86	8,000	81,614.87	60,000	612,111.51	800,000	8,161,486.80
1,500	15,302.79	9,000	91,816.73	70,000	714,130.10	900,000	9,181,672.66
2,000	20,403.72	10,000	102,018.59	80,000	816,148.68	1,000,000	10,201,858.50
2,500	25,504.65	15,000	153,027.88	90,000	918,167.26	2,000,000	20,403,717.00
3,000	30,605.58	20,000	204,037.16	100,000	1,020,185.86	3,029,000 ⁽¹⁾	30,901,429.40
3,500	35,706.50	25,000	255,046.47	200,000	2,040,371.70		
4,000	40,807.43	30,000	306,055.75	300,000	3,060,557.56		
4,500	45,908.37	35,000	357,065.04	400,000	4,080,743.40		
5,000	51,009.29	40,000	408,074.35	500,000	5,100,929.26		
6,000	61,211.15	45,000	459,083.63	600,000	6,121,115.10		

Notes:

- (1) Maximum number of Hong Kong Offer Shares you may apply for and this is approximately 50% of the Hong Kong Offer Shares initially offered.
- (2) The amount payable is inclusive of brokerage, SFC transaction levy, the Stock Exchange trading fee and AFRC transaction levy. If your application is successful, brokerage will be paid to the Exchange Participants (as defined in the Listing Rules) or to the **HK eIPO White Form** Service Provider (for applications made through the application channel of the **HK eIPO White Form** service) while the SFC transaction levy, the Stock Exchange trading fee and the AFRC transaction levy will be paid to the SFC, the Stock Exchange and the AFRC, respectively.

5. Multiple Applications Prohibited

You or your joint applicants shall not make more than one application for your own benefit, except where you are a nominee and provide the information of the underlying investor in your application as required under “– A. Applications for Hong Kong Offer Shares – 3. Information Required to Apply” above. If you are suspected of submitting or cause to submit more than one application, all of your applications will be rejected.

Multiple applications made either through (i) the **HK eIPO White Form** service, (ii) HKSCC EIPO channel, or (iii) both channels concurrently are prohibited and will be rejected. If you have made an application through the **HK eIPO White Form** service or HKSCC EIPO channel, you or the person(s) for whose benefit you have made the application shall not apply further for any Offer Shares in the Global Offering.

HOW TO APPLY FOR HONG KONG OFFER SHARES

The Hong Kong Share Registrar would record all applications into its system and identify suspected multiple applications with identical names and identification document numbers according to the Best Practice Note on Treatment of Multiple / Suspected Multiple Applications (“**Best Practice Note**”) issued by the Federation of Share Registrars Limited.

Since applications are subject to personal information collection statements, identification document numbers displayed are redacted.

6. Terms and Conditions of An Application

By applying for Hong Kong Offer Shares through the **HK eIPO White Form** service or HKSCC EIPO channel, you (or as the case may be, HKSCC Nominees will do the following things on your behalf):

- (i) undertake to execute all relevant documents and instruct and authorise us and/or the Overall Coordinators, as our agents, to execute any documents for you and to do on your behalf all things necessary to register any Hong Kong Offer Shares allocated to you in your name or in the name of HKSCC Nominees as required by the Articles of Association, and (if you are applying through the HKSCC EIPO channel) to deposit the allotted Hong Kong Offer Shares directly into CCASS for the credit of your designated HKSCC Participant’s stock account on your behalf;
- (ii) confirm that you have read and understand the terms and conditions and application procedures set out in this prospectus and the designated website of the **HK eIPO White Form** service (or as the case may be, the agreement you entered into with your broker or custodian), and agree to be bound by them;
- (iii) (if you are applying through the HKSCC EIPO channel) agree to the arrangements, undertakings and warranties under the participant agreement between your broker or custodian and HKSCC and observe the General Rules of HKSCC and the HKSCC Operational Procedures for giving application instructions to apply for Hong Kong Offer Shares;
- (iv) confirm that you are aware of the restrictions on offers and sales of shares set out in this prospectus and they do not apply to you, or the person(s) for whose benefit you have made the application;
- (v) confirm that you have read this prospectus and any supplement to it and have relied only on the information and representations contained therein in making your application (or as the case may be, causing your application to be made) and will not rely on any other information or representations;
- (vi) agree that the Joint Sponsors, the Overall Coordinators, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters, any of their or our Company’s respective directors, officers, employees, partners, agents, advisers and any other parties involved in the Global Offering

HOW TO APPLY FOR HONG KONG OFFER SHARES

(collectively, the “**Relevant Persons**”), the Hong Kong Share Registrar and HKSCC will not be liable for any information and representations not in this prospectus and any supplement to it;

- (vii) agree to disclose the details of your application and your personal data and any other personal data which may be required about you and the person(s) for whose benefit you have made the application to us, the Relevant Persons, the Hong Kong Share Registrar, HKSCC, HKSCC Nominees, the Stock Exchange, the SFC and any other statutory regulatory or governmental bodies or otherwise as required by laws, rules or regulations, for the purposes under the paragraphs headed “ – G. Personal Data – 3. Purposes” and “ – G. Personal Data – 4. Transfer of personal data” below;
- (viii) agree (without prejudice to any other rights which you may have once your application (or as the case may be, HKSCC Nominees’ application) has been accepted) that you will not rescind it because of an innocent misrepresentation;
- (ix) agree that subject to Section 44A(6) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, any application made by you or HKSCC Nominees on your behalf cannot be revoked once it is accepted, which will be evidenced by the notification of the result of the ballot by the Hong Kong Share Registrar by way of publication of the results at the time and in the manner as specified in the paragraph headed “– B. Publication of Results” in this section;
- (x) confirm that you are aware of the situations specified in “ – C. Circumstances In Which You Will Not Be Allocated Hong Kong Offer Shares” below;
- (xi) agree that your application or HKSCC Nominees’ application, any acceptance of it and the resulting contract will be governed by and construed in accordance with the laws of Hong Kong;
- (xii) agree to comply with the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the Articles of Association and laws of any place outside Hong Kong that apply to your application and that neither we nor the Relevant Persons will breach any law inside and/ or outside Hong Kong as a result of the acceptance of your offer to purchase, or any action arising from your rights and obligations under the terms and conditions contained in this prospectus;
- (xiii) confirm that (a) your application or HKSCC Nominees’ application on your behalf is not financed directly or indirectly by the Company, any of the directors, chief executives, substantial Shareholders or existing shareholders of the Company or any of its subsidiaries or any of their respective close associates; and (b) you are not accustomed or will not be accustomed to taking instructions from the Company, any of the directors, chief executives, substantial shareholders or existing shareholders of the Company or any of its subsidiaries or any of their respective close associates in relation to the acquisition, disposal, voting or other disposition of the Shares registered in your name or otherwise held by you;

HOW TO APPLY FOR HONG KONG OFFER SHARES

- (xiv) warrant that the information you have provided is true and accurate;
- (xv) confirm that you understand that we and the Overall Coordinators will rely on your declarations and representations in deciding whether or not to allocate any Hong Kong Offer Shares to you and that you may be prosecuted for making a false declaration;
- (xvi) agree to accept Hong Kong Offer Shares applied for or any lesser number allocated to you under the application;
- (xvii) declare and represent that this is the only application made and the only application intended by you to be made to benefit you or the person for whose benefit you are applying;
- (xviii) (if the application is made for your own benefit) warrant that no other application has been or will be made for your benefit by giving electronic application instructions to HKSCC directly or indirectly or through the application channel of the **HK eIPO White Form** service or by any one as your agent or by any other person; and
- (xix) (if you are making the application as an agent for the benefit of another person) warrant that (a) no other application has been or will be made by you as agent for or for the benefit of that person or by that person or by any other person as agent for that person by giving electronic application instructions to HKSCC and the **HK eIPO White Form** Service Provider and (b) you have due authority to give electronic application instructions on behalf of that other person as its agent.

B. PUBLICATION OF RESULTS

Results of Allocation

You can check whether you are successfully allocated any Hong Kong Offer Shares through:

Platform	Date/Time
Applying through the HK eIPO White Form service or HKSCC EIPO channel :	

HOW TO APPLY FOR HONG KONG OFFER SHARES

Platform		Date/Time
Website	From the “Allotment Results” page at www.hkeipo.hk/IPOResult (or www.tricor.com.hk/ipo/result) with a “search by ID” function. The full list of (i) wholly or partially successful applicants using the HK eIPO White Form service and HKSCC EIPO channel, and (ii) the number of Hong Kong Offer Shares conditionally allotted to them, among other things, will be displayed at www.hkeipo.hk/IPOResult or www.tricor.com.hk/ipo/result .	24 hours, from 11:00 p.m. on Wednesday, 2 July 2025 to 12:00 midnight on Tuesday, 8 July 2025 (Hong Kong time).
	The Stock Exchange’s website at www.hkexnews.hk and our website at www.cloudbreakpharma.com which will provide links to the above mentioned websites of the Hong Kong Share Registrar.	No later than 11:00 p.m. on Wednesday, 2 July 2025 (Hong Kong time).
Telephone	+852 3691 8488 – the allocation results telephone enquiry line provided by the Hong Kong Share Registrar.	between 9:00 a.m. and 6:00 p.m., from Thursday, 3 July 2025 to Tuesday, 8 July 2025 (Hong Kong time) on a business day.
For those applying through HKSCC EIPO channel, you may also check with your broker or custodian from 6:00 p.m. on Monday, 30 June 2025 (Hong Kong time).		

HKSCC Participants can log into FINI and review the allotment result from 6:00 p.m. on Monday, 30 June 2025 (Hong Kong time) on a 24-hour basis and should report any discrepancies on allotments to HKSCC as soon as practicable.

Allocation Announcement

We expect to announce the results of the final Offer Price, the level of indications of interest in the Global Offering, the level of applications in the Hong Kong Public Offering and the basis of allocations of Hong Kong Offer Shares on the Stock Exchange’s website at **www.hkexnews.hk** and our website at **www.cloudbreakpharma.com** by no later than 11:00 p.m. on Wednesday, 2 July 2025 (Hong Kong time).

HOW TO APPLY FOR HONG KONG OFFER SHARES

C. CIRCUMSTANCES IN WHICH YOU WILL NOT BE ALLOCATED HONG KONG OFFER SHARES

You should note the following situations in which the Hong Kong Offer Shares will not be allocated to you or the person(s) for whose benefit you are applying for:

1. If your application is revoked:

Your application or the application made by HKSCC Nominees on your behalf may be revoked pursuant to Section 44A(6) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

2. If we or our agents exercise our discretion to reject your application:

We, the Overall Coordinators, the Hong Kong Share Registrar and their respective agents and nominees have full discretion to reject or accept any application, or to accept only part of any application, without giving any reasons.

3. If the allocation of Hong Kong Offer Shares is void:

The allocation of Hong Kong Offer Shares will be void if the Stock Exchange does not grant permission to list the Shares either:

- within three weeks from the closing date of the application lists; or
- within a longer period of up to six weeks if the Stock Exchange notifies us of that longer period within three weeks of the closing date of the application lists.

4. If:

- you make multiple applications or suspected multiple applications. See “ – A. Applications for Hong Kong Offer Shares – 5. Multiple Applications Prohibited” on what constitutes multiple applications;
- your application instruction is incomplete;
- your payment (or confirmation of funds, as the case may be) is not made correctly;
- the Underwriting Agreements do not become unconditional or are terminated;
- we or the Overall Coordinators believe that by accepting your application, it or we would violate applicable securities or other laws, rules or regulations.

HOW TO APPLY FOR HONG KONG OFFER SHARES

5. If there is money settlement failure for allotted Shares:

Based on the arrangements between HKSCC Participants and HKSCC, HKSCC Participants will be required to hold sufficient application funds on deposit with their designated bank (the “**Designated Bank**”) before balloting. After balloting of Hong Kong Offer Shares, the Receiving Bank will collect the portion of these funds required to settle each HKSCC Participant’s actual Hong Kong Public Offering Share allotment from their Designated Bank.

There is a risk of money settlement failure. In the extreme event of money settlement failure by a HKSCC Participant (or its Designated Bank), who is acting on your behalf in settling payment for your allotted shares, HKSCC will contact the defaulting HKSCC Participant and its Designated Bank to determine the cause of failure and request such defaulting HKSCC Participant to rectify or procure to rectify the failure.

However, if it is determined that such settlement obligation cannot be met, the affected Hong Kong Offer Shares will be reallocated to the Global Offering. Hong Kong Offer Shares applied for by you through the broker or custodian may be affected to the extent of the settlement failure. In the extreme case, you will not be allocated any Hong Kong Offer Shares due to the money settlement failure by such HKSCC Participant. None of us, the Relevant Persons, the Hong Kong Share Registrar and HKSCC is or will be liable if Hong Kong Offer Shares are not allocated to you due to the money settlement failure.

D. DESPATCH/COLLECTION OF SHARE CERTIFICATES AND REFUND OF APPLICATION MONIES

You will receive one Share certificate for all Hong Kong Offer Shares allotted to you under the Hong Kong Public Offering (except pursuant to applications made through the HKSCC EIPO channel where the Share certificates will be deposited into CCASS as described below).

No temporary document of title will be issued in respect of the Shares. No receipt will be issued for sums paid on application.

Share certificates will only become valid at 8:00 a.m. on Thursday, 3 July 2025 (Hong Kong time) provided that the Global Offering has become unconditional and the right of termination described in the section headed “Underwriting” in this prospectus has not been exercised. Investors who trade Shares prior to the receipt of Share certificates or the Share certificates becoming valid do so entirely at their own risk.

The right is reserved to retain any Share certificate(s) and (if applicable) any surplus application monies pending clearance of application monies.

The following sets out the relevant procedures and time:

HOW TO APPLY FOR HONG KONG OFFER SHARES

	HK eIPO White Form service	HKSCC EIPO channel
Despatch/collection of Share certificate ^(note)		
For application of 1,000,000 Hong Kong Offer Shares or more	<p>Collection in person at the Hong Kong Share Registrar, Tricor Investor Services Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong</p> <p>Time: from 9:00 a.m. to 1:00 p.m. on Thursday, 3 July 2025 (Hong Kong time)</p> <p>If you are an individual, you must not authorise any other person to collect for you. If you are a corporate applicant, your authorised representative must bear a letter of authorisation from your corporation stamped with your corporation's chop.</p> <p>Both individuals and authorised representatives must produce, at the time of collection, evidence of identity acceptable to the Hong Kong Share Registrar.</p> <p><i>If you do not collect your Share certificate(s) personally within the time above, it/they will be sent to the address specified in your application instructions by ordinary post at your own risk</i></p>	<p>Share certificate(s) will be issued in the name of HKSCC Nominees, deposited into CCASS and credited to your designated HKSCC Participant's stock account.</p> <p>No action by you is required</p>

HOW TO APPLY FOR HONG KONG OFFER SHARES

	HK eIPO White Form service	HKSCC EIPO channel
For application of less than 1,000,000 Hong Kong Offer Shares	<p>Your Share certificate(s) will be sent to the address specified in your application instructions by ordinary post at your own risk</p> <p>Date: Wednesday, 2 July 2025</p>	
<p><i>Note:</i> Except in the event of a tropical cyclone warning signal number eight or above, a black rainstorm warning and/or an “extreme conditions” announcement issued after a super typhoon in force in Hong Kong, collectively (“Bad Weather signals”) in the morning on Wednesday, 2 July 2025 rendering it impossible for the relevant Share certificates to be dispatched to HKSCC in a timely manner, our Company shall procure the Hong Kong Share Registrar to arrange for delivery of the supporting documents and Share certificates in accordance with the contingency arrangements as agreed between them. See “– E. Bad Weather Arrangements” for details.</p>		
Refund mechanism for surplus application monies paid by you		
Date	Thursday, 3 July 2025	Subject to the arrangement between you and your broker or custodian
Responsible party	Hong Kong Share Registrar	Your broker or custodian
Application monies paid through single bank account	HK eIPO White Form e-Auto Refund payment instructions to your designated bank account	Your broker or custodian will arrange refund to your designated bank account subject to the arrangement between you and it
Application monies paid through multiple bank accounts	Refund cheque(s) will be despatched to the address as specified in your application instructions by ordinary post at your own risk	

E. BAD WEATHER ARRANGEMENTS

The Opening and Closing of the Application Lists

The application lists will not open or close on Friday, 27 June 2025 if, there is:

- a tropical cyclone warning signal number 8 or above;
- a black rainstorm warning; and/or

HOW TO APPLY FOR HONG KONG OFFER SHARES

- Extreme Conditions, (collectively, “**Bad Weather Signals**”),

in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon on Friday, 27 June 2025.

Instead they will open between 11:45 a.m. and 12:00 noon and/or close at 12:00 noon on the next business day which does not have Bad Weather Signals in force at any time between 9:00 a.m. and 12:00 noon.

Prospective investors should be aware that a postponement of the opening/closing of the application lists may result in a delay in the Listing Date. Should there be any changes to the dates mentioned in the section headed “Expected Timetable” in this prospectus, an announcement will be made and published on the Stock Exchange’s website at www.hkexnews.hk and our website at www.cloudbreakpharma.com of the revised timetable.

If a Bad Weather Signal is hoisted on Wednesday, 2 July 2025, the Hong Kong Share Registrar will make appropriate arrangements for the delivery of the Share certificates to the CCASS Depository’s service counter so that they would be available for trading on Thursday, 3 July 2025.

If a Bad Weather Signal is hoisted on Wednesday, 2 July 2025, the despatch of physical Share certificates for application of less than 1,000,000 Hong Kong Offer Shares, will be made by ordinary post when the post office re-opens after the Bad Weather Signal is lowered or cancelled (e.g. in the afternoon of Wednesday, 2 July 2025 or on Thursday, 3 July 2025).

If a Bad Weather Signal is hoisted on Thursday, 3 July 2025, for application of 1,000,000 Hong Kong Offer Shares or more, physical Share certificates will be available for collection in person at the Hong Kong Share Registrar’s office after the Bad Weather Signal is lowered or cancelled (e.g. in the afternoon of Thursday, 3 July 2025 or on Friday, 4 July 2025).

Prospective investors should be aware that if they choose to receive physical Share Certificates issued in their own name, there may be a delay in receiving the Share certificates.

F. ADMISSION OF THE SHARES INTO CCASS

If the Stock Exchange grants the listing of, and permission to deal in, the Shares on the Stock Exchange and we comply with the stock admission requirements of HKSCC, the Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the date of commencement of dealings in the Shares or any other date HKSCC chooses. Settlement of transactions between Exchange Participants (as defined in the Listing Rules) is required to take place in CCASS on the second business day after any trading day.

All activities under CCASS are subject to the General Rules of HKSCC and HKSCC Operational Procedures in effect from time to time.

HOW TO APPLY FOR HONG KONG OFFER SHARES

All necessary arrangements have been made enabling the Shares to be admitted into CCASS.

You should seek the advice of your broker or other professional adviser for details of the settlement arrangement as such arrangements may affect your rights and interests.

G. PERSONAL DATA

The following personal information collection statement (the “**Personal Information Collection Statement**”) applies to any personal data collected and held by the Company, the Hong Kong Share Registrar, the receiving bank and the Relevant Persons about you in the same way as it applies to personal data about applicants other than HKSCC Nominees. This personal data may include client identifier(s) and your identification information. By giving application instructions to HKSCC, you acknowledge that you have read, understood and agree to all of the terms of the Personal Information Collection Statement below.

1. Personal Information Collection Statement

This Personal Information Collection Statement informs the applicant for, and holder of, Hong Kong Offer Shares, of the policies and practices of the Company and the Hong Kong Share Registrar in relation to personal data and the Personal Data (Privacy) Ordinance (Chapter 486 of the Laws of Hong Kong).

2. Reasons for the collection of your personal data

It is necessary for applicants and registered holders of Hong Kong Offer Shares to ensure that personal data supplied to the Company or its agents and the Hong Kong Share Registrar is accurate and up-to-date when applying for Hong Kong Offer Shares or transferring Hong Kong Offer Shares into or out of their names or in procuring the services of the Hong Kong Share Registrar.

Failure to supply the requested data or supplying inaccurate data may result in your application for Hong Kong Offer Shares being rejected, or in the delay or the inability of the Company or the Hong Kong Share Registrar to effect transfers or otherwise render their services. It may also prevent or delay registration or transfers of Hong Kong Offer Shares which you have successfully applied for and/or the despatch of Share certificate(s) to which you are entitled.

It is important that applicants for and holders of Hong Kong Offer Shares inform the Company and the Hong Kong Share Registrar immediately of any inaccuracies in the personal data supplied.

HOW TO APPLY FOR HONG KONG OFFER SHARES

3. Purposes

Your personal data may be used, held, processed, and/or stored (by whatever means) for the following purposes:

- processing your application and refund cheque and **HK eIPO White Form** e-Auto Refund payment instruction(s), where applicable, verification of compliance with the terms and application procedures set out in this prospectus and announcing results of allocation of Hong Kong Offer Shares;
- compliance with applicable laws and regulations in Hong Kong and elsewhere;
- registering new issues or transfers into or out of the names of the holders of the Shares including, where applicable, HKSCC Nominees;
- maintaining or updating the register of members of the Company;
- verifying identities of applicants for and holders of the Shares and identifying any duplicate applications for the Shares;
- facilitating Hong Kong Offer Shares balloting;
- establishing benefit entitlements of holders of the Shares, such as dividends, rights issues, bonus issues, etc.;
- distributing communications from the Company and its subsidiaries;
- compiling statistical information and profiles of the holder of the Shares;
- disclosing relevant information to facilitate claims on entitlements;
- and any other incidental or associated purposes relating to the above and/or to enable the Company and the Hong Kong Share Registrar to discharge their obligations to applicants and holders of the Shares and/or regulators and/or any other purposes to which applicants and holders of the Shares may from time to time agree.

4. Transfer of personal data

Personal data held by the Company and the Hong Kong Share Registrar relating to the applicants for and holders of Hong Kong Offer Shares will be kept confidential but the Company and the Hong Kong Share Registrar may, to the extent necessary for achieving any of the above purposes, disclose, obtain or transfer (whether within or outside Hong Kong) the personal data to, from or with any of the following:

- the Company's appointed agents such as financial advisers, receiving bank and overseas principal share registrar;

HOW TO APPLY FOR HONG KONG OFFER SHARES

- HKSCC or HKSCC Nominees, who will use the personal data and may transfer the personal data to the Hong Kong Share Registrar, in each case for the purposes of providing its services or facilities or performing its functions in accordance with its rules or procedures and operating FINI and CCASS (including where applicants for the Hong Kong Offer Shares request a deposit into CCASS);
- any agents, contractors or third-party service providers who offer administrative, telecommunications, computer, payment or other services to the Company or the Hong Kong Share Registrar in connection with their respective business operation;
- the Stock Exchange, the SFC and any other statutory regulatory or governmental bodies or otherwise as required by laws, rules or regulations, including for the purpose of the Stock Exchange's administration of the Listing Rules and the SFC's performance of its statutory functions; and
- any persons or institutions with which the holders of Hong Kong Offer Shares have or propose to have dealings, such as their bankers, solicitors, accountants or brokers etc.

5. Retention of personal data

The Company and the Hong Kong Share Registrar will keep the personal data of the applicants and holders of Hong Kong Offer Shares for as long as necessary to fulfil the purposes for which the personal data were collected. Personal data which is no longer required will be destroyed or dealt with in accordance with the Personal Data (Privacy) Ordinance (Chapter 486 of the Laws of Hong Kong).

6. Access to and correction of personal data

Applicants for and holders of Hong Kong Offer Shares have the right to ascertain whether the Company or the Hong Kong Share Registrar hold their personal data, to obtain a copy of that data, and to correct any data that is inaccurate. The Company and the Hong Kong Share Registrar have the right to charge a reasonable fee for the processing of such requests. All requests for access to data or correction of data should be addressed to the Company and the Hong Kong Share Registrar, at their registered address disclosed in the section headed "Corporate information" in this prospectus or as notified from time to time, for the attention of the joint company secretaries, or the Hong Kong Share Registrar for the attention of the privacy compliance officer.

The following is the text of a report set out on pages I-1 to I-3, received from the Company's reporting accountant, PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus. It is prepared and addressed to the directors of the Company and to the Joint Sponsors pursuant to the requirements of HKSIR 200 Accountants' Reports on Historical Financial Information in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants.



羅兵咸永道

ACCOUNTANT'S REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF CLOUDBREAK PHARMA INC. AND CCB INTERNATIONAL CAPITAL LIMITED AND HUATAI FINANCIAL HOLDINGS (HONG KONG) LIMITED

Introduction

We report on the historical financial information of Cloudbreak Pharma Inc. (the "Company") and its subsidiaries (together, the "Group") set out on pages I-4 to I-74, which comprises the consolidated statements of financial position as at 31 December 2022, 2023 and 2024, the Company's statements of financial position as at 31 December 2022, 2023 and 2024, and the consolidated statements of comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows for each of the years ended 31 December 2022, 2023 and 2024 (the "Track Record Period") and material accounting policy information and other explanatory information (together, the "Historical Financial Information"). The Historical Financial Information set out on pages I-4 to I-74 forms an integral part of this report, which has been prepared for inclusion in the prospectus of the Company dated 24 June 2025 (the "Prospectus") in connection with the initial listing of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

Directors' responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountant's responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountant's judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountant considers internal control relevant to the entity's preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountant's report, a true and fair view of the financial position of the Company and consolidated financial position of the Group as at 31 December 2022, 2023 and 2024 and of the Group's consolidated financial performance and its consolidated cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 2 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 28 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Track Record Period.

No statutory financial statements for the Company

No statutory financial statements have been prepared for the Company since its date of incorporation.

PricewaterhouseCoopers
Certified Public Accountants
Hong Kong
24 June 2025

I. HISTORICAL FINANCIAL INFORMATION OF THE GROUP**Preparation of Historical Financial Information**

Set out below is the Historical Financial Information which forms an integral part of this accountant's report.

The financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, were audited by PricewaterhouseCoopers in accordance with International Standards on Auditing issued by the International Auditing and Assurance Standards Board ("Underlying Financial Statements").

The Historical Financial Information is presented in United States dollar ("US\$") and all values are rounded to the nearest thousand (US\$'000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

		Year ended 31 December		
	<i>Notes</i>	2022	2023	2024
		<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Revenue	5	–	–	10,000
Other income	6	471	880	214
Other gains, net	7	718	674	645
General and administrative expenses	8	(8,912)	(11,277)	(9,489)
Research and development expenses	8	<u>(15,290)</u>	<u>(27,492)</u>	<u>(37,946)</u>
Operating loss		(23,013)	(37,215)	(36,576)
Finance income	11	1,602	3,872	2,029
Finance costs	11	<u>(31)</u>	<u>(275)</u>	<u>(27)</u>
Finance income, net		<u>1,571</u>	<u>3,597</u>	<u>2,002</u>
Change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments		<u>(45,314)</u>	<u>(95,777)</u>	<u>(63,723)</u>
Loss before income tax		(66,756)	(129,395)	(98,297)
Income tax expenses	12	<u>(82)</u>	<u>(23)</u>	<u>(833)</u>
Loss for the year		<u><u>(66,838)</u></u>	<u><u>(129,418)</u></u>	<u><u>(99,130)</u></u>

APPENDIX I
ACCOUNTANT'S REPORT

	<i>Notes</i>	Year ended 31 December		
		2022	2023	2024
		<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Other comprehensive losses				
<i>Items that may be reclassified subsequently to profit or loss:</i>				
Currency translation difference		(1,815)	(801)	(877)
<i>Items that will not be reclassified subsequently to profit or loss:</i>				
Change in fair value of convertible redeemable preferred shares due to own credit risk	24(a)	(2,476)	(982)	(13)
Change in fair value of other financial liabilities due to own credit risk	24(b)	<u>(1,824)</u>	<u>—</u>	<u>—</u>
Other comprehensive loss for the year		<u>(6,115)</u>	<u>(1,783)</u>	<u>(890)</u>
Total comprehensive loss for the year		<u><u>(72,953)</u></u>	<u><u>(131,201)</u></u>	<u><u>(100,020)</u></u>
Loss per share attributable to the owners of the Company (expressed in US\$ per share)				
– Basic and diluted	13	<u><u>(0.15)</u></u>	<u><u>(0.28)</u></u>	<u><u>(0.21)</u></u>

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Notes</i>	As at 31 December		
		2022	2023	2024
		<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Assets				
Non-current assets				
Property, plant and equipment	14	363	1,106	375
Right-of-use assets	15	807	2,161	2,051
Prepayments and other receivables	18	<u>808</u>	<u>97</u>	<u>74</u>
		<u>1,978</u>	<u>3,364</u>	<u>2,500</u>
Current assets				
Prepayments and other receivables	18	869	1,263	2,325
Current income tax receivables		129	50	322
Short-term bank deposits	19	63,194	7,500	–
Cash and cash equivalents	19	<u>15,917</u>	<u>52,654</u>	<u>34,862</u>
		<u>80,109</u>	<u>61,467</u>	<u>37,509</u>
Total assets		<u>82,087</u>	<u>64,831</u>	<u>40,009</u>
Equity				
Share capital	20	48	48	48
Other reserves	21	(29,508)	(17,720)	(7,342)
Accumulated losses		<u>(115,704)</u>	<u>(245,122)</u>	<u>(344,252)</u>
Total deficit		<u>(145,164)</u>	<u>(262,794)</u>	<u>(351,546)</u>

APPENDIX I

ACCOUNTANT'S REPORT

		As at 31 December		
	Notes	2022	2023	2024
		US\$'000	US\$'000	US\$'000
Liabilities				
Non-current liability				
Lease liabilities	15	<u>548</u>	<u>228</u>	<u>209</u>
Current liabilities				
Trade and other payables	22	30,711	4,599	4,766
Convertible redeemable preferred shares	24	109,957	322,459	386,195
Other financial liabilities at fair value through profit or loss	24	73,960	–	–
Derivative financial instruments	25	11,783	–	–
Lease liabilities	15	292	317	302
Current income tax liabilities		<u>–</u>	<u>22</u>	<u>83</u>
		<u>226,703</u>	<u>327,397</u>	<u>391,346</u>
Total liabilities		<u>227,251</u>	<u>327,625</u>	<u>391,555</u>
Total deficit and liabilities		<u>82,087</u>	<u>64,831</u>	<u>40,009</u>
Net current liabilities		<u>(146,594)</u>	<u>(265,930)</u>	<u>(353,837)</u>

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	<i>Notes</i>	As at 31 December		
		2022	2023	2024
		US\$'000	US\$'000	US\$'000
Assets				
Non-current asset				
Investments in subsidiaries	1.2	324,376	324,376	324,376
Current assets				
Prepayments	18	–	338	452
Amounts due from subsidiaries	26	83,898	87,008	74,026
Cash and cash equivalents	19	–	11	11
		83,898	87,357	74,489
Total assets		408,274	411,733	398,685
Equity				
Share capital	20	48	48	48
Reserve	21	252,707	265,296	276,551
Accumulated losses		(68,827)	(182,100)	(265,552)
Total equity		183,928	83,244	11,047
Liabilities				
Current liabilities				
Trade and other payables	22	28,313	1,256	1,120
Convertible redeemable preferred shares	24	109,957	322,459	386,195
Other financial liabilities at fair value through profit or loss	24	73,960	–	–
Derivative financial instruments	25	11,783	–	–
Amounts due to subsidiaries	26	333	4,774	420
Current income tax liabilities		–	–	83
		224,346	328,489	387,818
Total liabilities		224,346	328,489	387,818
Total equity and liabilities		408,274	411,733	398,685

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to the owners of the Company			
	Share capital	Other reserves	Accumulated losses	Total deficits
	US\$'000	US\$'000	US\$'000	US\$'000
	(Note 20)	(Note 21)		
Balance at 1 January 2022	46	(24,736)	(48,866)	(73,556)
Comprehensive loss				
Loss for the year	–	–	(66,838)	(66,838)
Other comprehensive loss:				
Changes in fair value of convertible redeemable preferred shares due to own credit risk (Note 24(a))	–	(2,476)	–	(2,476)
Changes in fair value of other financial liabilities due to own credit risk (Note 24(b))	–	(1,824)	–	(1,824)
Currency translation differences	–	(1,815)	–	(1,815)
Total comprehensive loss for the year	–	(6,115)	(66,838)	(72,953)
Transactions with owners:				
Equity-settled share-based payment transactions (Note 10)	–	1,345	–	1,345
Share awards vested and granted (Note 20)	2	(2)	–	–
Total transactions with owners	2	1,343	–	1,345
Balance at 31 December 2022	48	(29,508)	(115,704)	(145,164)

	Attributable to the owners of the Company			
	Share capital <i>US\$'000</i> (Note 20)	Other reserves <i>US\$'000</i> (Note 21)	Accumulated losses <i>US\$'000</i>	Total deficits <i>US\$'000</i>
Balance at 1 January 2023	48	(29,508)	(115,704)	(145,164)
Comprehensive loss				
Loss for the year	–	–	(129,418)	(129,418)
Other comprehensive loss:				
Changes in fair value of convertible redeemable preferred shares due to own credit risk <i>(Note 24(a))</i>	–	(982)	–	(982)
Currency translation differences	–	(801)	–	(801)
Total comprehensive loss for the year	–	(1,783)	(129,418)	(131,201)
Transactions with owners:				
Equity-settled share-based payment transactions <i>(Note 10)</i>	–	13,571	–	13,571
Total transactions with owners	–	13,571	–	13,571
Balance at 31 December 2023	48	(17,720)	(245,122)	(262,794)

	Attributable to the owners of the Company			
	Share capital <i>US\$'000</i> (Note 20)	Other reserves <i>US\$'000</i> (Note 21)	Accumulated losses <i>US\$'000</i>	Total deficits <i>US\$'000</i>
Balance at 1 January 2024	48	(17,720)	(245,122)	(262,794)
Comprehensive loss				
Loss for the year	–	–	(99,130)	(99,130)
Other comprehensive loss:				
Changes in fair value of convertible redeemable preferred shares due to own credit risk <i>(Note 24(a))</i>	–	(13)	–	(13)
Currency translation differences	–	(877)	–	(877)
Total comprehensive loss for the year	–	(890)	(99,130)	(100,020)
Transactions with owners:				
Equity-settled share-based payment transactions <i>(Note 10)</i>	–	11,268	–	11,268
Total transactions with owners	–	11,268	–	11,268
Balance at 31 December 2024	48	(7,342)	(344,252)	(351,546)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>Notes</i>	Year ended 31 December		
		2022	2023	2024
		US\$'000	US\$'000	US\$'000
Cash flows from operating activities				
Cash used in operation	23(a)	(19,835)	(22,586)	(25,480)
Income tax (paid)/refund		<u>(215)</u>	<u>80</u>	<u>(1,042)</u>
Net cash used in operating activities		<u>(20,050)</u>	<u>(22,506)</u>	<u>(26,522)</u>
Cash flows from investing activities				
Purchase of property, plant and equipment		(778)	(556)	(155)
Purchase of land use rights		–	(1,655)	–
Proceeds from disposal of financial assets at fair value through profit or loss		32,552	–	–
Placement of short-term bank deposits		(326,848)	(74,713)	–
Repayment of short-term bank deposits		263,654	130,407	7,500
Interest received		<u>1,602</u>	<u>3,872</u>	<u>2,029</u>
Net cash (used in)/generated from investing activities		<u>(29,818)</u>	<u>57,355</u>	<u>9,374</u>
Cash flows from financing activities				
Repayment to a director	23(b)	(89)	–	–
Proceeds from issuance of preferred shares	23(b)	–	2,800	–
Proceeds from issuance of warrants and related financial liabilities	23(b)	15,975	–	–
Proceeds from bank borrowings	23(b)	–	284,930	14,000
Repayment of bank borrowings	23(b)	–	(284,930)	(14,000)
Interest paid on bank borrowings	23(b)	–	(240)	(4)
Payment for listing expenses		–	(173)	(102)
Payments for acquisition of Cloudbreak Therapeutics LLC	1.2(d), 23(b)	(30,000)	–	–
Payment for lease liabilities, principal portion	23(b)	(192)	(300)	(328)
Payment for lease liabilities, interest portion	23(b)	<u>(31)</u>	<u>(35)</u>	<u>(23)</u>
Net cash (used in)/generated from financing activities		<u>(14,337)</u>	<u>2,052</u>	<u>(457)</u>

	<i>Notes</i>	Year ended 31 December		
		2022	2023	2024
		<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Net (decrease)/increase in cash and cash equivalents		(64,205)	36,901	(17,605)
Cash and cash equivalents at beginning of the year	19	80,604	15,917	52,654
Exchange differences on cash and cash equivalents		<u>(482)</u>	<u>(164)</u>	<u>(187)</u>
Cash and cash equivalents at end of the year	19	<u>15,917</u>	<u>52,654</u>	<u>34,862</u>

II. NOTES TO THE FINANCIAL INFORMATION

1 General information, history and reorganisation

1.1 General information

Cloudbreak Pharma Inc. (the “Company”) was incorporated in the Cayman Islands on 20 November 2020. The address of the Company’s registered office is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.

The Company is an investment holding company and its subsidiaries (together the “Group”) are principally engaged in the research and developments of therapeutic biologics (the “Listing Business”).

These financial statements are presented in US\$, unless otherwise stated.

1.2 History and reorganisation of the Group

Prior to the incorporation of the Company and the completion of the reorganisation (the “Reorganisation”) in preparation for the listing (the “Listing”) of the Company’s shares on the Main Board of The Stock Exchange of Hong Kong Limited (the “HKEX”), the Listing Business was operated by Cloudbreak Therapeutics LLC (“Cloudbreak USA”) and its subsidiaries including ADS Therapeutics LLC (“ADS USA”), Cloudbreak Bio-Pharmaceutical Science and Technology (Guangzhou) Co., Ltd. (“Cloudbreak Guangzhou”) (collectively, the “Operating Companies”).

Upon the completion of the Reorganisation, each of the shareholders of Cloudbreak USA became the shareholders of the Company, and the Company became the holding company of the companies now comprising the Group. The Reorganisation mainly involved the following major steps:

(a) Incorporation of the Company

On 20 November 2020, the Company was incorporated as an exempted company with limited liability in the Cayman Islands with an initial authorised share capital of US\$50,000 divided into 500,000,000 ordinary shares with a par value of US\$0.0001 each. On the same day, the initial subscriber transferred one ordinary share at par to Water Lily Consultants Inc. (“Water Lily Consultants”). On 13 January 2021, Water Lily Consultants surrendered its one share in the Company.

(b) Transfer of entire equity interest in ADS USA to the Company

Immediately prior to the Reorganisation, ADS USA was held as to 58.82%, 28.82% and 4.12% by Cloudbreak USA, Water Lily Consultants and each of Ice Tree, LLC (“Ice Tree LLC”), VD&TL Capital and YDD Consulting Inc. (“YDD Consulting”), respectively.

On 13 January 2021, Cloudbreak USA, Water Lily Consultants, Ice Tree LLC, VD&TL Capital and YDD Consulting transferred the entire equity interest in ADS USA to the Company in exchange for 66,973,418, 32,816,975, 4,688,139, 4,688,139, 4,688,139 Class A ordinary shares of the Company, respectively.

Upon completion of the transaction, ADS USA became a subsidiary of the Company and the Company was held as to approximately 58.82% by Cloudbreak USA, 28.82% by Water Lily Consultants, and 4.12% by each of Ice Tree LLC, VD&TL Capital and YDD Consulting.

(c) Transfer of entire equity interest in Cloudbreak Pharmaceutical Inc. ("Cloudbreak Cayman") to the Company

On 12 March 2021, Cloudbreak USA, Water Lily Consultants and Ice Tree Consultants, Inc. ("Ice Tree Consultants") transferred the entire equity interest in Cloudbreak Cayman, the intermediate holding company of Cloudbreak Guangzhou, to the Company in exchange for 205,984 Class A and 130,769,200 Class B ordinary shares, 28,649 Class A and 18,096,200 Class B ordinary shares, and 5,770 Class A and 3,619,200 B ordinary shares of the Company, respectively.

Upon completion of the transaction, Cloudbreak Cayman became a wholly-owned subsidiary of the Company and the Company was held as to approximately 74.25% by Cloudbreak USA, 19.11% by Water Lily Consultants, 1.36% by Ice Tree Consultants, and 1.76% by each of Ice Tree LLC, VD&TL Capital and YDD Consulting.

(d) Transfer of entire membership interest in Cloudbreak USA to the Company

On 24 November 2021, the then members of Cloudbreak USA transferred the entire membership interest in Cloudbreak USA to the Company in exchange for ordinary shares of the Company and cash as set out below:

	Class C ordinary shares	Cash (US\$'000)
Water Lily Consultants	51,519,363	8,234
Bright Future Pharmaceutical Laboratories Ltd.	45,955,468	8,083
Dr. Li Junzhi	26,966,012	4,231
VD&TL Capital	24,405,636	4,080
Whitcup Life Sciences LLC	13,130,134	2,261
Other individual shareholders	<u>21,670,191</u>	<u>3,111</u>
	<u>183,646,804</u>	<u>30,000</u>

Upon completion of the transaction, Cloudbreak USA became a wholly-owned subsidiary of the Company.

Immediately prior to the Reorganisation, the Listing Business was held by Cloudbreak USA and mainly conducted through Cloudbreak USA and its subsidiaries. Pursuant to the Reorganisation, Cloudbreak USA and the Listing Business were transferred to and held by the Company. The Company has not been involved in any other business prior to the Reorganisation and does not meet the definition of a business. The Reorganisation is merely a recapitalisation of the Listing Business, with no change in management. Accordingly, the Group resulting from the Reorganisation is regarded as a continuation of the business held under Cloudbreak USA and, for the purpose of this report, the Historical Financial Information has been prepared and presented as a continuation of the consolidated financial statements of Cloudbreak USA and its subsidiaries, with the assets and liabilities of the Group recognised and measured at the carrying amounts under the consolidated financial statements of Cloudbreak USA throughout the periods presented.

APPENDIX I

ACCOUNTANT'S REPORT

Upon completion of the Reorganisation and as at the date of this report, the Company has direct or indirect interests in the following principal subsidiaries during the Track Record Period:

Name of subsidiaries	Place and date of incorporation	Issued and fully paid up share capital	Principal activities	Attributable equity interest of the Group			As the date of report	Notes
				As at 31 December 2022	2023	2024		
Directly held:								
Cloudbreak USA	United States, 14 September 2015	Nil	Research and developments of therapeutic biologics	100%	100%	100%	100%	(i)
Cloudbreak Pharma (HK) Limited	Hong Kong, 13 June 2022	Nil	Investment holding	100%	100%	100%	100%	(vi), (viii)
ADS USA	United States, 16 January 2017	Nil	Research and developments of therapeutic biologics	100%	100%	100%	100%	(i)
Cloudbreak Pharmaceutical GmbH	Germany, 4 November 2021	EUR25,000	Investment holding	100%	100%	100%	100%	(i)
Cloudbreak Cayman	Cayman, 1 November 2019	US\$24,331	Investment holding	100%	100%	100%	100%	(i)
Indirectly held:								
Cloudbreak Biotechnology Limited	BVI, 18 November 2019	US\$1	Investment holding	100%	100%	100%	100%	(i)
ADS Pharmaceuticals Pty Ltd	Australia, 20 November 2020	AUD1	Research and developments of therapeutic biologics	100%	100%	100%	100%	(i)
Cloudbreak Therapeutics Limited ("Cloudbreak HK")	Hong Kong, 28 November 2019	HK\$1	Investment holding	100%	100%	100%	100%	(iv), (viii)
Cloudbreak Guangzhou* 撥康視雲生物醫藥科技(廣州)有限公司 (former name: 撥雲生物醫藥科技(廣州)有限公司)	Mainland China, 30 September 2018	RMB10,970,620	Research and developments of therapeutic biologics	100%	100%	100%	100%	(ii), (viii)
Cloudbreak Bio-pharmaceutical Science and Technology (Suzhou) Co., Ltd* 撥康視雲生物醫藥科技(蘇州)有限公司 (former name: 撥雲生物醫藥科技(蘇州)有限公司)	Mainland China, 27 September 2021	US\$29,999,965	Research and developments of therapeutic biologics	100%	100%	100%	100%	(iii), (viii)
Cloudbreak Bio-pharmaceutical Science and Technology (Yixing) Co., Ltd* 撥康視雲生物醫藥科技(宜興)有限公司	Mainland China, 5 September 2023	US\$7,500,000	Research and developments of therapeutic biologics	N/A	100%	100%	100%	(v), (vii), (viii)
Cloudbreak Bio-pharmaceutical Science and Technology (Wenzhou) Co., Ltd* 撥康視雲生物醫藥科技(溫州)有限公司	Mainland China, 11 June 2024	RMB100,000	Research and developments of therapeutic biologics	N/A	N/A	100%	100%	(v), (viii)

- (i) No audited statutory financial statements were prepared for these subsidiaries as they are not required to issue audited financial statements under the statutory requirements of their respective of incorporation.
- (ii) The statutory financial statements for the years ended 31 December 2022 and 2023 were audited by Guangzhou Deyong Certified Public Accountants Limited (廣州德永會計師事務所有限公司) and Guanzhou Tiancheng Certified Public Accountants (廣州天誠會計師事務所) respectively.

- (iii) The statutory financial statements for the years ended 31 December 2022 and 2023 were audited by Suzhou Qianzheng Certified Public Accountants (蘇州乾正會計師事務所) and Suzhou Sucheng Joining Certified Public Accountants Co. Ltd. (蘇州蘇城會計師事務所有限公司) respectively.
- (iv) The statutory financial statements for the years ended 31 December 2022 and 2023 were audited by Sino Corp CPA Limited and Sino Corp CPA Limited respectively.
- (v) The subsidiary had not been incorporated in the relevant year with “N/A”.
- (vi) The statutory financial statements for the year ended 31 December 2022 and 2023 were audited by Shum Fai Nin Certified Public Accountant.
- (vii) The statutory financial statements for the year ended 31 December 2023 were audited by Guanzhou Tiancheng Certified Public Accountants (廣州天誠會計師事務所).
- (viii) The audited financial statements of these subsidiaries for the year ended 31 December 2024 have not been issued as of date of report.
- * The English names of the companies established in the People Republic of China (the “PRC” or “Mainland China”) and their statutory auditors referred to above represent management’s best efforts in translating the Chinese names of those companies as no English names have been registered or are available.

The investments in subsidiaries of the Company represent the fair values of the Listing Business attributable to owners of the Company upon the completion of the Reorganisation.

2 Basis of preparation

The principal accounting policies applied in the preparation of the Historical Financial Information are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

The Historical Financial Information of the Group has been prepared in accordance with all applicable IFRS Accounting Standards issued by International Accounting Standards Board (“IASB”). The Historical Financial Information has been prepared under the historical cost convention, as modified by the revaluation of convertible redeemable preferred shares, other financial liabilities at fair value through profit or loss (“FVPL”) and derivative financial instruments, which are carried at fair value.

The preparation of Historical Financial Information in conformity with IFRS Accounting Standards requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group’s accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the Historical Financial Information are disclosed in Note 4 below.

2.1 Going Concern

The Group is in the development phase of the therapeutic biologics and has been incurring losses from its operations since incorporation. The Historical Financial Information has been prepared on a going concern basis notwithstanding that, the Group reported a net loss of approximately US\$66,838,000, US\$129,418,000 and US\$99,130,000 during the years ended 31 December 2022, 2023 and 2024, respectively, and as at 31 December 2022, 2023 and 2024, the Group’s current liabilities exceeded its current assets by approximately US\$146,594,000, US\$265,930,000 and US\$353,837,000 and had a net liabilities of approximately US\$145,164,000, US\$262,794,000 and US\$351,546,000, respectively. As at 31 December 2024, the Group’s current liabilities included series A and series B convertible redeemable preferred shares of approximately US\$111,286,000 and series C convertible redeemable preferred shares of approximately US\$274,909,000.

Given that the conversion options are exercisable at the series A, series B and series C investors’ discretions, all the convertible redeemable preferred shares were classified as current liabilities as at 31 December 2022, 2023 and 2024.

For series A and series B convertible preferred shares, the redemption events of have not been triggered and the management considered that they will not be triggered for at least twelve months from 31 December 2024.

For series C convertible redeemable preferred shares, according to the shareholders' agreement entered into between the Company and all the preferred shareholders (the "Shareholders Agreement"), the holders of the series C convertible redeemable preferred shares were granted the right to redeem the preferred shares as a qualified initial public offering has not been consummated by the Company on or prior to 31 December 2022. Up to the date of this report, the Group had not received any redemption notice from the series C preferred shareholders.

Such redemption right shall be terminated on the date of the first submission by the Company of its listing application to certain particular stock exchange, but such redemption option shall be automatically restored if the Company fails to be listed in such listing application, or the Company decides to put on hold the listing procedures or withdraw the listing application. As at the date of this report, the redemption option is terminated as the Company has submitted the listing application for the proposed Listing and the Company does not have any intention to put on hold the listing procedures nor withdraw the listing application for at least twelve months from 31 December 2024 so that such redemption option shall not be restored for at least twelve months from 31 December 2024. The preferred shares shall automatically be converted into ordinary shares at the time immediately upon the closing of a qualified initial public offering. For details, please refer to Note 24.

In view of the above circumstances, the directors of the Company have given careful consideration to the future liquidity and performance of the Group and its available sources of financing and prepared a cash flow projection covering not less than 12 months from 31 December 2024 in assessing whether the Group will have sufficient financial resources to continue as a going concern for at least twelve months from 31 December 2024. Significant judgments and assumptions were made by directors as part of the Group's assessment, inter alia, the Series A, B and C convertible redeemable preferred share are not redeemable for at least twelve months from 31 December 2024.

The directors, believe that the Group will have sufficient working capital to finance its operations and to meet its financial obligations as and when they fall due in the next twelve months from 31 December 2024. Accordingly, taking into account the non-exercise of the redemption right of all the preferred shareholders for at least twelve months from 31 December 2024, the anticipated cash flows required by the Group and its available financial resources, the directors believe that it is appropriate to prepare the Historical Financial Information on a going concern basis.

2.2 New standards, amendments and improvements to existing standards not yet adopted

New standards, amendments and improvements to existing standards that have been issued but not yet effective and not been early adopted by the Group during the Track Record Period are as follows:

		Effective for annual periods beginning on or after
Amendments to IAS 21	Lack of Exchangeability	1 January 2025
Amendments to IFRS 9 and IFRS 7	Classification and Measurement of Financial Instruments	1 January 2026
Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7	Annual Improvements to IFRS Accounting Standards	1 January 2026
IFRS 18	Presentation and Disclosure in Financial Statements	1 January 2027
IFRS 19	Subsidiaries without Public Accountability: Disclosures	1 January 2027
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

IFRS 18 will replace IAS 1 Presentation of Financial Statements, introducing new requirements that will help to achieve comparability of the financial performance of similar entities and provide more relevant information and transparency to users. Even though IFRS 18 will not impact the recognition or measurement of items in the financial statements, its impacts on presentation and disclosure are expected to be pervasive, in particular those related to the consolidated statements of profit or loss and providing management-defined performance measures within the financial statements.

Management is currently assessing the detailed implications of applying the new standard on the Group's consolidated financial statements. The Group expects to apply the new standard from its mandatory effective date of 1 January 2027. Retrospective application is required, and so the comparative information for the financial year ending 31 December 2026 will be restated in accordance with IFRS 18.

Except for the abovementioned changes in presentation and disclosure, these pronouncements are not expected to have a material impact on the results or the financial position of the Group.

3 Financial risk management

3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (including foreign exchange risk and cash flow and fair value interest rate risk), credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the Group's financial performance. Risk management is carried out by the senior management of the Group.

3.1.1 Market risk

(a) Foreign exchange risk

Foreign exchange risk arises when future commercial transactions or recognised assets and liabilities are denominated in a currency that is not the respective group entities' functional currency.

Certain bank balances and cash are denominated in foreign currencies of respective group entities that are exposed to foreign currency risk. The Group has entities operating in United States, Hong Kong and Mainland China. The Group constantly reviews the economic situation and its foreign exchange risk profile, and considers appropriate hedging measures in the future, as may be necessary.

The Group is primarily exposed to changes in RMB/US\$ exchange rates in its entities operating in Mainland China that have functional currency in RMB.

As at 31 December 2022, 2023 and 2024, if RMB strengthened/weakened by 5% against the US\$ with all other variables held constant, loss before income tax for the year would have been approximately US\$473,000, US\$1,663,000 and US\$867,000 higher/lower, respectively, mainly as a result of foreign exchange gains/losses on the translation of US\$ denominated cash and cash equivalents in the entities operating in Mainland China.

There are certain US\$ and HK\$ financial assets and liabilities held by the Group with HK\$ and US\$ functional currency respectively. Since HK\$ are pegged to the US\$, management considers the foreign exchange risk arising from such financial assets and liabilities to the Group is not significant. Hence, the directors consider the Group does not have any material foreign exchange risk exposure. No sensitivity analysis is presented.

The Group does not hedge against any fluctuation in foreign currencies during the Track Record Period.

(b) Cash flow and fair value interest rate risk

Other than interest-bearing short-term bank deposit, the Group has no other significant interest-bearing assets. The directors of the Company do not anticipate there is any significant impact to interest-bearing assets resulted from the changes in interest rates, because the interest rates of short-term bank deposit are not expected to change significantly.

3.1.2 Credit risk

Credit risk refers to the risk that the counterparty to a financial instrument would fail to discharge its obligation under the terms of the financial instrument and cause a financial loss to the Group. The carrying amounts of other receivables, short-term bank deposits and cash and cash equivalents represent the Group's maximum exposure to credit risk in relation to financial assets.

(a) Other financial assets at amortised cost

For other receivables, it is measured as either 12-month expected credit losses or lifetime expected credit loss, depending on whether there has been significant increase in credit risk since initial recognition. Other financial assets that are not credit-impaired on initial recognition are classified in 'Stage 1' and the expected credit losses are measured as 12-month expected credit losses. If a significant increase in credit risk of other financial asset has occurred since initial recognition, the financial asset is moved to 'Stage 2' but is not yet deemed to be credit-impaired. The expected credit losses are measured as lifetime expected credit loss. If any financial asset is credit-impaired, it is then moved to 'Stage 3' and the expected credit loss is measured as lifetime expected credit loss.

Management has assessed that during the Track Record Period, other receivables have not had a significant increase in credit risk since initial recognition. Management considers that the expected credit loss for other financial assets at amortised cost to be immaterial.

(b) Credit risk of short-term bank deposits and cash and cash equivalents

The Group expects that there is no significant credit risk associated with short-term bank deposits and cash and cash equivalents since they are substantially deposited at state-owned banks or reputable commercial banks which are high-credit-quality financial institutions. Management considers that the expected credit loss for short-term bank deposits and cash and cash equivalents to be immaterial.

3.1.3 Liquidity risk

The Group aims to maintain sufficient cash and cash equivalents. Due to the dynamic nature of the underlying businesses, the policy of the Group is to regularly monitor the Group's liquidity risk and to maintain adequate cash and cash equivalents to meet the Group's liquidity requirements.

The Group recognises the financial liabilities issued to investors at fair value through profit or loss.

Accordingly, the financial liabilities at FVPL are managed on a fair value basis rather than by maturing dates (*Note 24*).

The table below analyses the Group's non-derivative financial liabilities that will be settled into relevant maturity grouping based on the remaining period at each balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	Less than one year US\$'000	Between 1 year and 2 years US\$'000	Between 2 years and 5 years US\$'000	Total US\$'000
As at 31 December 2022				
Trade and other payables (excluding non-financial liabilities)	29,855	–	–	29,855
Lease liabilities	327	340	235	902
Total	30,182	340	235	30,757
As at 31 December 2023				
Trade and other payables (excluding non-financial liabilities)	3,774	–	–	3,774
Lease liabilities	337	184	51	572
Total	4,111	184	51	4,346
As at 31 December 2024				
Trade and other payables (excluding non-financial liabilities)	3,465	–	–	3,465
Lease liabilities	320	157	60	537
Total	3,785	157	60	4,002

3.2 Capital management

The Group's objectives on managing capital are to safeguard the Group's ability to continue as a going concern and support the sustainable growth of the Group in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to enhance shareholders' value in the long term.

The Group monitors capital (including share capital, share premium and preferred shares on an as-if-converted basis) by regularly reviewing the capital structure. As part of this review, the Group may adjust the amount of return capital to shareholders, issue new shares or sell assets to reduce debt.

The liability-to-asset ratios as at the end of each of the Track Record Period are as follow:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Total assets	82,087	64,831	40,009
Total liabilities	227,251	327,625	391,555
Liability-to-asset ratio	277%	505%	979%

* Liability-to-asset ratios is calculated by dividing total liabilities by total assets and multiplying the product by 100%

3.3 Fair value estimation

This section explains the judgements and estimates made in determining the fair values of the financial instruments that are recognised and measured at fair value in the consolidated financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques which maximise the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

Specific valuation techniques used to value financial instruments include:

- Quoted market prices or dealer quotes for similar instruments;
- Discounted cash flow model and unobservable inputs mainly including assumptions of expected future cash flows and discount rate; and
- A combination of observable and unobservable inputs, including discount rate, risk-free interest rate, discount for lack of marketability ("DLOM"), and expected volatility, etc.

There were no transfers between levels 1, 2 and 3 during the Track Record Period. The Group has no financial instruments in level 1 and level 2.

The changes in level 3 instruments for the years ended 31 December 2022, 2023 and 2024 are presented in Notes 24 and 25.

Financial instruments at fair value

The following table presents the Group's assets and liabilities that were measured at fair value as at 31 December 2022, 2023 and 2024:

	Level 1 US\$'000	Level 2 US\$'000	Level 3 US\$'000	Total US\$'000
At 31 December 2022				
Liabilities				
Convertible redeemable preferred shares (Note 24(a))	–	–	109,957	109,957
Other financial liabilities at fair value through profit or loss (Note 24(b))	–	–	73,960	73,960
Derivative financial instruments (Note 25)	–	–	11,783	11,783
	<u>–</u>	<u>–</u>	<u>195,700</u>	<u>195,700</u>
At 31 December 2023				
Liability				
Convertible redeemable preferred shares (Note 24(a))	<u>–</u>	<u>–</u>	<u>322,459</u>	<u>322,459</u>
At 31 December 2024				
Liability				
Convertible redeemable preferred shares (Note 24(a))	<u>–</u>	<u>–</u>	<u>386,195</u>	<u>386,195</u>

For convertible redeemable preferred shares, other financial liabilities at fair value through profit or loss and derivative financial instruments, they are initially recognised at fair value, and subsequently stated at fair value with changes in fair value recognized in profit or loss. For details, please refer to Notes 24 and 25.

Financial instruments at amortised cost

The carrying amounts of the Group's financial assets measured at amortised costs, including other receivables, short-term bank deposits, cash and cash equivalents and the Group's financial liabilities measured at amortised costs, including trade and other payables and lease liabilities approximate their fair values due to their short maturities or the interest rates are close to the market interest rates.

3.4 Offsetting financial instruments

Financial assets and liabilities are offset, and the net amount reported in the consolidated statements of financial position where the Group currently has a legally enforceable right to offset the recognised amounts and there is an intention to settle on a net basis or realise the asset and settle the liability simultaneously.

4 Critical estimates and judgements

Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities are discussed below.

(a) *Fair value measurement of convertible redeemable preferred shares, derivative financial instruments and other financial liabilities at fair value through profit or loss*

The fair values of the Group's convertible redeemable preferred shares, derivative financial instruments and other financial liabilities at fair value through profit or loss, which are not traded in an active market, are determined by using valuation techniques. Significant judgements and assumptions are exercised by management in selecting valuation models and unobservable inputs at the end of each reporting periods. Changing the key assumptions used by management could materially affect the fair values of these financial liabilities and as a result affect the Group's financial position and results of operation. Details of the valuation models, key assumptions and inputs are disclosed in Notes 24 and 25.

(b) *Share-based compensation expenses*

As mentioned in Note 10, the Company has granted share awards and share options to the Group's employees. The Company has engaged an independent valuer to determine the grant date fair value of the share options to employees using the binomial option pricing model, which is to be expensed over the vesting period. Various assumptions are involved in the model and significant estimate on assumptions is required to be made by the management, including discount rate, risk-free interest, expected price volatility, expected dividend payout, expected option life, fair value of ordinary shares, milestone of the non-market vesting condition and subjective judgments regarding projected financial and operating results, its unique business risks, and its operating history and prospects at the time the grants are made. The Company measures the share awards and share-based compensation to the non-employees with reference to the fair value of the instruments at grant date or the date when services are rendered, whichever appropriate. The management applies judgements and estimate on those significant assumptions in determining the fair value of the share options and share awards to the Group's employees and share-based compensation to the non-employees.

At the end of each reporting period, the Group reassesses estimated number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognised in consolidated statements of comprehensive income such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payment reserve.

(c) *Research and development expenditures*

Development expenditures incurred on the Group's research and development activities, including conducting clinical trials and other activities related to regulatory filings for the Group's product candidates, are capitalised as intangible assets only when meet the capitalisation criteria. Expenditures that do not meet these capitalisation principles are recognised as research and development expenses. During the Track Record Period, the Group's research and development expenditures incurred did not meet these capitalisation principles for any products and were expensed as incurred.

5 Segment information and revenue

The executive directors are identified as the chief operating decision makers ("CODM") of the Group who review the Group's internal reporting in order to assess performance and allocate resources. The CODM identifies operating segments based on the internal organisation structure, management requirements and internal reporting system, and discloses segment information of reportable segments which is determined on the basis of operating segments.

The Group is principally engaged in the research and developments of therapeutic biologics. The CODM assesses the performance of the Listing Business based on a measure of operating results and considers the Listing Business in a single operating segment. Information reported to the CODM for the purposes of resources allocation and performance assessment focuses on the operation results of the Group as a whole as the Group's resources are integrated. Accordingly, the Group has identified one operating segment and no further analysis of this single segment is presented for the Track Record Period.

The Group's non-current assets by geographical location, which is determined by the location in which the asset is located, is as follows:

	As at 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Mainland China	1,014	2,755	2,205
Hong Kong	445	292	91
United States	425	316	203
Others	94	1	1
	<u>1,978</u>	<u>3,364</u>	<u>2,500</u>

	Year ended 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Revenue	<u>—</u>	<u>—</u>	<u>10,000</u>

During the year ended 31 December 2024, the timing of revenue recognition was at a point in time.

Revenue from customers contributing over 10% of the total revenue of the Group is as follow:

	Year ended 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Customer A	<u>—</u>	<u>—</u>	<u>10,000</u>

In August 2024, the Group entered into an agreement with a pharmaceutical company for licensing one of its know-how to the customer for development and commercialization. The license contract includes an upfront fee and certain development milestone payments. The contract also includes sales-based royalties. For the year ended 31 December 2024, there was no development milestone and commercial milestone achieved by the Group. The Group is further entitled to receive up to an aggregate of USD3,000,000 upon the achievement of additional specified milestones related to the development and regulatory approval. As at 31 December 2024, the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied (or partially unsatisfied) was US\$3,000,000 (2022 and 2023: nil). Management expects that the transaction price allocated to the unsatisfied performance obligations will be recognised as revenue when the related services are provided in a period of more than one year.

6 Other income

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Government grants	471	880	214

Various government grants have been received from the local government authority for supporting the research and development of therapeutic biologics in United States and the PRC. The Group recognised these government grants as other income when all the conditions specified in the government grants were satisfied.

7 Other gains, net

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Change in fair value on financial assets at fair value through profit or loss	55	–	–
Net losses on disposal of property, plant and equipment (Note 14)	(4)	–	–
Foreign exchange gains, net	623	662	647
Others	44	12	(2)
	718	674	645

8 Expenses by nature

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Clinical research expenses	11,711	11,212	22,014
Employee benefit expenses (including directors' remunerations) (Note 9)	6,590	21,814	18,922
Auditor's remunerations – audit services	3	3	6
Depreciation of property, plant and equipment (Note 14)	135	502	872
Depreciation of right-of use assets (Note 15)	194	327	360
Expense relating to short-term leases (Note 15)	155	179	111
Insurance expenses	58	112	82
Legal and professional fees	5,076	1,738	2,443
Listing expenses	–	2,118	1,478
Others	280	764	1,147
Total general and administrative expenses and research and development expenses	24,202	38,769	47,435

9 Employee benefit expenses (including directors' remunerations)*(a) Employee benefit expenses are analysed as follows:*

	Year ended 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Salaries, wages and bonuses	4,444	7,392	6,432
Pension costs – defined contribution plans	553	484	935
Other welfare and allowances	248	367	287
Share-based payment expenses (<i>Note 10</i>)	1,345	13,571	11,268
	<u>6,590</u>	<u>21,814</u>	<u>18,922</u>

During the years ended 31 December 2022, 2023 and 2024, no forfeited contributions were utilised by the Group to reduce its contributions. There is no balance available as at 31 December 2022, 2023 and 2024 to reduce future contributions.

(b) Five highest paid individuals

The five individuals whose emoluments were the highest in the Group for each of the years ended 31 December 2022, 2023 and 2024 include 3 directors whose emoluments are reflected in the analysis shown in Note 27. The emoluments payable to the remaining 2 individual is as follows:

	Year ended 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Salaries, wages and bonuses	1,209	1,707	996
Pension costs – defined contribution plans	41	46	58
Other welfare and allowances	124	160	21
Share-based payment expenses	1,297	3,269	2,237
	<u>2,671</u>	<u>5,182</u>	<u>3,312</u>

The emoluments of these individuals are within the following bands:

Number of individuals

	Year ended 31 December		
	2022	2023	2024
HK\$ 3,000,001 – HK\$ 3,500,000	1	–	–
HK\$ 6,500,001 – HK\$ 7,000,000	–	–	1
HK\$ 17,500,001 – HK\$ 18,000,000	1	–	–
HK\$ 18,500,001 – HK\$ 19,000,000	–	–	1
HK\$ 20,000,001 – HK\$ 20,500,000	–	1	–
HK\$ 20,500,001 – HK\$ 21,000,000	–	1	–

10 Share-based payment

The table below summarises the share-based payment expenses charged to the consolidated statements of comprehensive income during the Track Record Period.

	Year ended 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Shares issued under share award scheme (<i>Note a</i>)	1,345	13,546	11,245
Options issued under share option scheme (<i>Note b</i>)	—	25	23
	<u>1,345</u>	<u>13,571</u>	<u>11,268</u>

Share-based payment expenses charged to the consolidated statements of comprehensive income during the Track Record Period as follows:

	Year ended 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
Administrative expense	1,345	1,745	420
Research and development expenses	—	11,826	10,848
	<u>1,345</u>	<u>13,571</u>	<u>11,268</u>

Equity-settled share-based payment transactions

The Group granted share options, share awards and restricted share units (“RSUs”) to employees, under which the entity receives services from employees as consideration for equity instruments of the Group. The fair value of the employee services received in exchange for the grant of equity instruments (share options, share awards and RSUs) is recognised as an expense on the consolidated financial statements. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions (for example, the requirement for employees to serve); and
- including the impact of any non-vesting conditions.

The total expense is recognised over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each reporting period, the Group revises its estimates of the number of shares that are expected to vest based on the service conditions. It recognises the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

Where there is any modification of terms and conditions which increases the fair value of the equity instruments granted, the Group includes the incremental fair value granted in the measurement of the amount recognised for the services received over the remainder of the vesting period. The incremental fair value is the difference between the fair value of the modified equity instrument and that of the original equity instrument, both estimated as at the date of the modification. An expense based on the incremental fair value is recognised over the period from the modification date to the date when the modified equity instruments vest in addition to any amount in respect of the original instrument, which should continue to

be recognised over the remainder of the original vesting period. Where shares are forfeited due to a failure by the employee to satisfy the service conditions, any expenses previously recognised in relation to such shares are reversed effective at the date of the forfeiture.

(a) Share awards scheme

Under the share and warrant purchase agreement dated 24 November 2021, eligible senior management and employees may be granted Class A ordinary shares in the Company for no cash consideration. Offers under the scheme are at the discretion of the Company, in all other respects the shares rank equally with other fully-paid ordinary shares on issue.

Share awards granted in November 2021

In November 2021, eligible employees were granted 9,732,246 share awards which were vested immediately upon granted for Class A ordinary shares. The shares were also issued on the same date.

All these shares that were originally granted during the year ended 31 December 2021 were subsequently surrendered in March 2022. On the same day, same number of shares were agreed to grant to the same employees. Among these shares, 7,788,237 share awards were vested and granted immediately, while 1,944,009 share awards will be vested and granted on a five-year schedule, subject to the participant continuing to be an employee in each vesting date. For the vesting schedule, 10% of the granted shares are vested on the second anniversary from the vesting commencement date and 30% granted shares are vested in each of the following three subsequent years respectively. Management considers the incremental fair value between the share surrendered and granted at the replacement date is not material, therefore no additional expense was recognised and charged to consolidated statements of comprehensive income during the year ended 31 December 2022.

In May 2024, the vesting schedule of these 1,944,009 share awards was modified from above vesting schedule to be, 40% of the granted shares are vested on the third anniversary from the vesting commencement date and 30% granted shares are vested in each of the following two subsequent years, respectively. Management considers the incremental fair value between the share granted under original and modified vesting schedule is not material, therefore no additional expense was recognised and charged to consolidated statements of comprehensive income during the year ended 31 December 2024.

Share awards granted in April 2022

In April 2022, eligible employees were granted 17,371,448 Class A ordinary shares at an average fair value of US\$0.15 per share with no service condition, of which 137,326 share awards were vested immediately upon granted. The remaining 17,234,122 share awards contains a buy-back clause that requires the Company to buy back the shares if certain performance condition is not met by 30 September 2023. Although these 17,234,122 Class A ordinary shares have been awarded to the employees, as at 31 December 2022, they are not considered vested given that the shares are still subject to the buy-back clause. All the shares has been fully vested as at 31 December 2023.

Share awards granted in April 2023

In April 2023, eligible employees were granted 69,302,411 RSUs at a fair value of US\$0.71 per share of which will be vested on a five-year schedule and granted for Class A ordinary shares, subject to the participant continuing to be an employee in each vesting date. Class A ordinary shares will be issued upon vested and these shares may not be sold after one year.

The following shows the vesting schedule:

Tranche	% of the total share option	Vesting period
Tranche 1	10%	3 April 2023 to 2 April 2026
Tranche 2	30%	3 April 2023 to 2 April 2027
Tranche 3	30%	3 April 2023 to 2 April 2028
Tranche 4	30%	3 April 2023 to 2 April 2029

There is also a vesting acceleration term in which the remaining 50% of unvested share awards of each tranche are immediately vested if the Group's initial public offering ("IPO") is successful.

Fair value measurement

The fair value of services received in return for a share award granted is measured by reference to the fair value of the share award at the grant date. The fair value of the share award granted was determined using the spot fair value for underlying ordinary shares, except for the fair value of the 17,234,122 share award granted in April 2022 was subjected to adjustment on the buy-back clause, which was performed by an independent valuer.

The following table summarises the share awards issued during the Track Record Period:

	Number of shares '000	Weighted average grant date fair value USD
Outstanding as at 1 January 2022	–	–
Granted during the year	17,371	0.15
Vested and transferred during the year	<u>(137)</u>	0.35
Outstanding as at 31 December 2022 and 1 January 2023	17,234	0.15
Granted during the year	69,302	0.71
Vested and transferred during the year	<u>(17,234)</u>	0.15
Outstanding as at 31 December 2023, 1 January 2024 and 31 December 2024	<u><u>69,302</u></u>	0.71

Subsequence to the year ended 31 December 2024, eligible employees were granted 94,886,451 RSUs which will be vested on a five-year schedule and subject to certain conditions.

(b) Share option scheme

Under the share and warrant purchase agreement dated 24 November 2021, the Board may, at its discretion, offer to grant in whatever form of share options and share awards to subscribe of new shares in aggregate not exceeding 96,084,000 Class A ordinary shares. Participation in the plan is at the board's discretion and no individual has a contractual right to participate in the plan or to receive any guaranteed benefits.

198,192 Class A ordinary shares were granted to an employee of the Group on 3 April 2023. The fair value of share options granted was determined using the binomial option pricing model (the "Binomial Model") which was performed by an independent valuer.

The share options shall be subject to different vesting schedules of five years from the vesting commencement date, subject to the participant continuing to be an employee through each vesting date. The options are exercisable to subscribe Class A ordinary shares at any time provided the options have been vested.

The following shows the vesting schedule:

Tranche	% of the total share option	Vesting period	Exercisable period
Tranche 1	10%	3 April 2023 to 2 April 2026	3 April 2025 to 2 April 2035
Tranche 2	30%	3 April 2023 to 2 April 2027	3 April 2026 to 2 April 2036
Tranche 3	30%	3 April 2023 to 2 April 2028	3 April 2027 to 2 April 2037
Tranche 4	30%	3 April 2023 to 2 April 2029	3 April 2028 to 2 April 2038

There is also a vesting acceleration terms in which the remaining 50% of unvested share options of each tranche are immediately vested if the Group's IPO is successful.

The following table summarises the share option movement during the Track Record Period:

	Exercise price per share	No. of share options
At 1 January 2022, 31 December 2022 and 1 January 2023	–	–
Granted	US\$0.58	198,192
At 31 December 2023, 1 January 2024 and 31 December 2024		<u>198,192</u>

No options was expired during the Track Record Period.

Share options outstanding at the end of the year have the following expiry dates and exercise prices:

Grant date	Expiry date	Exercise price per share	Vesting years/condition	No. of share options As at 31 December		
				2022	2023	2024
3 April 2023	2 April 2038	US\$0.58	6 years from grant date	<u>–</u>	<u>198,192</u>	<u>198,192</u>
Weighted average remaining contractual life of option outstanding				<u>–</u>	<u>9.25 years</u>	<u>8.25 years</u>

Based on fair value of the underlying ordinary shares, the Group has used the Binomial Model to determine the fair value of the share option as at the grant date. Key assumptions are set as below:

As at the grant date	
Fair value per ordinary shares	US\$0.68
Risk-free interest rate	3.40%
Expected life	10 years
Expected volatility	90%
Fair value per share option	US\$0.50
Exercise price	US\$0.58

11 Finance income, net

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Finance income:			
Interest income from bank deposits	1,602	3,872	2,029
Finance costs:			
Interest expenses on bank borrowings	–	(240)	(4)
Interest expense on lease liabilities (<i>Note 15</i>)	(31)	(35)	(23)
	(31)	(275)	(27)
Finance income, net	1,571	3,597	2,002

12 Income tax expenses

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Current income tax	82	23	910
Over-provision in prior year	–	–	(77)
Current income tax expenses	82	23	833

The Group's principal applicable taxes and tax rates are as follows:

Cayman Islands

Under the current laws of the Cayman Islands, the Company and Cloudbreak Cayman are not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

British Virgin Islands ("BVI")

Subsidiary is incorporated in the BVI are exempted from income tax on their foreign-derived income in the BVI. There are no withholding taxes in the BVI.

Hong Kong

Hong Kong profits tax rate is 16.5% for the years ended 31 December 2022, 2023 and 2024. No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax during the Track Record Period.

The United States

Cloudbreak USA and ADS USA were established in California and Delaware, the United States. The corporate income tax rate of Cloudbreak USA and ADS USA are subject to both federal income tax rate and California income tax rate and Delaware income tax rate, which are 21%, 8.84% and 8.7% respectively for the years ended 31 December 2022, 2023 and 2024.

Mainland China

Provision for Mainland China corporate income tax is calculated at the statutory rate of 25% on the assessable income of the Group's subsidiaries incorporated and operated in Mainland China for the years ended 31 December 2022, 2023 and 2024.

During the years ended 31 December 2022, 2023 and 2024, an additional 75% to 100% of qualified research and development expenses incurred is allowed to be deducted from taxable income under the Mainland China Income Tax Law and its relevant regulations.

Income tax for other foreign countries

Taxes on profits in other foreign countries, including Germany and Australia, have been calculated at the rates of tax prevailing in the jurisdictions in which the Group operates, based on existing legislation, interpretations and practices in respect thereof. No income tax for other foreign countries was provided for as there was no estimated assessable profit that was subject to the income tax for other foreign countries during the Track Record Period.

The income tax expenses for the year can be reconciled to the loss before income tax per the consolidated statements of comprehensive income as follows:

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Loss before income tax	(66,756)	(129,395)	(98,297)
Tax calculated at domestic tax rates applicable to loss in respective jurisdictions	(3,878)	(3,275)	(4,427)
Income not subjected to tax	(262)	(444)	(611)
Super deduction of research and development expenses	(148)	—	—
Expenses not deductible for taxation purpose	234	179	220
Tax loss not recognised	4,136	3,563	5,728
Over-provision in prior year	—	—	(77)
Income tax expenses	<u>82</u>	<u>23</u>	<u>833</u>

The weighted average applicable tax rate is influenced by the change in the profitability of the Group's subsidiaries in the respective regions. There is no change of the tax rate of the respective regions during for the years ended 31 December 2022, 2023 and 2024.

13 Loss per share*(a) Basic loss per share*

Basic loss per share is calculated by dividing the loss for the year attributable to ordinary shareholders by the weighted average number of outstanding shares in issue during the years ended 31 December 2022, 2023 and 2024.

	Year ended 31 December		
	2022	2023	2024
Loss attributable to owners of the Company ('000)	(66,838)	(129,418)	(99,130)
Weighted average number of ordinary shares in issue	458,597,663	462,543,309	475,386,302
Basic losses per share (in US\$)	<u>(0.15)</u>	<u>(0.28)</u>	<u>(0.21)</u>

(b) Diluted losses per share

Diluted losses per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the years ended 31 December 2022, 2023 and 2024, the Company had certain potential ordinary shares: convertible redeemable preferred shares (Note 24(a)) and employee share award scheme (Note 10). As the Group incurred losses for the years ended 31 December 2022, 2023 and 2024, the potential ordinary shares were not included in the calculation of the diluted losses per share as their inclusion would be anti-dilutive. Accordingly, diluted losses per share for the years ended 31 December 2022, 2023 and 2024 are the same as basic losses per share.

14 Property, plant, and equipment

	Leasehold improvements US\$'000	Computer equipment US\$'000	Furniture and fixture US\$'000	Office and laboratory equipment US\$'000	Total US\$'000
As at 1 January 2022					
Cost	48	12	4	313	377
Accumulated depreciation	<u>(4)</u>	<u>(4)</u>	<u>(1)</u>	<u>(24)</u>	<u>(33)</u>
Net book amount	<u>44</u>	<u>8</u>	<u>3</u>	<u>289</u>	<u>344</u>
Year ended 31 December 2022					
Opening net book amount	44	8	3	289	344
Additions	122	23	28	10	183
Disposal (Note 7)	(4)	–	–	–	(4)
Depreciation (Note 8)	(28)	(8)	(4)	(95)	(135)
Currency translation	<u>(3)</u>	<u>–</u>	<u>–</u>	<u>(22)</u>	<u>(25)</u>
Net book amount	<u>131</u>	<u>23</u>	<u>27</u>	<u>182</u>	<u>363</u>

APPENDIX I

ACCOUNTANT'S REPORT

	Leasehold improvements <i>US\$'000</i>	Computer equipment <i>US\$'000</i>	Furniture and fixture <i>US\$'000</i>	Office and laboratory equipment <i>US\$'000</i>	Total <i>US\$'000</i>
As at 31 December 2022					
Cost	162	35	32	296	525
Accumulated depreciation	(31)	(12)	(5)	(114)	(162)
Net book amount	<u>131</u>	<u>23</u>	<u>27</u>	<u>182</u>	<u>363</u>
Year ended 31 December 2023					
Opening net book amount	131	23	27	182	363
Additions	847	25	9	362	1,243
Depreciation (<i>Note 8</i>)	(316)	(15)	(10)	(161)	(502)
Currency translation	5	–	–	(3)	2
Net book amount	<u>667</u>	<u>33</u>	<u>26</u>	<u>380</u>	<u>1,106</u>
As at 31 December 2023					
Cost	1,008	60	41	650	1,759
Accumulated depreciation	(341)	(27)	(15)	(270)	(653)
Net book amount	<u>667</u>	<u>33</u>	<u>26</u>	<u>380</u>	<u>1,106</u>
Year ended 31 December 2024					
Opening net book amount	667	33	26	380	1,106
Additions	51	6	3	95	155
Depreciation (<i>Note 8</i>)	(635)	(18)	(13)	(206)	(872)
Currency translation	(7)	–	–	(7)	(14)
Net book amount	<u>76</u>	<u>21</u>	<u>16</u>	<u>262</u>	<u>375</u>
As at 31 December 2024					
Cost	1,035	64	43	728	1,870
Accumulated depreciation	(959)	(43)	(27)	(466)	(1,495)
Net book amount	<u>76</u>	<u>21</u>	<u>16</u>	<u>262</u>	<u>375</u>

During the Track Record Period, depreciation expenses have been charged to consolidated statements of comprehensive income as follow:

	Year ended 31 December		
	2022	2023	2024
	<i>US\$'000</i>	<i>US\$'000</i>	<i>US\$'000</i>
General and administrative expenses	27	67	76
Research and development expenses	108	435	796
	<u>135</u>	<u>502</u>	<u>872</u>

Property, plant, and equipment are stated at historical cost less depreciation and accumulated impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the item can be measured reliably. The carrying amount of the replaced part is recognised. All other repairs and maintenance are charged to the consolidated statements of profit or loss during the periods in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives or, in the case of leasehold improvements and certain leased plant and equipment, the lease term if shorter, as follows:

	Estimated useful lives
Office and laboratory equipment	3 years
Computer equipment	3 years
Furniture and fixture	3 years
Leasehold improvements	Shorter of remaining lease term and 3-5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (*Note 32.5*).

Gains and losses on disposal are determined by comparing the proceeds with the carrying amounts. These are included in the consolidated statements of comprehensive income.

15 Leases

This note provides information for leases where the Group is a lessee.

(i) Amounts recognised in the consolidated statements of financial position

The consolidated statements of financial position shows the following amounts relating to leases:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Right-of-use assets			
Leased premises	807	505	494
Land use rights	—	1,656	1,557
	<u>807</u>	<u>2,161</u>	<u>2,051</u>
Lease liabilities			
Current portion	292	317	302
Non-current portion	548	228	209
	<u>840</u>	<u>545</u>	<u>511</u>

Additions to the right-of-use assets during the years ended 31 December 2022, 2023 and 2024 were US\$849,000, US\$1,655,000 and US\$329,000 respectively.

(ii) Amounts recognised in the consolidated statements of comprehensive income

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Depreciation of right-of-use assets (<i>Note 8</i>)	194	327	360
Interest expenses on lease liabilities (<i>Note 11</i>)	31	35	23
Expenses relating to short-term leases (<i>Note 8</i>)	155	179	111

The interest rate of each lease contracts is fixed at its contract date, and the interest rate of lease liabilities was 5% per annum as at 31 December 2022, 2023 and 2024.

The total cash outflows for leases including payments of short-term leases, lease liabilities and payments of interest expenses on leases for the years ended 31 December 2022, 2023 and 2024 were approximately US\$378,000, US\$514,000 and US\$462,000, respectively.

(iii) The Group's leasing activities and how these are accounted for

The right-of-use assets represent the Group's rights to use underlying leased premises under lease arrangements over the lease terms from 2 to 4 years and land use rights over the lease terms of 30 years. They are stated at cost less accumulated depreciation and accumulated impairment losses.

An arrangement, comprising a transaction or a series of transactions, is or contains a lease if the Group determines that the arrangement conveys a right to control the use of an identified asset for a period of time in exchange for consideration. Such determination is made on an evaluation of the substance of the arrangement, regardless of whether the arrangements take the legal form of a lease.

The Group enters into lease agreements as a lessee with respect to certain premises and leasehold land.

Leases are initially recognised as a right-of-use asset and corresponding liability at the date of which the leased asset is available for use by the Group. Each lease payment is allocated between the principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated on a straight-line basis over the shorter of the asset's estimated useful life and the lease term.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate;
- amounts expected to be payable by the lessee under residual value guarantees;
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option;
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option; and
- lease payments to be made under reasonably certain extension options are also included in the measurement of lease liabilities.

The lease payments are discounted using the interest rate implicit in the lease, if that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liabilities;
- any lease payments made at or before the commencement date, less any lease incentive received; and
- any initial direct costs.

Payments associated with short-term leases and leases of low-value assets are recognised on a straight-line basis as an expense. Short-term leases are leases with a lease term of 12 months or less.

Some of the property leases include extension options. These terms are used to maximise operational flexibility in terms of managing contracts. The extension options held are exercisable only by the Group and not by the respective lessor. The Group considers all facts and circumstances that create an economic incentive to exercise an extension option in determining the lease term. The assessment is revised if a significant event or a significant change in circumstances occurs which affects the assessment.

Land use rights are stated at cost less accumulated depreciation and accumulated impairment losses, if any. Cost represents consideration paid for the right to use the land for periods varying 30 years. Amortisation of land use rights is charged to the consolidated financial statements on a straight-line basis over the period of leases or when there is impairment, the impairment is charged to the consolidated financial statements.

16 Deferred income tax

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current income tax recoverable against current income tax liabilities and when the deferred income tax assets and liabilities relate to income tax levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis. The offset amounts are as follows:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Deferred income tax assets	206	135	131
Set-off of deferred tax liabilities pursuant to set-off provisions	(206)	(135)	(131)
	<u>—</u>	<u>—</u>	<u>—</u>
Deferred income tax liabilities	206	135	131
Set-off of deferred tax liabilities pursuant to set-off provisions	(206)	(135)	(131)
	<u>—</u>	<u>—</u>	<u>—</u>

The movements in deferred income tax assets during the Track Record Period, without taking into consideration the offsetting of balances within the same tax jurisdiction, are as follows:

	Lease liabilities US\$'000	Total US\$'000
At 1 January 2022	42	42
Credited to the consolidated statements of comprehensive income	<u>164</u>	<u>164</u>
At 31 December 2022 and 1 January 2023	206	206
Charged to the consolidated statements of comprehensive income	<u>(71)</u>	<u>(71)</u>
At 31 December 2023 and 1 January 2024	135	135
Charged to the consolidated statements of comprehensive income	<u>(4)</u>	<u>(4)</u>
At 31 December 2024	<u><u>131</u></u>	<u><u>131</u></u>

The movements in deferred income tax liabilities during the Track Record Period, without taking into consideration the offsetting of balances within the same tax jurisdiction, are as follows:

	Right-of-use asset US\$'000	Others US\$'000	Total US\$'000
At 1 January 2022	(41)	(1)	(42)
Charged to the consolidated statements of comprehensive income	<u>(157)</u>	<u>(7)</u>	<u>(164)</u>
At 31 December 2022 and 1 January 2023	(198)	(8)	(206)
Credited/(charged) to the consolidated statements of comprehensive income	<u>72</u>	<u>(1)</u>	<u>71</u>
At 31 December 2023 and 1 January 2024	(126)	(9)	(135)
(Charged)/credited to the consolidated statements of comprehensive income	<u>(1)</u>	<u>5</u>	<u>4</u>
At 31 December 2024	<u><u>(127)</u></u>	<u><u>(4)</u></u>	<u><u>(131)</u></u>

Deferred income tax assets are recognised for tax losses carried forward to the extent that the realisation of the related tax benefit through the future taxable profits is probable.

As at 31 December 2022, 2023 and 2024, the Group did not recognise deferred income tax assets of approximately US\$388,000, US\$519,000 and US\$4,110,000, respectively, in respect of unused tax losses of US\$1,552,000, US\$2,076,000 and US\$16,440,000 that can be carried forward for 5 years for offsetting against future taxable income. As at 31 December 2022, 2023 and 2024, the Group did not recognise deferred income tax assets of approximately US\$4,915,000, US\$8,338,000 and US\$10,456,000, respectively, in respect of unused tax losses of US\$23,762,000, US\$40,676,000 and US\$51,244,000, that can be used to offset future income with no expiry date.

As at 31 December 2022, 2023 and 2024, management is of the view that undistributed earnings totalling US\$385,000, US\$235,000 and US\$390,000, respectively, are for re-investment and not for distribution. Accordingly, deferred income tax liabilities of US\$39,000, US\$23,500 and US\$39,000 respectively have not been recognised for the withholding tax that would be payable upon distribution of profits of the subsidiaries.

17 Financial instruments by category

	As at 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Assets as per consolidated statements of financial position			
Financial assets measured at amortised cost:			
– Other receivables (<i>Note 18</i>)	810	855	1,898
– Short-term bank deposits (<i>Note 19</i>)	63,194	7,500	–
– Cash and cash equivalents (<i>Note 19</i>)	15,917	52,654	34,862
	<u>79,921</u>	<u>61,009</u>	<u>36,760</u>
Total	<u><u>79,921</u></u>	<u><u>61,009</u></u>	<u><u>36,760</u></u>
Liabilities as per consolidated statements of financial position			
Financial liabilities measured at amortised cost:			
– Trade and other payables (excluding non-financial liabilities) (<i>Note 22</i>)	29,855	3,774	3,465
– Lease liabilities (<i>Note 15</i>)	840	545	511
	<u>30,695</u>	<u>4,319</u>	<u>3,976</u>
Financial liabilities at fair value through profit or loss:			
– Convertible redeemable preferred shares (<i>Note 24(a)</i>)	109,957	322,459	386,195
– Other financial liabilities at fair value through profit or loss (<i>Note 24(b)</i>)	73,960	–	–
– Derivatives financial instrument (<i>Note 25</i>)	11,783	–	–
	<u>195,700</u>	<u>322,459</u>	<u>386,195</u>
Total	<u><u>226,395</u></u>	<u><u>326,778</u></u>	<u><u>390,171</u></u>

18 Prepayments and other receivables

The Group:

	As at 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Non-current assets			
Prepayments for property, plant and equipment	687	–	–
Rental deposits	<u>121</u>	<u>97</u>	<u>74</u>
	<u>808</u>	<u>97</u>	<u>74</u>
Current assets			
Prepayments	180	170	49
Deferred listing expenses (<i>Note</i>)	–	287	307
Prepayments for listing expenses	–	48	145
Rental deposits	5	34	60
Other receivables	<u>684</u>	<u>724</u>	<u>1,764</u>
	<u>869</u>	<u>1,263</u>	<u>2,325</u>
Total prepayments and other receivables	<u><u>1,677</u></u>	<u><u>1,360</u></u>	<u><u>2,399</u></u>

Note: Deferred listing expenses will be deducted from equity upon listing of the Group.

Information about the provision for impairment of other receivables and the Group's exposure to credit risk on other receivables are disclosed in Note 3.1.2(a).

As at 31 December 2022, 2023 and 2024, the carrying amounts of the other receivables approximate their fair values.

The prepayments and other receivables are denominated in the following currencies:

	As at 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
US\$	567	790	427
RMB	928	401	1,810
Others	<u>182</u>	<u>169</u>	<u>162</u>
	<u><u>1,677</u></u>	<u><u>1,360</u></u>	<u><u>2,399</u></u>

The Company:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Current assets			
Prepayments	–	3	–
Deferred listing expenses (<i>Note</i>)	–	287	307
Prepayments for listing expenses	–	48	145
	<u>–</u>	<u>48</u>	<u>145</u>
	<u>–</u>	<u>338</u>	<u>452</u>

Note: Deferred listing expenses will be deducted from equity upon listing of the Group.

19 Cash and cash equivalents and short-term deposits*The Group:*

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Cash at banks	1,938	2,645	3,143
Cash on hand	3	9	5
Short-term bank deposits with maturities of less than three months (<i>Note (i)</i>)	<u>13,976</u>	<u>50,000</u>	<u>31,714</u>
Cash and cash equivalents	15,917	52,654	34,862
Short-term bank deposits with maturities of more than three months (<i>Note (ii)</i>)	<u>63,194</u>	<u>7,500</u>	<u>–</u>
	<u>79,111</u>	<u>60,154</u>	<u>34,862</u>
Maximum exposure to credit risk	<u>79,108</u>	<u>60,145</u>	<u>34,862</u>

- (i) The effective interest rate of short-term bank deposits with maturities of less than three months was 4.96%, 5.51% and 4.33% as at 31 December 2022, 2023 and 2024 respectively.
- (ii) The effective interest rate of short-term bank deposits with maturities of more than three months was 5.29%, 5.23% and nil as at 31 December 2022, 2023 and 2024 respectively.

Cash and cash equivalents and short-term bank deposits are denominated in the following currencies:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
US\$	78,168	58,765	33,019
RMB	843	492	1,408
Others	100	897	435
	<u>79,111</u>	<u>60,154</u>	<u>34,862</u>

Bank balances of the Group amounting to US\$9,377,000, US\$33,492,000 and US\$18,743,000 were placed with certain banks in the Mainland China as at 31 December 2022, 2023 and 2024. The remittance of these balances is subject to the foreign exchange control restrictions imposed by the PRC government.

The Company:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Cash at banks	<u>—</u>	<u>11</u>	<u>11</u>
Maximum exposure to credit risk	<u>—</u>	<u>11</u>	<u>11</u>

Cash and cash equivalents of the Company are denominated in US\$.

20 Share capital

The Group and the Company:

Authorised:

Number of ordinary shares at US\$ 0.0001 each '000	Number of Class A ordinary shares at US\$ 0.0001 each '000	Number of Class B ordinary shares at US\$ 0.0001 each '000	Number of Class C ordinary shares at US\$ 0.0001 each '000	Total number of ordinary shares at US\$ 0.0001 each '000	Number of Series A preferred shares at US\$ 0.0001 each '000	Number of Series B preferred shares at US\$ 0.0001 each '000	Number of Series C preferred shares at US\$ 0.0001 each '000	Total number of preferred shares at US\$ 0.0001 each '000	Nominal value of preferred share US\$ '000	Total number of shares '000	Nominal value of share capital US\$ '000
-	358,206	152,484	183,647	694,337	69	8,873	81,708	215,082	305,663	31	1,000,000
											100

As at 1 January 2022, 31 December 2022,
2023 and 2024

Class C ordinary shares rank in priority to Class B ordinary shares and Class B ordinary shares rank in priority to Class A ordinary shares as to the repayment of capital upon liquidation, dissolution or winding up and also to repayment of capital upon sale or disposal of shares.

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Issued and fully paid:

	Number of Class A ordinary shares at US\$ 0.0001 each '000	Number of Class B Ordinary shares at US\$ 0.0001 each '000	Number of Class C Ordinary shares at US\$ 0.0001 each '000	Total number of ordinary shares at US\$ 0.0001 each '000	Nominal value of Class A ordinary shares US\$'000	Nominal value of Class B ordinary shares US\$'000	Nominal value of Class C ordinary shares US\$'000	Share capital US\$'000
As at 1 January 2022	123,827	152,485	183,647	459,959	13	15	18	46
Surrender of shares (Note 10(a))	(9,732)	–	–	(9,732)	(1)	–	–	(1)
Share awards vested (Note 10(a))	7,788	–	–	7,788	1	–	–	1
Share awards awarded and not yet vested (Note 10(a))	17,234	–	–	17,234	2	–	–	2
Share awards vested (Note 10(a))	137	–	–	137	–*	–	–	–*
As at 31 December 2022, 2023 and 2024	<u>139,254</u>	<u>152,485</u>	<u>183,647</u>	<u>475,386</u>	<u>15</u>	<u>15</u>	<u>18</u>	<u>48</u>

* Less than US\$1,000

21 Other reserves

The Group:

	Share premium US\$'000	Share-based payment reserves US\$'000	Currency translation differences US\$'000	Merger reserve US\$'000	Others US\$'000	Total US\$'000
At 1 January 2022	258,280	–	916	(281,989)	(1,943)	(24,736)
Changes in fair value of convertible redeemable preferred shares due to own credit risk (Note 24(a))	–	–	–	–	(2,476)	(2,476)
Changes in fair value of other financial liabilities due to own credit risk (Note 24(b))	–	–	–	–	(1,824)	(1,824)
Currency translation differences	–	–	(1,815)	–	–	(1,815)
Equity-settled share-based payment transactions (Note 10)	–	1,345	–	–	–	1,345
Share awards granted (Note 20)	–	(2)	–	–	–	(2)
At 31 December 2022	<u>258,280</u>	<u>1,343</u>	<u>(899)</u>	<u>(281,989)</u>	<u>(6,243)</u>	<u>(29,508)</u>

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	Share premium US\$'000	Share-based payment reserves US\$'000	Currency translation differences US\$'000	Merger reserve US\$'000	Others US\$'000	Total US\$'000
At 1 January 2023	258,280	1,343	(899)	(281,989)	(6,243)	(29,508)
Changes in fair value of convertible redeemable preferred shares due to own credit risk (Note 24(a))	–	–	–	–	(982)	(982)
Currency translation differences	–	–	(801)	–	–	(801)
Equity-settled share-based payment transactions (Note 10)	–	13,571	–	–	–	13,571
At 31 December 2023	<u>258,280</u>	<u>14,914</u>	<u>(1,700)</u>	<u>(281,989)</u>	<u>(7,225)</u>	<u>(17,720)</u>
	Share premium US\$'000	Share-based payment reserves US\$'000	Currency translation differences US\$'000	Merger reserve US\$'000	Others US\$'000	Total US\$'000
At 1 January 2024	258,280	14,914	(1,700)	(281,989)	(7,225)	(17,720)
Changes in fair value of convertible redeemable preferred shares due to own credit risk (Note 24(a))	–	–	–	–	(13)	(13)
Currency translation differences	–	–	(877)	–	–	(877)
Equity-settled share-based payment transactions (Note 10)	–	11,268	–	–	–	11,268
At 31 December 2024	<u>258,280</u>	<u>26,182</u>	<u>(2,577)</u>	<u>(281,989)</u>	<u>(7,238)</u>	<u>(7,342)</u>

The Company:

	Share premium US\$'000	Share-based payment reserves US\$'000	Others US\$'000	Total US\$'000
At 1 January 2022	258,280	–	(2,616)	255,664
Changes in fair value of convertible redeemable preferred shares due to own credit risk (Note 24(a))	–	–	(2,476)	(2,476)
Changes in fair value of other financial liabilities due to own credit risk (Note 24(b))	–	–	(1,824)	(1,824)
Equity-settled share-based payment transactions (Note 10)	–	1,345	–	1,345
Share awards granted (Note 20)	–	(2)	–	(2)
At 31 December 2022	<u>258,280</u>	<u>1,343</u>	<u>(6,916)</u>	<u>252,707</u>

	Share premium US\$'000	Share-based payment reserves US\$'000	Others US\$'000	Total US\$'000
At 1 January 2023	258,280	1,343	(6,916)	252,707
Changes in fair value of convertible redeemable preferred shares due to own credit risk (<i>Note 24(a)</i>)	–	–	(982)	(982)
Equity-settled share-based payment transactions (<i>Note 10</i>)	–	13,571	–	13,571
At 31 December 2023	<u>258,280</u>	<u>14,914</u>	<u>(7,898)</u>	<u>265,296</u>
At 1 January 2024	258,280	14,914	(7,898)	265,296
Changes in fair value of convertible redeemable preferred shares due to own credit risk (<i>Note 24(a)</i>)	–	–	(13)	(13)
Equity-settled share-based payment transactions (<i>Note 10</i>)	–	11,268	–	11,268
At 31 December 2024	<u>258,280</u>	<u>26,182</u>	<u>(7,911)</u>	<u>276,551</u>

22 Trade and other payables

The Group:

	As at 31 December		
	2022 US\$'000	2023 US\$'000	2024 US\$'000
Trade payables	1,225	2,102	1,760
Receipt in advance from an investor (<i>Note</i>)	27,200	–	–
Payable to a convertible redeemable preferred shareholder	435	–	–
Accrued legal and professional expenses	675	426	128
Accrued staff cost	856	825	1,301
Accrued listing expenses	–	781	947
Other accruals and payables	320	465	630
	<u>30,711</u>	<u>4,599</u>	<u>4,766</u>

The carrying amounts of trade and other payables are denominated in the following currencies:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
US\$	30,105	3,782	3,398
RMB	483	695	1,034
Others	123	122	334
	<u>30,711</u>	<u>4,599</u>	<u>4,766</u>

Trade and other payables of the Group were approximate their fair values, unsecured, interest-free and repayable on demand.

As at 31 December 2022, 2023 and 2024, the ageing analysis of the trade payables based on invoice date is as follows:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Within 30 days	1,188	1,899	1,760
31 – 60 days	25	144	–
More than 60 days	12	59	–
	<u>1,225</u>	<u>2,102</u>	<u>1,760</u>

The Company:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Trade payables	–	39	–
Receipt in advance from an investor (<i>Note</i>)	27,200	–	–
Payable to a convertible redeemable preferred shareholder	435	–	–
Accrued legal and professional expenses	675	426	128
Accrued listing expenses	–	781	947
Other accruals and payables	3	10	45
	<u>28,313</u>	<u>1,256</u>	<u>1,120</u>

Trade and other payables of the Company were approximate their fair values, unsecured, interest-free, repayable on demand and denominated in US\$.

Note: During the Track Record Period, receipt in advance from an investor represents payment in advance from preferred shareholders for the subscription of Series C preferred shares.

23 Cash flows information

(a) Cash used in operations:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Cash flows from operating activities			
Loss before income tax	(66,756)	(129,395)	(98,297)
Adjustment for:			
– Finance income (Note 11)	(1,602)	(3,872)	(2,029)
– Finance costs (Note 11)	31	275	27
– Share-based payment expenses (Note 10)	1,345	13,571	11,268
– Change in fair value of financial liabilities at fair value through profit or loss and derivative financial instruments	45,314	95,777	63,723
– Gain on early termination of lease	–	–	(2)
– Gain on financial assets at fair value through profit or loss (Note 7)	(55)	–	–
– Loss on disposal of property, plant and equipment, net (Note 7)	4	–	–
– Foreign exchange losses/(gains), net (Note 7)	(623)	(662)	(647)
– Depreciation of property, plant and equipment (Note 14)	135	502	872
– Depreciation of right-of use assets (Note 15)	194	327	360
Operating loss before working capital changes	(22,013)	(23,477)	(24,725)
Changes in working capital:			
– Prepayments and other receivables	(304)	(184)	(900)
– Trade and other payables	2,482	1,075	145
	<u>(19,835)</u>	<u>(22,586)</u>	<u>(25,480)</u>

APPENDIX I

ACCOUNTANT'S REPORT

(b) Cash flow information – financing activities

The movement of liabilities from financing activities for each of the years ended 31 December 2022, 2023 and 2024:

	Convertible redeemable preferred shares <i>US\$'000</i>	Financial instruments issued to investors <i>US\$'000</i>	Amount due to a director <i>US\$'000</i>	Amounts due to shareholders <i>US\$'000</i>	Bank borrowings <i>US\$'000</i>	Trade and other payables from financing activities <i>US\$'000</i>	Leases liabilities <i>US\$'000</i>	Total <i>US\$'000</i>
As at 1 January 2022	(84,935)	(38,725)	(89)	(30,000)	–	(27,200)	(168)	(181,117)
Financing cash flow	–	(15,975)	89	30,000	–	–	223	14,337
Non-cash items								
Change in fair value through profit or loss (Note 24)	(22,546)	(12,266)	–	–	–	–	–	(34,812)
Change in fair value through other comprehensive income (Note 24)	(2,476)	(1,824)	–	–	–	–	–	(4,300)
Derivative financial instruments (Note 25)	–	(4,457)	–	–	–	–	–	(4,457)
Addition of lease	–	–	–	–	–	–	(849)	(849)
Interest expense of lease	–	–	–	–	–	–	(31)	(31)
Currency translation	–	(713)	–	–	–	–	(15)	(728)
	(25,022)	(19,260)	–	–	–	–	(895)	(45,177)
As at 31 December 2022	(109,957)	(73,960)	–	–	–	(27,200)	(840)	(211,957)

	Convertible redeemable preferred shares <i>US\$'000</i>	Financial instruments issued to investors <i>US\$'000</i>	Bank borrowings <i>US\$'000</i>	Trade and other payables from financing activities <i>US\$'000</i>	Leases liabilities <i>US\$'000</i>	Total <i>US\$'000</i>
As at 1 January 2023	(109,957)	(73,960)	–	(27,200)	(840)	(211,957)
Financing cash flow	(2,800)	–	240	–	335	(2,225)
Non-cash items						
Change in fair value through profit or loss (Note 24)	(92,606)	–	–	–	–	(92,606)
Change in fair value through other comprehensive income (Note 24)	(982)	–	–	–	–	(982)
Exercise of warrants (Note 24)	(73,960)	73,960	–	–	–	–
Derivative financial instruments (Note 25)	(14,954)	–	–	–	–	(14,954)
Issuance of Series C CRPS	(27,200)	–	–	27,200	–	–
Interest expense of lease liabilities	–	–	–	–	(35)	(35)
Interest expense of bank borrowings	–	–	(240)	–	–	(240)
Currency translation	–	–	–	–	(5)	(5)
	(209,702)	73,960	(240)	27,200	(40)	(108,822)
As at 31 December 2023	(322,459)	–	–	–	(545)	(323,004)

	Convertible redeemable preferred shares US\$'000	Bank borrowing US\$'000	Leases liabilities US\$'000	Total US\$'000
As at 1 January 2024	(322,459)	–	(545)	(323,004)
Financing cash flow	–	4	351	355
Non-cash items				
Change in fair value through profit or loss (<i>Note 24</i>)	(63,723)	–	–	(63,723)
Changes in fair value through other comprehensive income (<i>Note 24</i>)	(13)	–	–	(13)
Addition of lease	–	–	(329)	(329)
Interest expense of lease liabilities	–	–	(23)	(23)
Early termination of lease	–	–	37	37
Interest expense of bank borrowing	–	(4)	–	(4)
Currency translation	–	–	(2)	(2)
	<u>(63,736)</u>	<u>(4)</u>	<u>(317)</u>	<u>(64,057)</u>
As at 31 December 2024	<u><u>(386,195)</u></u>	<u><u>–</u></u>	<u><u>(511)</u></u>	<u><u>(386,706)</u></u>

24 Convertible redeemable preferred shares and other financial liabilities at fair value through profit or loss

The Group and Company:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Current			
Convertible redeemable preferred shares (“CRPS”)	<u>109,957</u>	<u>322,459</u>	<u>386,195</u>
Other financial liabilities at fair value through profit or loss – current portion:			
Warrants and related financial liabilities to CRPS (“Warrants”)	<u>73,960</u>	<u>–</u>	<u>–</u>

Since the date of incorporation and during the Track Record Period, the companies now comprising the Group have completed a few rounds of financing by issuing convertible redeemable preferred shares and warrants and related financial liabilities to investors.

The details of the issuance are set out in the table below:

US\$'000	Date of issuance/ effective date	Number of instrument	Purchase price per convertible redeemable preferred shares	Exercise price per convertible redeemable preferred shares	Total cash consideration
Series A CRPS (<i>Note i</i>)	6 January 2021	Preferred shares: 8,873,587	US\$0.1587	N/A	(<i>Note i</i>)
Series B-1 CRPS (<i>Note ii</i>)	13 May 2020	Preferred shares: 26,789,367	US\$0.2103	N/A	5,634
Series B-2 CRPS (<i>Note ii</i>)	27 August 2020	Preferred shares: 46,881,393	US\$0.2103	N/A	9,859
Series B-2 CRPS (<i>Note ii</i>)	12 November 2020	Preferred shares: 8,036,810	US\$0.2103	N/A	1,690
Series C CRPS (<i>Note iii</i>)	17 December 2021	Preferred shares: 37,225,703	US\$0.6044	N/A	22,500
Series C CRPS (<i>Note iii</i>)	28 December 2021	Preferred shares: 24,817,136	US\$0.6044	N/A	15,000
Series C CRPS (<i>Note iii</i>)	30 December 2021	Preferred shares: 8,272,379	US\$0.6044	N/A	5,000
Series C warrants and related financial liabilities (<i>Note 24(b)</i>)	From 23 December 2021 to 20 January 2022	Warrants to subscribe for preferred shares: 90,168,926	N/A	US\$0.6044	54,500
Series C CRPS conversion (<i>Note 24(b)</i>)	From 4 August 2022 to 23 September 2022	(90,168,926)	N/A	N/A	(54,500)
Series C CRPS (<i>Note 24(b), Note (iii)</i>)	3 January 2023	Preferred shares: 90,168,926	US\$0.6044	N/A	54,500
Series C CRPS (<i>Note iii</i>)	24 April 2023	Preferred shares: 49,634,271	US\$0.6044	N/A	30,000

Notes:

- (i) On 29 October 2018 and 14 January 2019, Series A investor and Cloudbreak Guangzhou entered into an investment agreement and a supplement investment agreement, pursuant to which Series A investor conducted a capital injection of RMB10,000,000 (equivalent to approximately US\$1,480,000) into Cloudbreak Guangzhou in exchange of 3.64% shareholding of Cloudbreak Guangzhou.

As part of the group restructuring in 2020, Series A investor, Cloudbreak HK and Cloudbreak Cayman entered into certain agreements in which Series A investor gave up its entire shareholding in Cloudbreak Guangzhou in exchange of 8,873,587 Series A preferred shares of Cloudbreak Cayman. Pursuant to a share purchase agreement dated 1 July 2020 and the share transfer agreement dated 5 August 2020 entered into between Series A investor and Cloudbreak HK, Series A investor subscribed for 8,873,587 Series A preferred shares of Cloudbreak Cayman for a cash consideration of approximately US\$22,000, which was conditional upon the completion of disposal of the shareholding of Series A investor in Cloudbreak Guangzhou to Cloudbreak HK for a consideration of approximately RMB662,000 (equivalent to approximately US\$93,000). The entire transaction was completed on 6 January 2021.

On 12 March 2021, the share exchange was carried out to establish the Company as the holding company of all group companies. Pursuant to the share exchange agreement dated 28 December 2020, Series A investors transferred its 8,873,587 Series A preferred shares of Cloudbreak Cayman in exchange for the Company's 8,873,587 Series A preferred shares. Prior to the share exchange, the financial instrument was convertible into ordinary shares of Cloudbreak Cayman, while after the share exchange, it was convertible into ordinary shares of the Company. There was a substantial change of the fair value of the financial instrument before and after the share exchange. Based on the above, management considered that such modification of the terms and conditions arising from the share exchange constitute substantial modification, the original financial liabilities related to the CRPS before the amendments are distinguished whereas the new financial liabilities under the revised terms and conditions are recognised at fair value, with the difference recognised in the profit or loss, resulted in a loss of approximately US\$1,137,000. The accumulated changes in the fair value of the original CRPS attributable to changes in own credit risks included in other comprehensive income is transferred to the retained earnings.

As at 31 December 2022 and 2023 and 2024, the redemption events of Series A preferred shares have not been triggered and the management considered they will not be triggered within the next 12 months from the balance sheet dates. However, given that the conversion options are exercisable at the Series A investor's discretions as at 31 December 2022 and 2023 and 2024, Series A preferred shares amounted to US\$4,958,000, US\$8,747,000 and US\$10,835,000 respectively have been classified as current liabilities as the Series A investor has the option to convert within twelve months.

- (ii) Pursuant to a share purchase agreement dated 13 April 2020 entered among Series B-1 investor and Cloudbreak Cayman, Series B-1 investor subscribed for 26,789,367 Series B-1 preferred shares of Cloudbreak Cayman for a consideration of approximately US\$5,634,000. The entire transaction was completed on 13 May 2020.

Pursuant to a share purchase agreement dated 1 July 2020 entered among Series B-2 investors and Cloudbreak Cayman, Series B-2 investors agreed to invest a total of approximately US\$11,549,000 by subscribing for 54,918,203 Series B-2 preferred shares. The entire transactions were completed on 27 August 2020 and 12 November 2020.

On 12 March 2021, the share exchange was carried out to establish the Company as the holding company of all group companies. Pursuant to the share exchange agreement dated 28 December 2020, Series B-1 and B-2 investors transferred their 81,707,570 Series B-1 and B-2 preferred shares of Cloudbreak Cayman in exchange for the Company's 81,707,570 Series B-1 and B-2 preferred shares. Prior to the share exchange, the financial instrument was convertible into ordinary shares of Cloudbreak Cayman, while after the share exchange, it was convertible into ordinary shares of the Company. There was a substantial change of the fair value of the financial instrument before and after the share exchange. Based on the above, management considered that such modification of the terms and conditions arising from the share exchange constitute substantial modification, the original financial liabilities related to the CRPS before the amendments are distinguished whereas the new financial liabilities under the revised terms and conditions are recognised at fair value, with the difference recognised in the profit or loss, resulted in a loss of approximately US\$9,896,000. The accumulated changes in the fair value of the original CRPS attributable to changes in own credit risks included in other comprehensive income is transferred to the retained earnings.

As at 31 December 2022 and 2023 and 2024, the redemption events of Series B-1 and Series B-2 preferred shares have not been triggered and the management considered they will not be triggered within the next 12 months from the balance sheet dates. However, given that the conversion options are exercisable at the Series B-1 and Series B-2 investors' discretions as at 31 December 2022 and 2023 and 2024, Series B preferred shares amounted to US\$47,324,000, US\$81,391,000 and US\$100,451,000 respectively have been classified as current liabilities as the Series B-1 and Series B-2 investors have the option to convert within twelve months.

- (iii) Pursuant to a share and warrants purchase agreement dated 24 November 2021 entered among Series C investors and the Company, several Series C investors agreed to invest a total of US\$75,500,000 by subscribing for 124,912,916 Series C preferred shares of the Company. The entire transactions were completed on 17 December 2021, 28 December 2021, 30 December 2021 and 24 April 2023.

During the year ended 31 December 2023, several Series C investors, which were holders of the warrants and related financial liabilities, have exercised the warrants and related financial liabilities and converted them into 90,168,926 Series C preferred shares of the Company. The entire transaction was completed on 3 January 2023.

As at 31 December 2022 and 2023 and 2024, the redemption event of Series C preferred shares has been triggered, which the qualified initial public offering has not been consummated by the Company on or prior to 31 December 2022. The Series C preferred shares is redeemable since 31 December 2022, and convertible at the Series C investors' discretions as at 31 December 2022 and 2023 and 2024, therefore, Series C preferred shares amounted to US\$57,675,000, US\$232,321,000 and US\$274,909,000 respectively have been classified as current liabilities as at 31 December 2022 and 2023 and 2024.

Please refer to Note 24(a)(iii) for details.

(a) CRPS

Details of the movements of number of CRPS are as follows:

	Number of preferred shares
As at 1 January 2022 and 31 December 2022	160,896,375
Outstanding as at 31 December 2022 represent:	
– Series A CRPS	8,873,587
– Series B-1 CRPS	26,789,367
– Series B-2 CRPS	54,918,203
– Series C CRPS	70,315,218
	160,896,375
As at 1 January 2023	160,896,375
Issuance during the year ended 31 December 2023	
– Series C CRPS	49,634,271
– Series C CRPS through exercise of warrants	90,168,926
Outstanding as at 31 December 2023, 1 January 2024 and 31 December 2024	300,699,572
Outstanding as at 31 December 2023, 1 January 2024 and 31 December 2024 represent:	
– Series A CRPS	8,873,587
– Series B-1 CRPS	26,789,367
– Series B-2 CRPS	54,918,203
– Series C CRPS	210,118,415
	300,699,572

The key terms of the CRPS are summarised as follows:

(i) Dividends right

The dividends available for distribution to the shareholders shall be distributed ratably among all shareholders according to the relative number of shares held by such shareholder on an as-converted basis. No dividends shall be distributed to any shareholders unless and until such distribution has been approved by the majority of directors in the board of directors of the Company.

(ii) Conversion features

The CRPS shall be converted into ordinary shares at the options of holders at any time, or automatically converted into fully-paid and non-assessable ordinary shares upon the earlier of (i) the qualified initial public offering (“Qualified IPO”), or (ii) the date specified by written consent or agreement of the holders representing at least 51% of the Series A preferred shares, Series B preferred shares and the Series C preferred shares, respectively.

Qualified IPO mean an underwritten initial public offering of ordinary shares on the Shanghai Stock Exchange, Shenzhen Stock Exchange, Hong Kong Stock Exchange, New York Stock Exchange or Nasdaq or any other reputable stock exchange as approved by the shareholders that implies a market reorganisation of the Company immediately prior to such offering of not less than US\$1 billion provided that such offering completes on or prior to 31 December 2022.

(iii) Redemption features

If any of the following events occurs, and if the Group fails to fix the failures within thirty days after the preferred shareholder's notice to fix such failures, at the written request of the preferred shareholder and subject to the applicable Laws, the Company shall redeem all or a portion of the preferred shares held by the preferred shareholder as requested at the redemption price:

Redemption events of the Series A preferred share

- (a) Occurrence of the Group's illegal acts and such illegal acts fail to be cured within the time limit that the Series A preferred shareholder requested in its written notice to improve it, and the foregoing results in a material adverse effect to the Group; or
- (b) the Company suffers significant losses due to violation of Company and the ordinary shareholders of any covenants or warranties and failure to cure such violation within the time limit that the Series A preferred shareholder requested in its written notice to cure it, and the foregoing results in a material adverse effect to the Group.

The Series A redemption price shall equal to the sum of Series A preferred share issue price plus an amount of interest at a simple annual rate of 10% on the Series A preferred share issue price from the completion date of the subscription of equity interest. The redemption rights of the Series A preferred shareholder shall be exercised within three months upon the occurrence of such events or otherwise be deemed to forfeit. The Group shall redeem all or a portion of the preferred shares held by the Series A preferred shareholder within one month upon the request of the Series A preferred shareholder under the Series A redemption event.

Redemption events of the Series B preferred share

- (a) within two years after the closing under the Series B share purchase agreement dated 1 July 2020, any of the Series B preferred shareholder is aware of any untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein during the Series B preferred shareholder's due diligence leading to the transactions contemplated by the transaction document, and the foregoing results in a material adverse effect to the Group;
- (b) any breach of any of the representations and warranties by any of the warrantors contained in the shareholders agreement dated 3 December 2021 or in any of the other transaction documents, and the foregoing results in a material adverse effect to the Group;
- (c) any breach of the obligations of non-compete set forth in the shareholders agreement dated 3 December 2021 or in any of the other transaction documents by the Jinsong NI, Van Dinh, Yang Rong and Leng Bing (the "Founders" and each, a "Founder"), and the foregoing results in a material adverse effect to the Group;
- (d) any false or fictitious entries in the books or records of any companies within the Group by any person;
- (e) any annual audit report with the Company's auditor's qualified opinion, or adverse opinion, or disclaimer of opinion; or
- (f) any material action due to the Group's non-compliance that results in any material adverse effect to the business of the Group.

The Series B redemption price shall equal to the sum of (a) the purchase price per share as determined in accordance with the Series B-1 share purchase agreement dated 13 April 2020 and the Series B-2 share purchase agreement dated 1 July 2020, and adjusted for share dividends, splits, combinations, recapitalisations or similar events, plus (b) an amount of interest at a compounded annual rate of 10% (when calculating the period, calculated based on 365 days per calendar year and

be rounded up to 2 decimal places) on the purchase price per share for the holder of the preferred shares held by the respective Series B preferred shareholder from the completion date of the subscription for such preferred share till the full payment of the Series B redemption price to the respective Series B preferred shareholders.

Each of the Series B preferred shareholder may exercise its redemption rights within ten business days after its such determination to do so upon the occurrence of a Series B redemption event by delivering a written notice by the respective Series B preferred shareholder to the Company, notifying the Company the number of the preferred shares that it requires the Company to redeem.

Redemption events of the Series C preferred share

- (a) a Qualified IPO has not been consummated by the Company on or prior to 31 December 2022;
- (b) there is any material breach by any of the warrantors, as defined in the share purchase agreement, of any of their respective representations, warranties, covenants or other obligations under the transaction documents;
- (c) there is any material breach by any Founder of any of the applicable laws, regulations, leading to the result that such Founder is unable to devote the majority of his professional time to attend the business of the Group;
- (d) any Founder departs from the Group without prior consent of at least fifty percent of the preferred shares of the Company without reasonable reason (such as physical problem) prior to the Qualified IPO;
- (e) prior to the Qualified IPO, any Founder no longer holds, directly or indirectly, at least 50% of the shares held by him/her on an as-converted basis, both directly and indirectly, as of the date hereof; or
- (f) any other series of preferred shares becomes redeemable by the Company.

The Series C redemption price shall equal to the sum of (a) the purchase price per share (as determined in accordance with the share purchase agreement and adjusted for share dividends, splits, combinations, recapitalisations or similar events), plus (b) an amount of interest at a simple annual rate of 10% (when calculating the period, calculated based on 365 days per calendar year and be rounded up to 2 decimal places) on the purchase price per share for the holder of the preferred shares held by the Series C preferred shareholder from the completion date of the subscription for such preferred share till the full payment of the Series C redemption price to the Series C preferred shareholders.

Each of the Series C investor may exercise its redemption rights within ten business days after its such determination to do so upon the occurrence of a Series C redemption event by delivering a written notice by the respective Series C investor to the Company, notifying the Company the number of the preferred shares that it requires the Company to redeem.

Termination of redemption rights of the Series A, Series B and Series C preferred share

The redemption rights of the Series A, Series B and Series C preferred shares shall be automatically terminated on the date of the first submission by the Company of its listing application to stock exchange. As at the date of this report, the redemption right is terminated as the Company has submitted the listing application to the Main Board of the HKEX. But this redemption rights shall be automatically restored if the Company fails to be listed in such listing application, or the Company decides to put on hold the IPO procedures or withdraw the listing application.

(iv) Liquidation preferences

Upon the occurrence of (i) any liquidation, winding up or dissolution of the Company, (ii) any sale, lease, transfer, or other disposal of, in a single transaction or series of related transactions, all or substantially all of the assets of the Group, (iii) any transfer or exclusive license-out of all or substantially all of the intellectual property of the Group, (iv) any sale, transfer or other disposal of a majority of the issued (including any (primary issuance)) and outstanding share capital of any companies within the Group or a majority of the voting power of any companies within the Group or (v) any merger, consolidation, amalgamation or acquisition of any companies within the Group with or into another party, or any other corporate reorganisation or scheme of arrangement, including a sale or acquisition of shares or equity interest of such companies within the Group in which the shareholders of the Company immediately before such transaction own less than a majority of the voting power of such companies within the Group, the surviving entity or the entity controlling the surviving entity immediately after such transaction (excluding any transaction effected solely for tax purposes or to change the Company's domicile) holders of the preferred shares shall be entitled to receive distributions in the following manner:

The respective holders of the preferred shares shall be entitled to receive, prior to and in preference to any distribution or payment to any ordinary shareholder.

First to the holders of Series C preferred shares, entitled to receive for each Series C preferred share fully paid and held by such holder, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of Series B preferred shares and Series A preferred shares, plus an amount of interest at simple annual rate of 10% on the Series C preferred share issue price from the completion date of the subscription. If the assets and funds of the Company shall be insufficient to settle the Series C preferred liquidation preference in full, then such assets and funds shall be distributed among the holders of such Series C preferred shares ratably in proportion to the full amount to which they would otherwise be respectively entitled thereon.

After distribution or payment in full of the Series C preferred liquidation preference, and before any distribution or payment shall be made to the holders of Series A preferred shares and ordinary shares of the Company, the holders of Series B preferred shares shall be entitled to receive for each Series B preferred share fully paid and held by such holder, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of Series A preferred shares, plus an amount of interest at simple annual rate of 10% on the Series B preferred share issue price from the completion date of the subscription. If the assets and funds of the Company shall be insufficient to settle the Series B preferred liquidation preference in full, then such assets and funds shall be distributed among the holders of such Series B preferred shares ratably in proportion to the full amount to which they would otherwise be respectively entitled thereon.

After distribution or payment in full of the Series C preferred liquidation preference and Series B preferred liquidation preference, and before any distribution or payment shall be made to the holders of ordinary shares of the Company, the holders of Series A preferred shares shall be entitled to receive for each Series A preferred share fully paid and held by such holder, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of Series A preferred shares, plus an amount of interest at simple annual rate of 10% on the Series A preferred share issue price from the completion date of the subscription of equity interest of Cloudbreak Guangzhou. If the assets and funds of the Company shall be insufficient to settle the Series A preferred liquidation preference in full, then such assets and funds shall be distributed among the holders of such Series A preferred shares ratably in proportion to the full amount to which they would otherwise be respectively entitled thereon.

After distribution or payment in full of the amount distributable or payable on the preferred shares pursuant to paragraph above, and different classes of ordinary shares, the remaining assets of the Company available for distribution shall be distributed ratably among the holders of outstanding ordinary shares and the holders of outstanding preferred share in proportion to the number of outstanding ordinary shares held by them (with outstanding preferred shares treated on an as-if-converted basis).

Accounting policy

The Group does not bifurcate any embedded derivatives from the host instruments and designates the entire instruments as financial liabilities at fair value through profit or loss with the changes in the fair value changes related to market risk recognised in the profit or loss and the component of fair value changes relating to the Company's own credit risk is recognised in other comprehensive income.

The movements of the CRPS are set out as below:

	<i>US\$'000</i>
At 1 January 2022	84,935
Change in fair value through profit or loss	22,546
Change in fair value through other comprehensive income due to own credit risk	<u>2,476</u>
At 31 December 2022 and 1 January 2023	109,957
Issuance of Series C CRPS	44,954
Issuance of Series C CRPS through exercise of warrants (<i>Note 24(b)</i>)	73,960
Change in fair value through profit or loss	92,606
Change in fair value through other comprehensive income due to own credit risk	<u>982</u>
At 31 December 2023	<u><u>322,459</u></u>
At 31 December 2023 and 1 January 2024	322,459
Change in fair value through profit or loss	63,723
Change in fair value through other comprehensive income due to own credit risk	<u>13</u>
At 31 December 2024	<u><u>386,195</u></u>

(b) Warrants and related financial liabilities

Pursuant to a share and warrants purchase agreement dated 24 November 2021 entered among Series C investors and the Company, several Series C investors agreed to subscribe 90,168,926 Series C CRPS with a total consideration of US\$54,500,000. These Series C investors located at the PRC and are subject to relevant rules and regulations imposed by the PRC government for a right to subscribe for Series C CRPS and unable to remit the subscription proceeds to the Company prior to obtaining the approval from the PRC government.

As agreed in the share and warrants purchase agreement, the Series C investors entered into arrangement with Cloudbreak Guangzhou, Cloudbreak Guangzhou received loans from the Series C investors and the Company issued warrants to the Series C investors to convert for a consideration representing the principal amount of the Series C CRPS. In case that all necessary approvals has been obtained, the Cloudbreak Guangzhou are required to repay the loans to the Series C investors, and such repayment amount will be converted into US\$ and remitted to the Company by the Series C investors to exercise the warrants.

During the year ended 31 December 2022, all holders of the warrants and related financial liabilities obtained all necessary approvals from the PRC authority and issued a form of notices of exercise to the Company to exercise its right to subscribe Series C CRPS at the exercise price of US\$0.6044 per share pursuant to the term of such warrants. The entire transaction was completed on 3 January 2023 which warrants and related financial liabilities have been exercised and converted to Series C CRPS.

The warrants and related financial liabilities do not qualify for hedging accounting and the changes in fair values are recognised in profit or loss.

The Group designated the warrants and related financial liabilities as financial liabilities at fair value through profit or loss because the purpose of the warrants and related financial liabilities are to enable the investors located in the PRC to subscribe for the Series C CRPS which are measured at fair value prior to obtaining the approvals from the PRC government.

The movements of the warrants and related financial liabilities are set out as below:

	<i>US\$'000</i>
At 1 January 2022	38,725
Issuance of warrants and related financial liabilities to Series C CRPS investors	21,145
Change in fair value through profit or loss	12,266
Change in fair value through other comprehensive income due to own credit risk	1,824
At 31 December 2022 and 1 January 2023	73,960
Transfer to Series C CRPS upon exercise of warrants (<i>Note 24 (a)</i>)	(73,960)
At 31 December 2023, 1 January 2024 and 31 December 2024	—

(c) *Fair value measurements*

CRPS

The Group has a team that manages the valuation of level 3 instruments for financial reporting purposes. The team manages the valuation of the investments on a case by case basis. The team would use valuation techniques to determine the fair value of the Group's level 3 instruments which includes CRPS. External valuation experts will be involved when necessary.

As the instruments are not traded in an active market, their fair values have been determined by using various applicable valuation techniques.

The Group applied the discounted cash flow method to determine the underlying equity value of the Group and adopted equity allocation model to determine the fair value of the CRPS. Key assumptions are set as below:

	As at 31 December		
	2022	2023	2024
Discount rate	16.5%	16.0%	16.0%
Risk-free interest rate	4.7%	5.19%	4.28%
DLOM	12.0%-21.0%	9.0%-13.0%	8.0%-11.0%
Volatility	85.0%	75.0%	75.0%
IPO probability	30.0%	60.0%	70.0%

Discount rate (post-tax) was estimated by weighted average cost of capital as at each valuation date. Management estimated the risk-free interest rate based on the market yield of US Treasury Curve with maturity close to expected liquidation date/redemption date as at the valuation date.

The DLOM was estimated based on the option-pricing method. Under option-pricing method, the cost of put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the lack of marketability discount.

Volatility was estimated based on annualised standard deviation of the daily return embedded in historical stock prices of comparable companies with a time horizon close to the expected term.

Probability weight among redemption, liquidation and IPO scenarios was based on the Company's best estimates. In addition to the assumptions adopted above, the Company's projections of future performance were also factored into the determination of the fair value of the preferred shares at each valuation date.

Changes in fair value of the CRPS were recorded in "Change in fair value of financial liabilities at fair value through profit or loss" in the profit or loss, and the fair value changes in the CRPS that are attributable to changes of own credit risk of this liabilities are recorded in other comprehensive income.

Fair value of CRPS is affected by changes in the Company's equity value. If the Company's equity value had increased/decreased by 10% with all other variables held constant, the loss before income tax for the years ended 31 December 2022, 2023 and 2024 would have been approximately US\$9,649,000/9,375,000 higher/lower, US\$29,645,000/29,717,000 higher/lower and US\$37,234,000/36,583,000 higher/lower respectively.

Fair value of CRPS is also affected by changes in the discount rate. If the discount rate had increased/decreased by 1% with all other variables held constant, the loss before income tax for the years ended 31 December 2022, 2023 and 2024 would have been approximately US\$10,897,000/13,227,000 lower/higher, US\$32,610,000/38,264,000 lower/higher and US\$36,140,000/42,833,000 lower/higher respectively.

Warrants and related financial liabilities

The Group applied the discounted cash flow method to determine the underlying equity value of the Group and adopted equity allocation model to determine the fair value of warrants and related financial liabilities. Key assumptions are set as below:

	As at 31 December		
	2022	2023	2024
Discount rate	16.5%	N/A	N/A
Risk-free interest rate	4.7%	N/A	N/A
DLOM	12.0%-18.0%	N/A	N/A
Volatility	85.0%	N/A	N/A
IPO probability	30.0%	N/A	N/A

Discount rate (post-tax) was estimated by weighted average cost of capital as at each valuation date. Management estimated the risk-free interest rate based on the market yield of US Treasury Curve with maturity close to expected liquidation date/redemption date as at the valuation date.

The DLOM was estimated based on the option-pricing method. Under option-pricing method, the cost of put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the lack of marketability discount.

Volatility was estimated based on annualised standard deviation of the daily return embedded in historical stock prices of comparable companies with a time horizon close to the expected term.

Probability weight among redemption, liquidation and IPO scenarios was based on the Company's best estimates. In addition to the assumptions adopted above, the Company's projections of future performance were also factored into the determination of the fair value of the warrants and related liabilities at each valuation date.

Changes in fair value of the warrants and related financial liabilities were recorded in "Change in fair value of financial liabilities at fair value through profit or loss" in the profit or loss, and the fair value changes in the warrants and related financial liabilities that are attributable to changes of own credit risk of this liabilities are recorded in other comprehensive income.

Fair value of warrants and related financial liabilities is affected by changes in the Company's equity value. If the Company's equity value had increased/decreased by 10% with all other variables held constant, the loss before income tax for the year ended 31 December 2022 would have been approximately US\$5,102,000/4,770,000 higher/lower.

Fair value of warrants and related financial liabilities is also affected by changes in the discount rate. If the discount rate had increased/decreased by 1% with all other variables held constant, the loss before income tax for the year ended 31 December 2022 would have been approximately US\$5,603,000/7,026,000 lower/higher.

Accounting policy for the convertible redeemable preferred shares and other financial liabilities at fair value through profit or loss

Financial instruments issued to investors consist of convertible redeemable preferred shares and other financial liabilities at fair value through profit or loss. Accounting policies and other explanatory information of these financial instruments are elaborated as follows:

(a) Convertible redeemable preferred shares

The Company entered into a series of share purchase agreements with investors and issued Series A, Series B-1, Series B-2 and Series C preferred shares, respectively (collectively, "Preferred Shares").

Preferred Shares issued by the Company are redeemable upon occurrence of certain future events as disclosed in Note 24(a)(iii). Those instruments can be converted into ordinary shares of the Company at any time at the option of the holders or automatically converted into ordinary shares upon occurrence of an initial public offering ("IPO") of the Company or at any time after the date of issuance of such shares as detailed in Note 24(a)(ii).

The Group designated the Preferred Shares as financial liabilities at FVPL. They are initially recognised at fair value. Subsequent to initial recognition, the Preferred Shares are carried at fair value with changes in fair value recognised in the profit or loss, except for the gains or losses arising from the Company's own credit risk which are presented in other comprehensive income with no subsequent reclassification to the profit or loss.

(b) Other financial liabilities at fair value through profit or loss

The Company issued warrants and related financial liabilities under which the holders have the rights to subscribe for the Company's Series C preferred shares at a predetermined exercise price when the holders have obtained the approval from the PRC government (Note 24(b)).

Warrants and related financial liabilities are initially recognised at fair value on the date a warrant contract is entered into and are subsequently re-measured to their fair value at the end of each reporting period. The Group's warrants and related financial liabilities were classified as current liabilities, as the management expected these warrants will be converted to Series C CRPS within the next twelve month from the balance sheet dates after the holders have obtained the approval from the PRC government for a right to subscribe for Series C CRPS.

25 Derivative financial instruments

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Forward contract	11,783	—	—

Derivative financial instruments are recognised when there are commitment to issue the underlying preferred shares and warrants and related financial liabilities at a predetermined price and would be derecognised upon the issuance of the underlying preferred shares and warrants and related financial liabilities. The changes in fair value of derivative financial instruments are recognised in the profit or loss.

The movements of the derivative financial instruments are set out as below:

	<i>US\$'000</i>
At 1 January 2022	5,738
Change in fair value through profit or loss	10,502
Derecognised upon the issuance of the underlying warrants and related financial liabilities	<u>(4,457)</u>
At 31 December 2022 and 1 January 2023	11,783
Change in fair value through profit or loss	3,171
Derecognised upon the issuance of the underlying preferred shares	<u>(14,954)</u>
At 31 December 2023, 1 January 2024 and 31 December 2024	<u><u>–</u></u>

The Group applied the discounted cash flow method to determine the underlying equity value of the Group and adopted equity allocation model to determine the fair value of derivative financial instruments. Key assumptions are set as below:

	As at 31 December		
	2022	2023	2024
Discount rate	16.5%	N/A	N/A
Risk-free interest rate	4.7%	N/A	N/A
DLOM	12.0%-18.0%	N/A	N/A
Volatility	85.0%	N/A	N/A
IPO probability	30.0%	N/A	N/A

Discount rate (post-tax) was estimated by weighted average cost of capital as at each valuation date. Management estimated the risk-free interest rate based on the market yield of US Treasury Curve with maturity close to expected liquidation date/redemption date as at the valuation date.

The DLOM was estimated based on the option-pricing method. Under option-pricing method, the cost of put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the lack of marketability discount.

Volatility was estimated based on annualised standard deviation of the daily return embedded in historical stock prices of comparable companies with a time horizon close to the expected term.

Probability weight among redemption, liquidation and IPO scenarios was based on the Company's best estimates. In addition to the assumptions adopted above, the Company's projections of future performance were also factored into the determination of the fair value of the derivative financial instruments at each valuation date.

Fair value of derivative financial instruments is affected by changes in the Company's equity value. If the Company's equity value had increased/decreased by 10% with all other variables held constant, the loss before income tax for the year ended 31 December 2022 would have been approximately US\$3,090,000/2,888,000 higher/lower.

Fair value of derivative financial instruments is also affected by changes in the discount rate. If the discount rate had increased/decreased by 1% with all other variables held constant, the loss before income tax for the years ended 31 December 2022 would have been approximately US\$3,393,000/4,254,000 lower/higher.

26 Related party transactions

Related parties are those parties that have the ability to control, jointly control or exercise significant influence over the other party in holding power over the investee; exposure or rights, to variable returns from its involvement with the investee; and the ability to use its power over the investee to affect the amount of the investor's returns. Parties are also considered to be related if they are subject to common control or joint control. Related parties may be individuals or other entities.

(a) Year end balances with related parties

The Company:

	As at 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Non-trade nature			
Amounts due from subsidiaries	83,898	87,008	74,026
Non-trade nature			
Amounts due to subsidiaries	333	4,774	420

As at 31 December 2022, 2023 and 2024 the balances with subsidiaries of the Company were unsecured, interest-free, repayable on demand, approximate their fair values and denominated in US\$. None of the related parties provided loans, advances, guarantees or pledge of securities to the Group as at 31 December 2022, 2023 and 2024.

(b) Key management compensation

Key management includes directors (executive and non-executive) and senior management of the Group.

The compensation paid or payable to senior management for employee services is shown below:

	Year ended 31 December		
	2022	2023	2024
	US\$'000	US\$'000	US\$'000
Salaries, wages and bonuses	3,036	5,491	3,780
Pension costs – defined contribution plans	162	209	205
Other welfare and allowances	136	194	102
Share-based payment expenses	1,297	12,745	10,510
	4,631	18,639	14,597

27 Benefits and interests of directors

(a) Directors' emoluments

The remuneration of each director paid/payable for each of the years ended 31 December 2022, 2023 and 2024 were set out below:

	Year ended 31 December 2022					Total US\$'000
	Director's fee US\$'000	Salaries, wages and bonus US\$'000	Pension cost-defined contribution plan US\$'000	Other social security costs and housing benefits US\$'000	Share-based compensation expense US\$'000	
Executive directors:						
Ni Jinsong	–	758	40	3	–	801
Zhao Jianghua (i), (iv)	–	–	–	–	–	–
Van Son Dinh (ii)	–	392	40	–	–	432
Chan Chak Yeung (iii), (iv)	–	–	–	–	–	–
Yang Rong (iii)	–	393	40	3	–	436
Non-executive directors:						
Li Junzhi (ii), (v)	–	–	–	–	–	–
Zhou Chao (iii), (v), (vi)	–	–	–	–	–	–
Xu Cao (iii), (v)	–	–	–	–	–	–
	–	1,543	120	6	–	1,669

	Year ended 31 December 2023					Total US\$'000
	Director's fee US\$'000	Salaries, wages and bonus US\$'000	Pension cost-defined contribution plan US\$'000	Other social security costs and housing benefits US\$'000	Share-based compensation expense US\$'000	
Executive directors:						
Ni Jinsong	–	2,162	41	9	6,729	8,941
Zhao Jianghua (i), (iv)	–	–	–	–	–	–
Van Son Dinh (ii)	–	467	42	8	801	1,318
Chan Chak Yeung (iii), (iv)	–	–	–	–	–	–
Yang Rong (iii)	–	467	40	9	801	1,317
Non-executive directors:						
Li Junzhi (ii), (v)	–	–	–	–	–	–
Zhou Chao (iii), (v), (vi)	–	–	–	–	–	–
Xu Cao (iii), (v)	–	–	–	–	–	–
	–	3,096	123	26	8,331	11,576

	Year ended 31 December 2024					Total US\$'000
	Director's fee US\$'000	Salaries, wages and bonus US\$'000	Pension cost-defined contribution plan US\$'000	Other social security costs and housing benefits US\$'000	Share-based compensation expense US\$'000	
Executive directors:						
Ni Jinsong	–	898	38	22	6,172	7,130
Van Son Dinh (ii)	–	442	38	12	735	1,227
Yang Rong (iii)	–	442	38	12	735	1,227
Non-executive directors:						
Li Junzhi (ii), (v)	–	–	–	–	–	–
Zhou Chao (iii), (v), (vi)	–	–	–	–	–	–
Xu Cao (iii), (v)	–	–	–	–	–	–
Xia Zhi Dong (vii)	–	–	–	–	–	–
	<u>–</u>	<u>1,782</u>	<u>114</u>	<u>46</u>	<u>7,642</u>	<u>9,584</u>

- (i) Zhao Jianghua was appointed as the director on 15 July 2021.
- (ii) Van Son Dinh and Li Junzhi were appointed as director on 22 July 2021.
- (iii) Zhou Chao, Xu Cao, Chan Chak Yeung and Yang Rong were appointed as director on 24 November 2021.
- (iv) Chan Chak Yeung and Zhao Jianghua were resigned as executive directors on 12 October 2023 and 1 November 2023, respectively.
- (v) Li Junzhi, Zhou Chao and Xu Cao were re-designed as non-executive directors on 9 November 2023.
- (vi) Zhou Chao was resigned as non-executive director on 24 June 2024.
- (vii) Xia Zhidong was appointed as director on 26 June 2024.

(b) Directors' retirement and termination benefits

No retirement or termination benefits have been paid to the Company's directors for the years ended 31 December 2022, 2023 and 2024.

(c) Consideration provided to third parties for making available directors' services

No consideration was provided to third parties for making available directors' services during the years ended 31 December 2022, 2023 and 2024.

(d) Information about loans, quasi-loans or other dealings in favor of directors, controlled bodies corporate by and connected entities with such directors

No loans, quasi-loans or other dealings were entered into by the Company in favor of directors, controlled body corporates by and connected entities with such directors for the years ended 31 December 2022, 2023 and 2024.

(e) *Directors' material interests in transactions, arrangements or contracts*

Save as disclosed in Note 26, no significant transactions, arrangements and contracts in relation to the Company's business to which the Company was a party and in which a director of the Company had a material interest, whether directly or indirectly, subsisted during the years ended 31 December 2022, 2023 and 2024.

28 Dividends

No dividend has been paid or declared by the Company or the companies now comprising the Group during each of the years ended 31 December 2022, 2023 and 2024.

29 Contingent liabilities

As of 31 December 2022, 2023 and 2024, the Group did not have any material contingent liabilities.

30 Commitments

As at 31 December 2022, 2023 and 2024, the Group had capital commitments of US\$241,000, nil and nil primarily in connection with capital expenditure not yet incurred, with respect to its purchase of property, plant and equipment.

31 Subsequent events

There have been no material events subsequent to the Track Record Period.

32 Summary of other accounting policies

32.1 Principles of consolidation

Subsidiaries

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

32.2 Separate financial statements

Investments in subsidiaries are accounted for at cost less impairment. Cost includes direct attributable costs of investment. The results of subsidiaries are accounted for by the Company on the basis of dividend received and receivable.

Impairment testing of the investments in subsidiaries is required upon receiving a dividend from these investments if the dividend exceeds the total comprehensive income of the subsidiary in the period the dividend is declared or if the carrying amount of the investment in the separate financial statements exceeds the carrying amount of the investee's net assets including goodwill in the financial statements.

32.3 Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker ("CODM"). The CODM, who is responsible for allocating resources, assessing performance of the operating segments, and has been identified as the executive directors of the Company that make strategic decisions.

32.4 Foreign currency translation**(a) Functional and presentation currency**

Items included in the Historical Financial Information of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the “**functional currency**”). The functional currency of the Company is US\$. As the major operations of the Group during the Track Record Period are within United States, the Group determined to present its Historical Financial Information in US\$.

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the “functional currency”). The functional currency of the companies in United States, Cayman Islands and British Virgin Islands are US\$. The functional currency of the companies in PRC is RMB. The functional currency of the company in Australia is AUD. The functional currency of the company in Hong Kong is HK\$.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognised in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the statement of profit or loss, within finance costs. All other foreign exchange gains and losses are presented in the statement of profit or loss on a net basis within other gains, net.

(c) Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each statement of position presented are translated at the closing rate at the date of that statement of financial position; and
- income and expenses for each consolidated statements of profit or loss are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions); and
- all resulting currency translation differences are recognised in other comprehensive income.

32.5 Impairment of non-financial assets

Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

32.6 Financial assets**(a) Classification**

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income (“OCI”) or through profit or loss), and
- those to be measured at amortised cost.

The classification depends on the entity’s business model for managing the financial assets and the contractual terms of the cash flows.

For financial assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (“FVOCI”).

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

(b) Recognition and derecognition

Regular way purchases and sales of financial assets are recognised on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

(c) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (“FVPL”), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Debt instruments

Subsequent measurement of debt instruments depends on the Group’s business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- Amortised cost: Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortised cost. Interest income from these financial assets is included in profit or loss using the effective interest rate method. Any gain or loss arising on derecognition is recognised directly in profit or loss and presented in other gains, net together with foreign exchange gains and losses. Impairment losses are presented as separate line item in the statement of profit or loss.
- FVOCI: Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets’ cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognised in profit or loss. When the financial asset is derecognised, the cumulative gain or loss previously recognised in OCI is reclassified from equity to profit or loss and recognised in other gains, net. Interest income from these financial

assets is included in other income using the effective interest rate method. Foreign exchange gains and losses are presented in other gains, net and impairment expenses are presented as separate line item in the statement of profit or loss.

- FVPL: Assets that do not meet the criteria for amortised cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognised in profit or loss and presented net within other gains, net in the period in which it arises.

During the Track Record Period, no amount is recognised in respect of financial assets at FVOCI.

(d) Impairment

The Group assesses on a forward-looking basis the expected credit loss associated with its debt instruments carried at amortised cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For cash and cash equivalents, the expected credit loss risk is considered immaterial.

Impairment on other receivables from third parties and related parties are measured as either 12-month expected credit losses or lifetime expected credit losses, depending on whether there has been a significant increase in credit risk since initial recognition. If no significant increase in credit risk of a receivable has occurred since initial recognition, then impairment is measured as 12-month expected credit losses.

32.7 Other receivables

Majority of other receivables are rental deposits. If collection of other receivables is expected in one year or less (or in the normal operating cycle of the business if longer), they are classified as current assets. If not, they are presented as non-current assets.

Other receivables are recognised initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognised at fair value. The Group holds the other receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method. See Note 3.1 for a description of the Group's impairment policies.

32.8 Cash and cash equivalents

For the purpose of presentation in the consolidated statements of cash flows, cash and cash equivalents includes cash at banks and in hand, and term deposit with financial institutions that with original maturity less than 3 months are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

32.9 Share capital

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

Preferred shares are classified as financial liabilities based on the respective contract terms.

32.10 Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the end of financial year which are unpaid. The amounts are unsecured. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognised initially at their fair value and subsequently measured at amortised cost using the effective interest method.

32.11 Derivatives

Derivatives are initially recognised at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value at the end of each reporting period. Changes in the fair value of derivative instruments that do not qualify for hedge accounting are recognised immediately in profit or loss. Derivatives are classified as current assets or liabilities if they are expected to be settled within twelve months; otherwise, they are classified as non-current.

32.12 Current and deferred income tax

The income tax expense or credit for the period is the tax payable or recoverable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

(a) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and considers whether it is probable that a taxation authority will accept an uncertain tax treatment. The Group measures its tax balances either based on the most likely amount or the expected value, depending on which method provides a better prediction of the resolution of the uncertainty.

(b) Deferred income tax

Deferred income tax is recognised, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognised if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the date of statement of financial position and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

Deferred income tax assets are recognised only to the extent that it is probable that future taxable profit will be available to utilise those temporary differences and losses.

Deferred tax liabilities and assets are not recognised for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Company is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred income tax assets and liabilities are offset where there is a legally enforceable right to offset current income tax assets and liabilities and where the deferred income tax balances relate to the same taxation authority. Current income tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Current and deferred income tax is recognised in profit or loss, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity respectively.

32.13 Employee benefits**(a) Short-term obligations**

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognised in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the consolidated statements of financial position.

(b) Pension, housing funds, medical insurances and other social insurances obligations

Employees of the Group are covered by various government-sponsored defined-contribution pension plans under which the employees are entitled to a monthly pension based on certain formulas. The relevant government agencies are responsible for the pension liability to these employees when they retire. The Group contributes on a monthly basis to these pension plans for the employees which are determined at certain percentage of their salaries. Under these plans, the Group has no obligation for post-retirement benefits beyond the contribution made. Contributions to these plans are expensed as incurred and contributions paid to the defined contribution pension plans for a staff are not available to reduce the Group's future obligations to such defined-contribution pension plans even if the staff leaves the Group.

(c) Employee leave entitlement

Employee entitlements to annual leave are recognised when they have accrued to employees. A provision is made for the estimated liability for annual leave as a result of services rendered by employees up to the end of each reporting period. Employee entitlements to sick leave and maternity leave are not recognised until the time of leave.

(d) Bonus plan

The expected cost of bonuses is recognised as a liability when the Group has a present legal or constructive obligation for payment of bonus as a result of services rendered by employees and a reliable estimate of the obligation can be made. Liabilities for bonus plans are expected to be settled within 1 year and are measured at the amounts expected to be paid when they are settled.

32.14 Provisions

Provisions are recognised when the Group has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and the amount can be reliably estimated. Provisions are not recognised for future operating losses.

Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole. A provision is recognised even if the likelihood of an outflow with respect to any one item included in the same class of obligations may be small.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the end of the reporting period. The increase in the provisions due to the passage of time is recognised as interest expense.

32.15 Interest income

Interest income from financial assets at FVPL is included in the net fair value losses-net on these assets.

Interest income is presented as finance income where it is earned from financial assets that are held for cash management purposes. Any other interest income is included in other income.

Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that subsequently become credit-impaired. For credit-impaired financial assets the effective interest rate is applied to the net carrying amount of the financial asset (after deduction of the loss allowance).

32.16 Dividend distribution

Dividend distribution to the shareholders is recognised as a liability in the consolidated financial statements in the period in which the dividends are approved by the entities' shareholders or directors, where appropriate.

32.17 Government grants

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all attached conditions.

Where the grants related to an expense item, it is recognised as income on a systematic basis over the period that the costs, which it is intended to compensate, are expensed. Where the grants related to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss over the expected useful life of the relevant asset on straight-line basis.

32.18 Revenue recognition

Revenue is recognised to depict the transfer of promised services to customers in an amount that reflects the consideration to which the Group expects to be entitled in exchange for those services. Revenue is recognised when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Group expects to receive in exchange for transferring products or services to a customer ("transaction price"). A performance obligation represents a good and service (or a bundle of goods or services) that is distinct or a series of distinct goods or services that are substantially the same. Depending on the terms of the contract and the laws applicable, control of the goods and services may be transferred over time or at a point in time. A contract asset represents the Group's right to consideration in exchange for goods or services that the Group has transferred to a customer that is not yet unconditional. It is assessed for impairment in accordance with using the same approach as for trade receivables. In contrast, a receivable represents the Group's unconditional right to consideration, i.e. only the passage of time is required before payment of that consideration is due. There is normally no significant cost to obtain contract. A contract liability represents the Group's obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer. The following is a description of the accounting policy for the principal revenue streams of the Group.

Revenue from license granted

The Group provides license of its intellectual properties ("IP") to customers as well as providing certain R&D service. The license of IP and the R&D service are distinct performance obligations. The consideration comprises fixed and variable elements. Initially only fixed consideration is included in the transaction price. The amount of the variable consideration is only included in the transaction price when it is highly probable that no significant reversal of revenue when the uncertainty is resolved. The transaction price is allocated between performance obligations based on the stand-alone selling price. The control of the license transfers at point in time, when the customer obtains the right to use the underlying IP of the license. Control of the R&D service is transferred over time based on the progress measured towards complete satisfaction of that performance obligation.

III. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company or any of the companies now comprising the Group in respect of any period subsequent to 31 December 2024 and up to the date of this report. No dividend or distribution has been declared or made by the Company or any of the companies now comprising the Group in respect of any period subsequent to 31 December 2024.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

The information set forth in this Appendix does not form part of the Accountant's Report received from the Company's reporting accountant, PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, as set forth in Appendix I to this prospectus, and is included herein for illustrative purpose only.

The unaudited pro forma financial information should be read in conjunction with the section headed "Financial Information" in this prospectus and the Accountant's Report set forth in Appendix I to this prospectus.

A. UNAUDITED PRO FORMA ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following is an illustrative statement of unaudited pro forma adjusted consolidated net tangible assets which has been prepared in accordance with Rule 4.29 of the Listing Rules for the purpose of illustrating the effect of the Global Offering as if it had taken place on 31 December 2024 and based on the unaudited consolidated net tangible liabilities attributable to owners of the Company as at 31 December 2024 and adjusted as described below.

The unaudited pro forma statement of adjusted net tangible assets has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group had the Global Offering been completed as of 31 December 2024 or any future date.

	Unaudited consolidated net tangible liabilities of the Group attributable to the owners of the Company as at 31 December 2024 USD'000 (Note 1)	Estimated net proceeds from the Global Offering USD'000 (Note 2)	Estimated impact on the conversion of redeemable preferred shares USD'000 (Note 3)	Unaudited pro forma adjusted consolidated net tangible assets attributable to the owners of the Company as of 31 December 2024 USD'000	Unaudited pro forma adjusted consolidated net tangible assets per Share	
					USD (Note 4)	HK\$ (Note 5)
Based on an Offer price of HK\$10.10 per share	(351,546)	70,121	386,195	104,770	0.13	1.02

Notes:

- (1) The unaudited consolidated net tangible liabilities of the Group attributable to the owners of the Company as at 31 December 2024 is extracted from the Accountant's Report set out in Appendix I to this prospectus, which is based on the unaudited consolidated net liabilities of the Group attributable to the owners of the Company as at 31 December 2024 of USD351,546,000.
- (2) The estimated net proceeds from the Global Offering are based on the indicative Offer Price of HK\$10.10 per share, after deduction of the underwriting fees and other related expenses (excluding listing expenses of approximately USD3,596,000 which have been accounted for during the Track Record Period) paid/payable by the Company and takes no account of exercise of options or awards granted under the Share Incentive Plan or any Shares which may be issued or repurchased by the Company pursuant to the general mandates.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

- (3) Upon Listing and completion of the Global Offering, all the redeemable convertible preferred shares will be automatically converted into ordinary shares. These redeemable convertible preferred shares will be re-designated from liabilities to equity. Accordingly, for the purpose of the unaudited pro forma financial information, the unaudited pro forma adjusted net tangible assets attributable to the owners of the Company will be increased by USD386,195,000, being the carrying amount of the redeemable convertible preferred shares as at 31 December 2024.
- (4) The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after the adjustments referred to in the preceding paragraph and on the basis that 836,667,874 Shares are issued, assuming that (i) 776,085,874 Shares are in issue (including the Shares upon re-designation of the Preferred Shares), and (ii) 60,582,000 Shares are issued pursuant to the Global Offering but does not take into account the shares to be issued after 31 December 2024 pursuant to RSUs that subject to satisfaction of future service condition in accordance with the vesting schedule pursuant to the Equity Incentive Arrangements as described in the section headed “Share Capital” in this prospectus.
- (5) For the purpose of this unaudited pro forma net tangible assets per Share, the amount stated in US dollars are converted into Hong Kong dollars at the rate of USD1.00 to HK\$7.8499. No representation is made that the amounts in US dollars have been, could have been or may be converted to the amounts in Hong Kong dollars, or vice versa, at that rate or at all.
- (6) No adjustment has been made to reflect any trading result or other transaction of our Group entered into subsequent to 31 December 2024.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

The following is the text of a report received from PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus.



羅兵咸永道

INDEPENDENT REPORTING ACCOUNTANT'S ASSURANCE REPORT ON THE COMPILATION OF UNAUDITED PRO FORMA FINANCIAL INFORMATION

To the Directors of Cloudbreak Pharma Inc.

We have completed our assurance engagement to report on the compilation of unaudited pro forma financial information of Cloudbreak Pharma Inc. (the "Company") and its subsidiaries (collectively the "Group") by the directors of the Company (the "Directors") for illustrative purposes only. The unaudited pro forma financial information consists of the unaudited pro forma statement of adjusted consolidated net tangible assets of the Group as at 31 December 2024, and related notes (the "Unaudited Pro Forma Financial Information") as set out on pages II-1 to II-2 of the Company's prospectus dated 24 June 2025, in connection with the proposed initial public offering of the shares of the Company (the "Prospectus"). The applicable criteria on the basis of which the Directors have compiled the Unaudited Pro Forma Financial Information are described on pages II-1 to II-2 of the Prospectus.

The Unaudited Pro Forma Financial Information has been compiled by the Directors to illustrate the impact of the proposed initial public offering on the Group's financial position as at 31 December 2024 as if the proposed initial public offering had taken place at 31 December 2024. As part of this process, information about the Group's financial position has been extracted by the Directors from the Group's financial information for the year ended 31 December 2024, on which an accountant's report has been published.

Directors' Responsibility for the Unaudited Pro Forma Financial Information

The Directors are responsible for compiling the Unaudited Pro Forma Financial Information in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and with reference to Accounting Guideline 7, *Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars*, ("AG 7") issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA").

Our Independence and Quality Management

We have complied with the independence and other ethical requirements of the *Code of Ethics for Professional Accountants* issued by the HKICPA, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

Our firm applies Hong Kong Standard on Quality Management (HKSQM) 1, *Quality Management for Firms that Perform Audits or Reviews of Financial Statements, or Other Assurance or Related Services Engagements*, issued by the HKICPA, which requires the firm to design, implement and operate a system of quality management including policies or procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Reporting Accountant's Responsibilities

Our responsibility is to express an opinion, as required by paragraph 4.29(7) of the Listing Rules, on the Unaudited Pro Forma Financial Information and to report our opinion to you. We do not accept any responsibility for any reports previously given by us on any financial information used in the compilation of the Unaudited Pro Forma Financial Information beyond that owed to those to whom those reports were addressed by us at the dates of their issue.

We conducted our engagement in accordance with Hong Kong Standard on Assurance Engagements 3420, *Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus*, issued by the HKICPA. This standard requires that the reporting accountant plans and performs procedures to obtain reasonable assurance about whether the Directors have compiled the Unaudited Pro Forma Financial Information in accordance with paragraph 4.29 of the Listing Rules and with reference to AG 7 issued by the HKICPA.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the Unaudited Pro Forma Financial Information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the Unaudited Pro Forma Financial Information.

The purpose of unaudited pro forma financial information included in a prospectus is solely to illustrate the impact of a significant event or transaction on unadjusted financial information of the entity as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the proposed initial public offering at 31 December 2024 would have been as presented.

A reasonable assurance engagement to report on whether the unaudited pro forma financial information has been properly compiled on the basis of the applicable criteria involves performing procedures to assess whether the applicable criteria used by the directors in the compilation of the unaudited pro forma financial information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient appropriate evidence about whether:

- The related pro forma adjustments give appropriate effect to those criteria; and
- The unaudited pro forma financial information reflects the proper application of those adjustments to the unadjusted financial information.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

The procedures selected depend on the reporting accountant's judgment, having regard to the reporting accountant's understanding of the nature of the company, the event or transaction in respect of which the unaudited pro forma financial information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the unaudited pro forma financial information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our work has not been carried out in accordance with auditing standards or other standards and practices generally accepted in the United States of America or auditing standards of the Public Company Accounting Oversight Board (United States) or standards and practices of any professional body in any other overseas jurisdiction and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

Opinion

In our opinion:

- (a) the Unaudited Pro Forma Financial Information has been properly compiled by the Directors on the basis stated;
- (b) such basis is consistent with the accounting policies of the Group; and
- (c) the adjustments are appropriate for the purposes of the Unaudited Pro Forma Financial Information as disclosed pursuant to paragraph 4.29(1) of the Listing Rules.

PricewaterhouseCoopers
Certified Public Accountants
Hong Kong, 24 June 2025

APPENDIX III SUMMARY OF THE CONSTITUTION OF THE COMPANY AND THE CAYMAN COMPANIES ACT

Set out below is a summary of certain provisions of the constitution of the Company and certain aspects of the company laws of the Cayman Islands.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 20 November 2020 under the Companies Act. The Company's constitutional documents consist of the Memorandum of Association and the Articles of Association.

1. MEMORANDUM OF ASSOCIATION

The Memorandum provides, *inter alia*, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted (and therefore include acting as an investment holding company) and that the Company shall have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

2. ARTICLES OF ASSOCIATION

The Articles were conditionally adopted on 14 March 2025 and will become effective on the Listing Date. A summary of certain provisions of the Articles is set out below.

2.1 Shares

(a) *Classes of Shares*

The share capital of the Company consists of a single class of ordinary shares.

(b) *Variation of Rights of Existing Shares or Classes of Shares*

If at any time the share capital of the Company is divided into different classes of Shares, all or any of the rights attached to any class of Shares for the time being issued (unless otherwise provided by the terms of issue of the Shares of that class) may, whether or not the Company is being wound up, be varied with the consent in writing of the holders of at least three-fourths of the issued Shares of that class, or with the approval of a resolution passed by at least three-fourths of the votes cast by the holders of the Shares of that class present and voting in person (whether physically or by virtual attendance with the use of technology) or by proxy at a separate meeting of such holders. The provisions of the Articles relating to general meetings shall apply *mutatis mutandis* to every such separate meeting, except that the necessary quorum shall be two persons together holding (or, in the case of a member being a corporation, by its duly authorised representative), or representing by proxy, at least one-third of the issued Shares of that class. Every holder of Shares of the class shall be entitled on a poll to one vote for every such Share held by him, and any holder of Shares of the class present in person (whether physically or by virtual attendance with the use of technology), or, by proxy may demand a poll.

APPENDIX III SUMMARY OF THE CONSTITUTION OF THE COMPANY AND THE CAYMAN COMPANIES ACT

For the purposes of a separate class meeting, the Board may treat two or more classes of Shares as forming one class of Shares if the Board considers that such classes of Shares would be affected in the same way by the proposals under consideration, but in any other case shall treat them as separate classes of Shares.

Any rights conferred upon the holders of Shares of any class shall not, unless otherwise expressly provided in the rights attaching to the terms of issue of the Shares of that class, be deemed to be varied by the creation or issue of further Shares ranking *pari passu* therewith.

(c) *Alteration of Capital*

The Company may by ordinary resolution:

- (i) increase its share capital by the creation of new Shares of such amount and with such rights, priorities and privileges attached to such Shares as it may determine;
- (ii) consolidate and divide all or any of its share capital into Shares of a larger amount than its existing Shares. On any consolidation of fully paid Shares and division into Shares of a larger amount, the Board may settle any difficulty which may arise as it thinks expedient and, in particular (but without prejudice to the generality of the foregoing), may as between the holders of Shares to be consolidated determine which particular Shares are to be consolidated into a consolidated Share, and if it shall happen that any person shall become entitled to fractions of a consolidated Share or Shares, such fractions may be sold by some person appointed by the Board for that purpose and the person so appointed may transfer the Shares so sold to the purchaser(s) thereof and the validity of such transfer shall not be questioned, and the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated Share or Shares rateably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;
- (iii) sub-divide its Shares or any of them into Shares of an amount smaller than that fixed by the Memorandum; and
- (iv) cancel any Shares which, as at the date of passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the Shares so cancelled.

The Company may by special resolution reduce its share capital or any undistributable reserve, subject to the provisions of the Companies Act.

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(d) Transfer of Shares

Subject to the terms of the Articles, any member of the Company may transfer all or any of his Shares by an instrument of transfer. If the Shares in question were issued in conjunction with rights, options, warrants or units issued pursuant to the Articles on terms that one cannot be transferred without the other, the Board shall refuse to register the transfer of any such Share without evidence satisfactory to it of the like transfer of such right, option, warrant or unit.

Subject to the Articles and the requirements of the Stock Exchange, all transfers of Shares shall be effected by an instrument of transfer in the usual or common form or in such other form as the Board may approve and may be under hand or, if the transferor or transferee is a recognised clearing house or its nominee(s), under hand or by machine imprinted signature, or by such other manner of execution as the Board may approve from time to time.

Execution of the instrument of transfer shall be by or on behalf of the transferor and the transferee, provided that the Board may dispense with the execution of the instrument of transfer by the transferor or transferee or accept mechanically executed transfers. The transferor shall be deemed to remain the holder of a Share until the name of the transferee is entered in the register of members of the Company in respect of that Share.

Subject to the provisions of the Companies Act, if the Board considers it necessary or appropriate, the Company may establish and maintain a branch register or registers of members at such location or locations within or outside the Cayman Islands as the Board thinks fit. The Board may, in its absolute discretion, at any time transfer any Share on the principal register to any branch register or any Share on any branch register to the principal register or any other branch register.

The Board may, in its absolute discretion, decline to register a transfer of any Share (not being a fully paid Share) to a person of whom it does not approve or on which the Company has a lien, or a transfer of any Share issued under any share option scheme upon which a restriction on transfer subsists or a transfer of any Share to more than four joint holders. It may also decline to recognise any instrument of transfer if the proposed transfer does not comply with the Articles or any requirements of the Listing Rules.

The Board may decline to recognise any instrument of transfer unless a certain fee, up to such maximum sum as the Stock Exchange may determine to be payable, is paid to the Company, the instrument of transfer is properly stamped (if applicable), is in respect of only one class of Share and is lodged at the relevant registration office or the place at which the principal register is located accompanied by the relevant share certificate(s) and such other evidence as the

APPENDIX III SUMMARY OF THE CONSTITUTION OF THE COMPANY AND THE CAYMAN COMPANIES ACT

Board may reasonably require is provided to show the right of the transferor to make the transfer (and if the instrument of transfer is executed by some other person on his behalf, the authority of that person so to do).

The register of members may, subject to the Listing Rules and the relevant section of the Companies Ordinance, be closed at such time or for such period not exceeding in the whole 30 days in each year as the Board may determine (or such longer period as the members of the Company may by ordinary resolution determine, provided that such period shall not be extended beyond 60 days in any year).

Fully paid Shares shall be free from any restriction on transfer (except when permitted by the Stock Exchange) and shall also be free from all liens.

(e) Redemption of Shares

Subject to the provisions of the Companies Act, the Listing Rules and any rights conferred on the holders of any Shares or attaching to any class of Shares, the Company may issue Shares that are to be redeemed or are liable to be redeemed at the option of the members or the Company. The redemption of such Shares shall be effected in such manner and upon such other terms as the Company may by special resolution determine before the issue of such Shares.

(f) Power of the Company to Purchase its own Shares

Subject to the Companies Act, or any other law or so far as not prohibited by any law and subject to any rights conferred on the holders of any class of Shares, the Company shall have the power to purchase or otherwise acquire all or any of its own Shares (which includes redeemable Shares), provided that the manner and terms of purchase have first been authorised by ordinary resolution and that any such purchase shall only be made in accordance with the relevant code, rules or regulations issued from time to time by the Stock Exchange and/or the Securities and Futures Commission of Hong Kong from time to time in force.

(g) Power of any Subsidiary of the Company to own Shares in the Company

There are no provisions in the Articles relating to the ownership of Shares in the Company by a subsidiary.

(h) Calls on Shares and Forfeiture of Shares

Subject to the terms of allotment and issue of any Shares (if any), the Board may, from time to time, make such calls as it thinks fit upon the members in respect of any monies unpaid on the Shares held by them (whether in respect of par value or share premium). A member who is the subject of the call shall (subject to receiving at least 14 clear days' notice specifying the time or times for payment) pay to the Company at the time or times so specified the amount called

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on his Shares. A call may be made payable either in one sum or by instalments, and shall be deemed to have been made at the time when the resolution of the Board authorising such call was passed. The joint holders of a Share shall be severally as well as jointly liable for the payment of all calls and instalments due in respect of such Share.

If a call remains unpaid after it has become due and payable, the member from whom the sum is due shall pay interest on the unpaid amount at such rate as the Board shall determine (together with any expenses incurred by the Company as a result of such non-payment) from the day it became due and payable until it is paid, but the Board may waive payment of such interest or expenses in whole or in part.

If a member fails to pay any call or instalment of a call after it has become due and payable, the Board may, for so long as any part of the call or instalment remains unpaid, give to such member not less than 14 clear days' notice requiring payment of the unpaid amount together with any interest which may have accrued and which may still accrue up to the date of payment (together with any expenses incurred by the Company as a result of such non-payment). The notice shall specify a further day on or before which the payment required by the notice is to be made. The notice shall also state that, in the event of non-payment at or before the appointed time, the Shares in respect of which the call was made will be liable to be forfeited.

If such notice is not complied with, any Share in respect of which the notice was given may, before the payment required by the notice has been made, be forfeited by a resolution of the Board. Such forfeiture shall include all dividends, other distributions and other monies payable in respect of the forfeited Share and not paid before the forfeiture.

A person whose Shares have been forfeited shall cease to be a member in respect of the forfeited Shares, shall surrender to the Company for cancellation the certificate(s) for the Shares forfeited and shall remain liable to pay to the Company all monies which, as at the date of forfeiture, were payable by him to the Company in respect of the Shares together with (if the Board shall in its discretion so require) interest thereon from the date of forfeiture until the date of payment as the Board may determine and any expenses incurred by the Company as a result of such non-payment.

2.2 Directors

(a) Appointment, Retirement and Removal

The Company may by ordinary resolution of the members elect any person to be a Director. The Board may also appoint any person to be a Director at any time, either to fill a casual vacancy or as an additional Director subject to any maximum number fixed by the members in general meeting or the Articles. Any

APPENDIX III SUMMARY OF THE CONSTITUTION OF THE COMPANY AND THE CAYMAN COMPANIES ACT

Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election at such meeting. Any Director so appointed by the Board shall not be taken into account in determining the Directors or the number of Directors who are to retire by rotation at an annual general meeting.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The members may by ordinary resolution remove any Director (including a managing or executive Director) before the expiration of his term of office, notwithstanding anything in the Articles or any agreement between the Company and such Director, and may by ordinary resolution elect another person in his stead. Nothing shall be taken as depriving a Director so removed of any compensation or damages payable to such Director in respect of the termination of his appointment as Director or of any other appointment or office as a result of the termination of his appointment as Director.

The office of a Director shall be vacated if:

- (i) the Director gives notice in writing to the Company that he resigns from his office as Director;
- (ii) the Director is absent, without being represented by proxy or an alternate Director appointed by him, for a continuous period of 12 months without special leave of absence from the Board, and the Board passes a resolution that he has by reason of such absence vacated his office;
- (iii) the Director becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors generally;
- (iv) the Director dies or an order is made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs and the Board resolves that his office be vacated;
- (v) the Director is prohibited from being or ceases to be a Director by operation of law;
- (vi) the Director has been required by the Stock Exchange to cease to be a Director or no longer qualifies to be a Director pursuant to the Listing Rules; or

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- (vii) the Director is removed from office by notice in writing served upon him signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors (including himself) then in office.

At each annual general meeting, one-third of the Directors for the time being shall retire from office by rotation. If the number of Directors is not a multiple of three, then the number nearest to but not less than one-third shall be the number of retiring Directors, provided that every Director shall be subject to retirement by rotation at least once every three years. The Directors to retire at each annual general meeting shall be those who have been in office longest since their last re-election or appointment and, as between persons who became or were last re-elected Directors on the same day, those to retire shall (unless they otherwise agree among themselves) be determined by lot.

(b) Power to Allot and Issue Shares and other Securities

Subject to the provisions of the Companies Act, the Memorandum and Articles and, where applicable, the Listing Rules, and without prejudice to any rights or restrictions for the time being attached to any Shares, the Board may allot, issue, grant options over or otherwise dispose of Shares with or without preferred, deferred or other rights or restrictions, whether with regard to dividend, voting, return of capital or otherwise, to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, provided that no Shares shall be issued at a discount to their par value.

The Company may issue rights, options, warrants or convertible securities or securities of a similar nature conferring the right upon the holders thereof to subscribe for, purchase or receive any class of Shares or other securities in the Company on such terms as the Board may from time to time determine.

Neither the Company nor the Board shall be obliged, when making or granting any allotment of, offer of, option over or disposal of Shares, to make, or make available, any such allotment, offer, option or Shares to members or others whose registered addresses are in any particular territory or territories where, in the absence of a registration statement or other special formalities, this is or may, in the opinion of the Board, be unlawful or impracticable. However, no member affected as a result of the foregoing shall be, or be deemed to be, a separate class of members for any purpose whatsoever.

(c) Power to Dispose of the Assets of the Company or any of its Subsidiaries

Subject to the provisions of the Companies Act, the Memorandum and Articles and any directions given by special resolution of the Company, the Board may exercise all powers and do all acts and things which may be exercised or done by the Company to dispose of the assets of the Company or any of its subsidiaries. No alteration to the Memorandum or Articles and no direction given

APPENDIX III SUMMARY OF THE CONSTITUTION OF THE COMPANY AND THE CAYMAN COMPANIES ACT

by special resolution of the Company shall invalidate any prior act of the Board which would have been valid if such alteration or direction had not been made or given.

(d) Borrowing Powers

The Board may exercise all the powers of the Company to raise or borrow money, secure the payment of any sum or sums of money for the purposes of the Company, mortgage or charge all or any part of its undertaking, property and uncalled capital of the Company, and, subject to the Companies Act, issue debentures, debenture stock, bonds and other securities, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

(e) Remuneration

A Director shall be entitled to receive such sums as shall from time to time be determined by the Board or the Company in general meetings. The Directors shall also be entitled to be repaid all expenses reasonably incurred by them in connection with attendance at meetings of the Board or committees of the Board, or general meetings of the Company or separate meetings of the holders of any class of Shares or debentures of the Company, or otherwise in connection with the business of the Company and the discharge of their duties as Directors, and/or to receive fixed allowances in respect thereof as may be determined by the Board.

The Board or the Company in general meetings may also approve additional remuneration to any Director for any services which in the opinion of the Board or the Company in general meetings go beyond such Director's ordinary routine work as a Director.

(f) Compensation or Payments for Loss of Office

There are no provisions in the Articles relating to compensation or payment for loss of office.

(g) Loans to Directors

There are no provisions in the Articles relating to making of loans to Directors.

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(h) Disclosure of Interest in Contracts with the Company or any of its Subsidiaries

With the exception of the office of auditor of the Company, a Director may hold any other office or place of profit with the Company in conjunction with his office of Director for such period and upon such terms as the Board may determine, and may be paid such extra remuneration for that other office or place of profit, in whatever form, in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director, officer or member of any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration or other benefits received by him as a director, officer or member of such other company.

No person shall be disqualified from the office of Director or alternate Director or prevented by such office from contracting with the Company, nor shall any such contract or any other contract or transaction entered into by or on behalf of the Company in which any Director or alternate Director is in any way interested be or be liable to be avoided, nor shall any Director or alternate Director so contracting or being so interested be liable to account to the Company for any profit realised by or arising in connection with any such contract or transaction by reason of such Director or alternate Director holding such office or of the fiduciary relationship established by it, provided that the nature of interest of any Director or alternate Director in any such contract or transaction shall be disclosed by such Director or alternate Director at or prior to the consideration and vote thereon.

A Director shall not vote on (or be counted in the quorum in relation to) any resolution of the Board in respect of any contract or arrangement or other proposal in which he or any of his close associate(s) has a material interest, and if he shall do so his vote shall not be counted and he shall not be counted in the quorum for such resolution. This prohibition shall not apply to any of the following matters:

- (i) the giving of any security or indemnity to the Director or his close associate(s) in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries;
- (ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his close associate(s) has/have himself/themselves assumed responsibility in whole or in part whether alone or jointly under a guarantee or indemnity or by the giving of security;

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- (iii) any proposal concerning an offer of Shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase, where the Director or his close associate(s) is/are or is/are to be interested as a participant in the underwriting or sub-underwriting of the offer;
- (iv) any proposal or arrangement concerning the benefit of employees of the Company or any of its subsidiaries, including the adoption, modification or operation of (A) any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit or (B) any pension fund or retirement, death or disability benefits scheme which relates to the Director, his close associates and employees of the Company or any of its subsidiaries and does not provide in respect of any Director or his close associate(s) any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and
- (v) any contract or arrangement in which the Director or his close associate(s) is/are interested in the same manner as other holders of Shares, debentures or other securities of the Company by virtue only of his/their interest in those Shares, debentures or other securities.

2.3 Proceedings of the Board

The Board may meet anywhere in the world for the despatch of business and may adjourn and otherwise regulate its meetings as it thinks fit. Unless otherwise determined, two Directors shall be a quorum. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have a second or casting vote.

2.4 Alterations to the Constitutional Documents and the Company's Name

The Memorandum and Articles may only be altered or amended, and the name of the Company may only be changed, by special resolution of the Company.

2.5 Meetings of Members

(a) Special and Ordinary resolutions

A special resolution must be passed by a majority of not less than two-thirds (other than in relation to any resolution approving changes to the Company's constitutional documents or a voluntary winding up of the Company, in which case a special resolution must be passed by a majority of not less than three-fourths) of the voting rights held by such members as, being entitled so to do, vote in person (whether physically or by virtual attendance with the use of technology), or by proxy or, in the case of any members which is a corporation,

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by its duly authorised representative(s) or by proxy, at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given. A special resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

An ordinary resolution, in contrast, is a resolution passed by a simple majority of the voting rights held by such members as, being entitled to do so, vote in person (whether physically or by virtual attendance with the use of technology), or by proxy or, in the case of any member which is a corporation, by its duly authorised representative(s) or by proxy, at a general meeting. An ordinary resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

The provisions of special resolutions and ordinary resolutions shall apply *mutatis mutandis* to any resolutions passed by the holders of any class of shares.

(b) Voting Rights and Right to Demand a Poll

Subject to any rights, restrictions or privileges as to voting for the time being attached to any class or classes of Shares, at any general meeting: (a) on a poll every member present in person (whether physically or by virtual attendance with the use of technology), (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote for every Share and (b) on a show of hands every member who is present in person (whether physically or by virtual attendance with the use of technology), (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote. For the avoidance of doubt, votes may be cast by members by electronic means.

In the case of joint holders, the vote of the senior holder who tenders a vote, whether in person or by proxy shall be accepted to the exclusion of the votes of the other joint holders, and seniority shall be determined by the order in which the names of the holders stand in the register of members of the Company.

No person shall be counted in a quorum or be entitled to vote at any general meeting unless he is registered as a member on the record date for such meeting, nor unless all calls or other monies then payable by him in respect of the relevant Shares have been paid.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of poll save that the chairman of the meeting may, pursuant to the Listing Rules, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands (whether physically or by virtual attendance with the use of technology).

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Any corporation or other non-natural person which is a member of the Company may in accordance with its constitutional documents, or in the absence of such provision by resolution of its directors or other governing body or by power of attorney, authorise such person as it thinks fit to act as its representative at any meeting of the Company or of any class of members, and the person so authorised shall be entitled to exercise the same powers as the corporation or other non-natural person could exercise as if it were a natural person member of the Company.

If a recognised clearing house or its nominee(s) is a member of the Company, it may appoint proxies or authorise such person or persons as it thinks fit to act as its representative(s), who enjoy rights equivalent to the rights of other members, at any meeting of the Company (including but not limited to general meetings and creditors meetings) or at any meeting of any class of members of the Company, provided that if more than one person is so authorised, the authorisation shall specify the number and class of Shares in respect of which each such person is so authorised. A person so authorised shall be entitled to exercise the same rights and powers on behalf of the recognised clearing house or its nominee(s) as if such person were a natural person member of the Company, including the right to speak and vote individually on a show of hands or on a poll (whether physically or by virtual attendance with the use of technology).

All members of the Company (including a member which is a recognised clearing house (or its nominee(s))) shall have the right to (i) speak at a general meeting and (ii) vote at a general meeting (whether physically or by virtual attendance with the use of technology) except where a member is required by the Listing Rules to abstain from voting to approve the matter under consideration. Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

(c) Annual General Meetings and Extraordinary General Meetings

The Company must hold a general meeting as its annual general meeting in each financial year. Such meeting shall be specified as such in the notices calling it, and must be held within six months after the end of the Company's financial year. A meeting of the members or any class thereof may be held by telephone, tele-conferencing or other electronic means, provided that all participants can attend the meeting virtually with the use of technology and are able to communicate contemporaneously with one another, and participation in a meeting in such manner shall constitute presence at such meetings.

The Board may convene an extraordinary general meeting whenever it thinks fit. In addition, one or more members holding, as at the date of deposit of the requisition, in aggregate not less than one-tenth of the voting rights (on a one vote per Share basis) in the share capital of the Company may make a requisition to convene an extraordinary general meeting and/or add resolutions to the agenda of a meeting. Such requisition, which must state the objects and the resolutions to

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be added to the agenda of the meeting and must be signed by the requisitionists, shall be deposited at the principal place of business of the Company in Hong Kong or, in the event the Company ceases to have such a principal place of business, the registered office of the Company. If the Board does not within 21 days from the date of deposit of such requisition duly proceed to convene a general meeting to be held within the following 21 days, the requisitionists or any of them representing more than one-half of the total voting rights of all the requisitionists may themselves convene a general meeting, but any such meeting so convened shall be held no later than the day falling three months after the expiration of the said 21-day period. A general meeting convened by requisitionists shall be convened in the same manner as nearly as possible as that in which general meetings are to be convened by the Board, and all reasonable expenses incurred by the requisitionists shall be reimbursed to the requisitionists by the Company.

(d) Notices of Meetings and Business to be Conducted

An annual general meeting of the Company shall be called by at least 21 days' notice in writing, and any other general meeting of the Company shall be called by at least 14 days' notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and must specify the date, time, place and agenda of the meeting, the particulars of the resolution(s) to be considered at the meeting, and the general nature of the business to be considered at the meeting and details for members to attend the meeting virtually with the use of technology.

Except where otherwise expressly stated, any notice or document (including a share certificate) to be given or issued under the Articles shall be in writing, and may be served by the Company on any member personally, by post to such member's registered address, (to the extent permitted by the Listing Rules and all applicable laws and regulations) by electronic means or (in the case of a notice) by advertisement published in the manner prescribed under the Listing Rules.

Notwithstanding that a meeting of the Company is called by shorter notice than as specified above, if permitted by the Listing Rules, such meeting may be deemed to have been duly called if it is so agreed:

- (i) in the case of an annual general meeting, by all members of the Company entitled to attend and vote thereat; and
- (ii) in the case of an extraordinary general meeting, by a majority in number of the members having a right to attend and vote at the meeting holding not less than 95% of the total voting rights held by such members.

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If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Board in its absolute discretion consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, it may change or postpone the meeting to another date, time and place.

The Board also has the power to provide in every notice calling a general meeting that in the event of a gale warning, a black rainstorm warning or extreme conditions is/are in force at any time on the day of the general meeting (unless such warning is cancelled at least a minimum period of time prior to the general meeting as the Board may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date.

Where a general meeting is postponed:

- (A) the Company shall endeavour to cause a notice of such postponement, which shall set out the reason for the postponement in accordance with the Listing Rules, to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, provided that failure to place or publish such notice shall not affect the automatic postponement of a general meeting due to a gale warning, a black rainstorm warning or extreme conditions being in force on the day of the general meeting;
- (B) the Board shall determine the date, time, place and details for members to attend virtually with the use of technology for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting. Such notice shall specify the date, time and place at which the postponed meeting will be reconvened, details for members to attend such postponed meeting virtually with the use of technology and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and
- (C) only the business set out in the notice of the original meeting shall be considered at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be considered at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where any new business is to be considered at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles.

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(e) Quorum for Meetings and Separate Class Meetings

No business shall be considered at any general meeting unless a quorum is present when the meeting proceeds to business, and continues to be present until the conclusion of the meeting.

The quorum for a general meeting shall be two members present in person (whether physically or by virtual attendance with the use of technology), (or in the case of a member being a corporation, by its duly authorised representative) or by proxy and entitled to vote. In respect of a separate class meeting (other than an adjourned meeting) convened to approve the variation of class rights, the necessary quorum shall be two persons holding or representing by proxy not less than one-third of the issued Shares of that class.

(f) Proxies

Any member of the Company (including a member which is a recognised clearing house (or its nominee(s))) entitled to attend and vote at a meeting of the Company is entitled to appoint another person (being a natural person) as his proxy to attend and vote in his place. A member who is the holder of two or more Shares may appoint more than one proxy to represent him and vote on his behalf at a general meeting of the Company or at a class meeting. A proxy need not be a member of the Company and shall be entitled to exercise the same powers on behalf of a member who is a natural person and for whom he acts as proxy as such member could exercise. In addition, a proxy shall be entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise as if it were a natural person member present in person (whether physically or by virtual attendance with the use of technology) at any general meeting. On a poll or on a show of hands, votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

The instrument appointing a proxy shall be in writing and executed under the hand of the appointor or of his attorney duly authorised in writing, or if the appointor is a corporation or other non-natural person, either under its seal or under the hand of a duly authorised representative.

The Board shall, in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, specify the manner by which the instrument appointing a proxy shall be deposited and the place and time (being no later than the time appointed for the commencement of the meeting or adjourned meeting to which the instrument of proxy relates) at which such instrument shall be deposited.

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Every instrument of proxy, whether for a specified meeting or otherwise, shall be in such form that complies with the Listing Rules as the Board may from time to time approve. Any form issued to a member for appointing a proxy to attend and vote at a general meeting at which any business is to be considered shall be such as to enable the member, according to his intentions, to instruct the proxy to vote in favour of or against (or, in default of instructions, to exercise the discretion of the proxy in respect of) each resolution dealing with any such business.

2.6 Accounts and Audit

The Board shall cause to be kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions in accordance with the Companies Act.

The books of accounts of the Company shall be kept at the principal place of business of the Company in Hong Kong or, subject to the provisions of the Companies Act, at such other place or places as the Board thinks fit and shall always be open to inspection by any Director. No member (not being a Director) or other person shall have any right to inspect any account, book or document of the Company except as conferred by the Companies Act or ordered by a court of competent jurisdiction or as authorised by the Board or the Company in general meeting.

The Board shall cause to be prepared and laid before the Company at every annual general meeting a profit and loss account for the period since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up, a Directors' report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an auditors' report on such accounts and such other reports and accounts as may be required by law and the Listing Rules.

The members shall at each annual general meeting appoint auditor(s) to hold office by ordinary resolution of the members until the conclusion of the next annual general meeting on such terms and with such duties as may be agreed with the Board. The auditors' remuneration shall be fixed by the members at the annual general meeting at which they are appointed by ordinary resolution of the members or in any other manner as specified in such ordinary resolution. The members may, at any general meeting convened and held in accordance with the Articles, remove the auditors by ordinary resolution at any time before the expiration of the term of office and shall, by ordinary resolution, at that meeting appoint new auditors in their place for the remainder of the term.

The accounts of the Company shall be prepared and audited based on the generally accepted accounting principles of Hong Kong, the International Accounting Standards or such other standards as may be permitted by the Stock Exchange.

2.7 Dividends and other Methods of Distribution

Subject to the Companies Act and the Articles, the Company may by ordinary resolution resolve to declare dividends and other distributions on Shares in issue in any currency and authorise payment of the dividends or distributions out of the funds of the Company lawfully available therefor, provided that (i) no dividends shall exceed the amount recommended by the Board, and (ii) no dividends or distributions shall be paid except out of the realised or unrealised profits of the Company, out of the share premium account or as otherwise permitted by law.

The Board may from time to time pay to the members of the Company such interim dividends as appear to the Board to be justified by the financial conditions and the profits of the Company. In addition, the Board may from time to time declare and pay special dividends on Shares of such amounts and on such dates as it thinks fit.

Except as otherwise provided by the rights attached to any Shares, all dividends and other distributions shall be paid according to the amounts paid up on the Shares that a member holds during the period in respect of which the dividends and distributions are paid. No amount paid up on a Share in advance of calls shall for this purpose be treated as paid up on the Share.

The Board may deduct from any dividends or other distributions payable to any member of the Company all sums of money (if any) then payable by him to the Company on account of calls or otherwise. The Board may retain any dividends or distributions payable on or in respect of a Share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists.

No dividends or other distributions payable by the Company on or in respect of any Share shall carry interest against the Company.

Where the Board or the Company in general meeting has resolved that a dividend should be paid or declared, the Board may further resolve:

- (a) that such dividend be satisfied in whole or in part in the form of an allotment of Shares credited as fully paid on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee, provided that the members entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or
- (b) that the members entitled to such dividend will be entitled to elect to receive an allotment of Shares credited as fully paid in lieu of the whole or such part of the dividend as the Board may think fit on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee.

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Upon the recommendation of the Board, the Company may by ordinary resolution resolve in respect of any one particular dividend of the Company determine that notwithstanding the foregoing, a dividend may be satisfied wholly in the form of an allotment of Shares credited as fully paid without offering any right to members to elect to receive such dividend in cash in lieu of such allotment.

Any dividends, distributions or other monies payable in cash in respect of Shares may be paid by wire transfer to the holder of such Shares or by cheque or warrant sent by post to the registered address of such holder, or in the case of joint holders, to the registered address of the holder who is first named on the register of members of the Company, or to such person and to such address as the holder or joint holders may in writing direct. Any one of two or more joint holders may give effectual receipts for any dividends, distributions or other monies payable in respect of the Shares held by them as joint holders.

Whenever the Board or the Company in general meeting has resolved that a dividend be paid or declared, the Board may further resolve that such dividend be satisfied in whole or in part by the distribution of specific assets of any kind.

Any dividends or other distributions which remain unclaimed for six years from the date on which such dividends or distributions become payable shall be forfeited and shall revert to the Company.

2.8 Inspection of Corporate Records

For so long as any part of the share capital of the Company is listed on the Stock Exchange, any member may inspect any register of members of the Company maintained in Hong Kong (except when the register of members is closed in accordance with the Companies Ordinance) without charge and require the provision to him of copies or extracts of such register in all respects as if the Company were incorporated under and were subject to the Companies Ordinance.

2.9 Rights of Minorities in relation to Fraud or Oppression

There are no provisions in the Articles concerning the rights of minority members in relation to fraud or oppression. However, certain remedies may be available to members of the Company under the Cayman Islands laws, as summarised in paragraph 3.6 below.

2.10 Procedures on Liquidation

Subject to the Companies Act, the members of the Company may by special resolution resolve to wind up the Company voluntarily or by the court.

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Subject to any rights, privileges or restrictions as to the distribution of available surplus assets on liquidation for the time being attached to any class or classes of Shares:

- (a) if the assets available for distribution among the members of the Company are more than sufficient to repay the whole of the Company's paid up capital at the commencement of the winding up, the surplus shall be distributed *pari passu* among such members in proportion to the amount paid up on the Shares held by them at the commencement of the winding up; and
- (b) if the assets available for distribution among the members of the Company are insufficient to repay the whole of the Company's paid up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up, or ought to be paid up, on the Shares held by them at the commencement of the winding up.

If the Company is wound up (whether the liquidation is voluntary or compelled by the court), the liquidator may, with the approval of a special resolution and any other approval required by the Companies Act, divide among the members in kind the whole or any part of the assets of the Company, whether the assets consist of property of one kind or different kinds, and the liquidator may, for such purpose, set such value as he deems fair upon any one or more class or classes of property to be so divided and may determine how such division shall be carried out as between the members or different classes of members and the members within each class. The liquidator may, with the like approval, vest any part of the assets in trustees upon such trusts for the benefit of the members as the liquidator thinks fit, provided that no member shall be compelled to accept any shares or other property upon which there is a liability.

3. COMPANY LAWS OF THE CAYMAN ISLANDS

The Company was incorporated in the Cayman Islands as an exempted company on 20 November 2020 subject to the Companies Act. Certain provisions of the company laws of the Cayman Islands are set out below but this section does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of the company laws of the Cayman Islands, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

3.1 Company Operations

An exempted company such as the Company must conduct its operations mainly outside the Cayman Islands. An exempted company is also required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the amount of its authorised share capital.

3.2 Share Capital

Under the Companies Act, a Cayman Islands company may issue ordinary, preference or redeemable shares or any combination thereof. Where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount or value of the premium on those shares shall be transferred to an account, to be called the share premium account. At the option of a company, these provisions may not apply to premium on shares of that company allotted pursuant to any arrangements in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation, the following:

- (a) paying distributions or dividends to members;
- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;
- (c) any manner provided in section 37 of the Companies Act;
- (d) writing-off the preliminary expenses of the company; and
- (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

Notwithstanding the foregoing, no distribution or dividend may be paid to members out of the share premium account unless, immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

Subject to confirmation by the court, a company limited by shares or a company limited by guarantee and having a share capital may, if authorised to do so by its articles of association, by special resolution reduce its share capital in any way.

3.3 Financial Assistance to Purchase Shares of a Company or its Holding Company

There are no statutory prohibitions in the Cayman Islands on the granting of financial assistance by a company to another person for the purchase of, or subscription for, its own, its holding company's or a subsidiary's shares. Therefore, a company may provide financial assistance provided the directors of the company, when proposing to grant such financial assistance, discharge their duties of care and act in good faith, for a proper purpose and in the interests of the company. Such assistance should be on an arm's-length basis.

3.4 Purchase of Shares and Warrants by a Company and its Subsidiaries

A company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a member and, for the avoidance of doubt, it shall be lawful for the rights attaching to any shares to be varied, subject to the provisions of the company's articles of association, so as to provide that such shares are to be or are liable to be so redeemed. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares; an ordinary resolution of the company approving the manner and terms of the purchase will be required if the articles of association do not authorise the manner and terms of such purchase. A company may not redeem or purchase its shares unless they are fully paid. Furthermore, a company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any issued shares of the company other than shares held as treasury shares. In addition, a payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless, immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

Shares that have been purchased or redeemed by a company or surrendered to the company shall not be treated as cancelled but shall be classified as treasury shares if held in compliance with the requirements of section 37A(1) of the Companies Act. Any such shares shall continue to be classified as treasury shares until such shares are either cancelled or transferred pursuant to the Companies Act.

A Cayman Islands company may be able to purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. Thus there is no requirement under the Cayman Islands laws that a company's memorandum or articles of association contain a specific provision enabling such purchases. The directors of a company may under the general power contained in its memorandum of association be able to buy, sell and deal in personal property of all kinds.

A subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

3.5 Dividends and Distributions

Subject to a solvency test, as prescribed in the Companies Act, and the provisions, if any, of the company's memorandum and articles of association, a company may pay dividends and distributions out of its share premium account. In addition, based upon English case law which is likely to be persuasive in the Cayman Islands, dividends may be paid out of profits.

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For so long as a company holds treasury shares, no dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made, in respect of a treasury share.

3.6 Protection of Minorities and Shareholders' Suits

It can be expected that the Cayman Islands courts will ordinarily follow English case law precedents (particularly the rule in the case of *Foss vs. Harbottle* and the exceptions to that rule) which permit a minority member to commence a representative action against or derivative actions in the name of the company to challenge acts which are ultra vires, illegal, fraudulent (and performed by those in control of the Company) against the minority, or represent an irregularity in the passing of a resolution which requires a qualified (or special) majority which has not been obtained.

Where a company (not being a bank) is one which has a share capital divided into shares, the court may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine the affairs of the company and, at the direction of the court, to report on such affairs. In addition, any member of a company may petition the court, which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

In general, claims against a company by its members must be based on the general laws of contract or tort applicable in the Cayman Islands or be based on potential violation of their individual rights as members as established by a company's memorandum and articles of association.

3.7 Disposal of Assets

There are no specific restrictions on the power of directors to dispose of assets of a company, however, the directors are expected to exercise certain duties of care, diligence and skill to the standard that a reasonably prudent person would exercise in comparable circumstances, in addition to fiduciary duties to act in good faith, for proper purpose and in the best interests of the company under English common law (which the Cayman Islands courts will ordinarily follow).

3.8 Accounting and Auditing Requirements

A company must cause proper records of accounts to be kept with respect to: (i) all sums of money received and expended by it; (ii) all sales and purchases of goods by it; and (iii) its assets and liabilities.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

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If a company keeps its books of account at any place other than at its registered office or any other place within the Cayman Islands, it shall, upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2021 Revision) of the Cayman Islands, make available, in electronic form or any other medium, at its registered office copies of its books of account, or any part or parts thereof, as are specified in such order or notice.

3.9 Exchange Control

There are no exchange control regulations or currency restrictions in effect in the Cayman Islands.

3.10 Taxation

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save for certain stamp duties which may be applicable, from time to time, on certain instruments.

3.11 Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies save for those which hold interests in land in the Cayman Islands.

3.12 Loans to Directors

There is no express provision prohibiting the making of loans by a company to any of its directors. However, the company's articles of association may provide for the prohibition of such loans under specific circumstances.

3.13 Inspection of Corporate Records

The members of a company have no general right to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

3.14 Register of Members

A Cayman Islands exempted company may maintain its principal register of members and any branch registers in any country or territory, whether within or outside the Cayman Islands, as the company may determine from time to time. There is no requirement for an exempted company to make any returns of members to the Registrar of Companies in the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. However, an exempted company shall make available at its registered office, in electronic form or any other medium, such register of members, including any branch

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register of member, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2021 Revision) of the Cayman Islands.

3.15 Register of Directors and Officers

Pursuant to the Companies Act, the Company is required to maintain at its registered office a register of directors, alternate directors and officers. The Registrar of Companies shall make available the list of the names of the current directors of the Company (and, where applicable, the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. A copy of the register of directors and officers must be filed with the Registrar of Companies in the Cayman Islands, and any change must be notified to the Registrar of Companies within 30 days of any change in such directors or officers, including a change of the name of such directors or officers.

3.16 Winding up

A Cayman Islands company may be wound up by: (i) an order of the court; (ii) voluntarily by its members; or (iii) under the supervision of the court.

The court has authority to order winding up in a number of specified circumstances including where, in the opinion of the court, it is just and equitable that such company be so wound up.

A voluntary winding up of a company (other than a limited duration company, for which specific rules apply) occurs where the company resolves by special resolution that it be wound up voluntarily or where the company in general meeting resolves that it be wound up voluntarily because it is unable to pay its debt as they fall due. In the case of a voluntary winding up, the company is obliged to cease to carry on its business from the commencement of its winding up except so far as it may be beneficial for its winding up. Upon appointment of a voluntary liquidator, all the powers of the directors cease, except so far as the company in general meeting or the liquidator sanctions their continuance.

In the case of a members' voluntary winding up of a company, one or more liquidators are appointed for the purpose of winding up the affairs of the company and distributing its assets.

As soon as the affairs of a company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and the property of the company disposed of, and call a general meeting of the company for the purposes of laying before it the account and giving an explanation of that account.

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When a resolution has been passed by a company to wind up voluntarily, the liquidator or any contributory or creditor may apply to the court for an order for the continuation of the winding up under the supervision of the court, on the grounds that: (i) the company is or is likely to become insolvent; or (ii) the supervision of the court will facilitate a more effective, economic or expeditious liquidation of the company in the interests of the contributories and creditors. A supervision order takes effect for all purposes as if it was an order that the company be wound up by the court except that a commenced voluntary winding up and the prior actions of the voluntary liquidator shall be valid and binding upon the company and its official liquidator.

For the purpose of conducting the proceedings in winding up a company and assisting the court, one or more persons may be appointed to be called an official liquidator(s). The court may appoint to such office such person or persons, either provisionally or otherwise, as it thinks fit, and if more than one person is appointed to such office, the court shall declare whether any act required or authorised to be done by the official liquidator is to be done by all or any one or more of such persons. The court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the court.

3.17 Mergers and consolidations

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) “merger” means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) “consolidation” means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorised by (a) a special resolution of each constituent company and (b) such other authorisation, if any, as may be specified in such constituent company’s articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting members have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

3.18 Mergers and Consolidations involving a Foreign Company

Where the merger or consolidation involves a foreign company, the procedure is similar, save that with respect to the foreign company, the directors of the Cayman Islands exempted company are required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the merger or consolidation is permitted or not prohibited by the constitutional documents of the foreign company and by the laws of the jurisdiction in which the foreign company is incorporated, and that those laws and any requirements of those constitutional documents have been or will be complied with; (ii) that no petition or other similar proceeding has been filed and remains outstanding or order made or resolution adopted to wind up or liquidate the foreign company in any jurisdictions; (iii) that no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the foreign company, its affairs or its property or any part thereof; (iv) that no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the foreign company are and continue to be suspended or restricted.

Where the surviving company is the Cayman Islands exempted company, the directors of the Cayman Islands exempted company are further required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the foreign company is able to pay its debts as they fall due and that the merger or consolidated is bona fide and not intended to defraud unsecured creditors of the foreign company; (ii) that in respect of the transfer of any security interest granted by the foreign company to the surviving or consolidated company (a) consent or approval to the transfer has been obtained, released or waived; (b) the transfer is permitted by and has been approved in accordance with the constitutional documents of the foreign company; and (c) the laws of the jurisdiction of the foreign company with respect to the transfer have been or will be complied with; (iii) that the foreign company will, upon the merger or consolidation becoming effective, cease to be incorporated, registered or exist under the laws of the relevant foreign jurisdiction; and (iv) that there is no other reason why it would be against the public interest to permit the merger or consolidation.

3.19 Reconstructions and Amalgamations

Reconstructions and amalgamations may be approved by (i) 75% in value of the members or class of members or (ii) a majority in number representing 75% in value of the creditors or class of creditors, in each case depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting member has the right to express to the court his view that the transaction for which approval is being sought would not provide the members with a fair value for their shares, it can be expected that the court would approve the transaction if it is satisfied that (i) the company is not proposing to act illegally or beyond the scope of our corporate authority and the statutory provisions as to majority vote have been complied with, (ii) the members have been fairly represented at the meeting in question, (iii) the transaction is such as a businessman would reasonable approve and (iv) the transaction is not one that would more properly be sanctioned under some other provisions of the Companies Act or that would amount to a “fraud on the minority”.

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If the transaction is approved, no dissenting member would have any rights comparable to the appraisal rights (namely the right to receive payment in cash for the judicially determined value of his shares), which may be available to dissenting members of corporations in other jurisdictions.

3.20 Takeovers

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may, at any time within two months after the expiration of that four-month period, by notice require the dissenting members to transfer their shares on the terms of the offer. A dissenting member may apply to the Cayman Islands courts within one month of the notice objecting to the transfer. The burden is on the dissenting member to show that the court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority members.

3.21 Indemnification

The Cayman Islands laws do not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, save to the extent any such provision may be held by the court to be contrary to public policy, for example, where a provision purports to provide indemnification against the consequences of committing a crime.

3.22 Economic Substance

The Cayman Islands enacted the International Tax Co-operation (Economic Substance) Act (2024 Revision) together with the Guidance Notes published by the Cayman Islands Tax Information Authority from time to time. If a company is considered to be a "relevant entity" and is conducting one or more of the nine "relevant activities", then such company will be required to comply with the economic substance requirements in relation to the relevant activity from 1 July 2019. All companies whether a relevant entity or not is required to file an annual report with the Registrar of Companies of the Cayman Islands confirming whether or not it is carrying on any relevant activities.

4. GENERAL

Harney Westwood & Riegels, the Company's legal adviser on Cayman Islands laws, has sent to the Company a letter of advice summarising the aspects of the Companies Act set out in section 3 above. This letter, together with copies of the Companies Act and the Memorandum and the Articles, is on display on the websites of the Stock Exchange and the Company as referred to in "Documents Delivered to the Registrar of Companies and Available for Inspection – 2. Documents on display" in Appendix V to this prospectus. Any person wishing to have a detailed summary of the Companies Act or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT OUR GROUP**1. Incorporation**

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on 20 November 2020 under the Companies Act. Our Company's registered office is at Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands. Our Company has established a principal place of business in Hong Kong at Unit 2308, 23/F, Tower 1, Lippo Centre, 89 Queensway, Hong Kong, and was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on 6 February 2024. Dr. Ni and Ms. Fung Nga Fong have been appointed as the authorised representatives of our Company for the acceptance of service of process in Hong Kong.

As our Company was incorporated in the Cayman Islands, its operation is subject to the laws of the Cayman Islands and its constitutive documents comprising the Memorandum and the Articles of Association. A summary of certain provisions of its constitution and relevant aspects of the Companies Act is set out in Appendix III to this prospectus.

2. Changes in share capital of our Company

The authorised share capital of our Company as of the date of its incorporation was US\$50,000 divided into 500,000,000 Shares of par value of US\$0.0001 each. The following alterations in the share capital of our Company have taken place within the two years immediately preceding the date of this prospectus:

- (a) On the Listing Date, upon the Global Offering becoming unconditional, each of the Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares, Series A Preferred Shares, Series B Preferred Shares and Series C Preferred Shares will be converted into one Share immediately prior to the Listing, and the authorised share capital of the Company will become US\$200,000 divided into 2,000,000,000 Shares with a par value of US\$0.0001 each.
- (b) Under the Equity Incentive Arrangements, upon Listing, RSUs representing 2,225,000 Class A Ordinary Shares shall become immediately vested and issued as Shares.

Save as disclosed above, there has been no alteration in the share capital of our Company during the two years immediately preceding the date of this prospectus.

3. Changes in share capital of subsidiaries in our Company

Our material operating subsidiaries are listed in “History, Development and Corporate Structure” in this prospectus and all of our subsidiaries are listed in Note 1 under the Accountant’s Report set out in Appendix I to this prospectus. Save for the subsidiaries mentioned in Appendix I to this prospectus, our Company has no other subsidiaries.

Save as disclosed below, there has been no other alteration in the share capital of any of the subsidiaries in our Company within the two years immediately preceding the date of this prospectus:

Cloudbreak Yixing

Cloudbreak Yixing was established in the PRC on 5 September 2023 with an initial registered capital of US\$35 million. Upon establishment, Cloudbreak Yixing was wholly-owned by Cloudbreak HK.

Cloudbreak Wenzhou

Cloudbreak Wenzhou was established in the PRC on 11 June 2024 with an initial registered capital of RMB10 million. Upon establishment, Cloudbreak Wenzhou was wholly-owned by Cloudbreak Suzhou.

4. Resolutions of the Shareholders of our Company dated 14 March 2025

Resolutions of our Shareholders were passed at a general meeting held on 14 March 2025, pursuant to which, among others:

- (a) with effect immediately prior to the Listing, the authorised share capital of the Company was approved to change from US\$100,000 divided into (i) 358,205,597 Class A Ordinary Shares, with par value of US\$0.0001 each; (ii) 152,484,600 Class B Ordinary Shares, with par value of US\$0.0001 each; (iii) 183,646,804 Class C Ordinary Shares, with par value of US\$0.0001 each; (iv) 8,873,587 Series A Preferred Shares, with par value of US\$0.0001 each; (v) 81,707,570 Series B Preferred Shares, with par value of US\$0.0001 each; and (vi) 215,081,842 Series C Preferred Shares, with par value of US\$0.0001 each, to US\$100,000 divided into 1,000,000,000 Ordinary Shares of US\$0.0001 each, by the reclassification of all issued Class A Ordinary Shares, Class B Ordinary Shares, Class C Ordinary Shares, Series A Preferred Shares, Series B Preferred Shares and Series C Preferred Shares with par value US\$0.0001 each to Ordinary Shares of US\$0.0001 each;

- (b) with effect immediately prior to the Listing, authorised share capital was increased from US\$100,000 to US\$200,000 by the creation of additional 1,000,000,000 Shares, such that following such increase, the authorised share capital of our Company was US\$200,000 divided into 2,000,000,000 Shares of US\$0.0001 each;
- (c) conditional on: (i) the Listing Committee of the Stock Exchange granting the listing of, and the permission to deal in, the Shares in issue and to be issued pursuant to the Global Offering (including any additional Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme), and such listing and permission not subsequently having been revoked prior to the commencement of dealing in the Shares on the Stock Exchange; (ii) the Offer Price having been agreed in the manner as stipulated in this prospectus; (iii) the execution and delivery of the Underwriting Agreements on or around the respective dates as mentioned in this prospectus (or any other date any Director might decide); and (iv) the obligations of the Underwriters and the Capital Market Intermediaries under each of the Underwriting Agreements having become unconditional and not having been terminated in accordance with the terms therein or otherwise, in each case on or before such dates as may be specified in such agreements:
 - (1) the Global Offering was approved and the Board or any committee of the Board or any one Director was authorised severally to approve the allotment and issue of the Shares pursuant to the Global Offering;
 - (2) the Listing was approved and the Board or any committee of the Board or any one Director be and is hereby authorised severally and directed to do all such things and execute all such documents to implement the Listing;
 - (3) each Class A Ordinary Share, Class B Ordinary Share, Class C Ordinary Share, Series A Preferred Share, Series B Preferred Share and Series C Preferred Share was approved to be automatically converted, without the payment of any additional consideration, into one fully-paid and non-assessable ordinary Share, on a 1:1 basis by way of re-designation and re-classification, with such conversion to take effect immediately prior to Listing;
 - (4) the terms of the 2023 Equity Incentive Scheme were approved and adopted;
 - (5) the terms of the Post-IPO Equity Incentive Scheme were approved and adopted;

- (6) a general unconditional mandate (the “**Issuing Mandate**”) was given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares (including resale of any treasury shares of the Company) or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, otherwise than by way of the Global Offering, rights issue or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association or any specific authority granted by our Shareholders in general meeting, shall not exceed 20% of the aggregate nominal value of the Shares in issue immediately following the completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements);
 - (7) a general unconditional mandate (the “**Repurchase Mandate**”) was given to our Directors to exercise all powers of our Company to repurchase on the Stock Exchange or on any other stock exchange on which the securities of our Company may be listed and which is recognised by the SFC and the Stock Exchange for this purpose, such number of Shares shall not exceed 10% of the total number of Shares in issue immediately following the completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements);
 - (8) the extension of the general mandate to allot, issue and deal with the Shares mentioned in sub-paragraph (6) above by the addition to the total number of Shares in issue which may be allotted and issued or agreed conditionally or unconditionally to be allotted or issued by the Directors pursuant to such Issuing Mandate of the aggregate number of Shares repurchased by our Company pursuant to the Repurchase Mandate, provided that such extended amount shall not exceed 10% of the total number of Shares in issue immediately upon completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements); and
- (d) our Company conditionally approved and adopted the Memorandum of Association and Articles of Association with effect from the Listing.

Each of the general mandates referred to in paragraphs (c)(6), (c)(7) and (c)(8) above will remain in effect until whichever is the earliest of:

- (a) the conclusion of the next annual general meeting of our Company;
- (b) the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles of Association; or

- (c) the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in general meeting.

5. Repurchase by our Company of its own securities

This paragraph includes information relating to the repurchase of our Shares, including information required by the Stock Exchange to be included in this prospectus concerning such repurchase.

(a) Provisions of the Listing Rules

The Listing Rules permit companies whose primary listing is on the Stock Exchange to repurchase their securities on the Stock Exchange subject to certain restrictions, the most important of which are summarised below:

(i) Shareholders' approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company listed on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders in general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to the resolutions passed by our Shareholders at a general meeting held on 14 March 2025, a general unconditional mandate was given to our Directors authorising any repurchase by our Company of Shares on the Stock Exchange and/or on any other stock exchange on which the securities of our Company may be listed and which is recognised by the SFC and the Stock Exchange for this purpose in accordance with all applicable laws and requirements of the Stock Exchange (or of such other stock exchange), of up to 10% of the total number of Shares in issue immediately following completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme), such mandate to expire at the conclusion of the next annual general meeting of our Company, or the date by which the next annual general meeting of our Company is required by the Articles of Association or applicable laws to be held, or the passing of an ordinary resolution by our Shareholders in general meeting revoking or varying the mandate given to our Directors, whichever occurs first.

(ii) Source of funds

Repurchases must be funded out of funds legally available for the purpose in accordance with a company's constitutional documents, the Listing Rules and the laws of the jurisdiction in which the company is incorporated or otherwise established. A listed company must not repurchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the

Stock Exchange from time to time. Under the Cayman Islands law, any repurchase by our Company may be made out of profits of our Company, out of the share premium account or out of the proceeds of a new issue of Shares made for the purpose of the repurchase. Any premium payable on a redemption or purchase over the par value of our Shares to be repurchased must be provided for out of either or both of the profits or the sums standing to the credit of the share premium account of our Company. Subject to the Articles of Association and the Cayman Companies Act, a repurchase may also be made out of capital.

(iii) Trading restrictions

Our Company may repurchase up to 10% of the total number of Shares in issue immediately following the completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme). Our Company may not issue or announce a proposed issue of our Shares for a period of 30 days immediately following a repurchase of Shares without the prior approval of the Stock Exchange. Our Company is also prohibited from repurchasing our Shares on the Stock Exchange if the repurchase would result in the number of listed Shares which are in the hands of the public falling below the minimum percentage required by the Stock Exchange. The broker appointed by our Company to effect a repurchase of our Shares is required to disclose to the Stock Exchange any information with respect to a Share repurchase as the Stock Exchange may require. Our Company shall not purchase Shares if the purchase price is higher by 5% or more than the average closing market price for the five preceding trading days on which our Shares were traded on the Stock Exchange.

(iv) Status of repurchased Shares

All repurchased Shares (whether effected on the Stock Exchange or otherwise) will be cancelled and the certificates for those Shares must be cancelled and destroyed. Under the Cayman Islands law, a company's repurchased shares may be treated as cancelled and the amount of the company's issued share capital shall be reduced by the aggregate nominal value of the repurchased shares accordingly although the authorised share capital of the company will not be reduced.

(v) Suspension of buy-back

Repurchase of Shares are prohibited after inside information has come to the knowledge of our Company until such information has been made publicly available. In particular, during the period of one month immediately preceding the earlier of: (aa) the date of the Board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the results of our Company for any year, half-year or quarter-year period or any other interim period (whether or not required under the Listing Rules); and (bb) the deadline for our Company to announce its results for any year, half-year or quarter-year period under the Listing Rules or any other interim period (whether or not required under the Listing Rules) and ending on the date of the results announcement, our Company may not repurchase its securities on the Stock Exchange unless the circumstances are exceptional. In addition, the Stock Exchange reserves the right to prohibit repurchases of Shares on the Stock Exchange if our Company has breached the Listing Rules.

(vi) Reporting requirements

Certain information relating to repurchase of securities on the Stock Exchange or otherwise must be submitted for publication to the Stock Exchange no later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following business day. In addition, our Company's annual report and accounts are required to disclose details regarding repurchases of Shares made during the financial year under review, including the number of Shares repurchased each month (whether on the Stock Exchange or otherwise) and the purchase price per Share or the highest and lowest prices paid for all such repurchases, where relevant, and the aggregate prices paid. The directors' report is also required to contain reference to the repurchases made during the year and the directors' reasons for making such repurchases.

(vii) Core connected persons

According to the Listing Rules, a company is prohibited from knowingly repurchasing securities on the Stock Exchange from a "core connected person", that is, a Director, chief executive or substantial shareholder of our Company or any of its subsidiaries or any of their close associates and a core connected person shall not knowingly sell his/her/its securities to our Company on the Stock Exchange.

(b) *Reasons for repurchases*

Our Directors believe that it is in the best interests of our Company and our Shareholders for our Directors to have general authority from our Shareholders to enable our Company to repurchase Shares in the market. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value of our Company and/or earnings per Share and will only be made if our Directors believe that such repurchases will benefit our Company and our Shareholders.

(c) *Funding of repurchases*

In repurchasing securities, our Company may only apply funds legally available for such purpose in accordance with the Memorandum, the Articles of Association, the applicable laws and regulations of Hong Kong and the Cayman Islands and any other laws and regulations applicable to the Company.

On the basis of the current financial position of our Group as disclosed in this prospectus and taking into account the current working capital position of our Group, our Directors consider that, if the Repurchase Mandate is to be exercised in full, it might have a material adverse effect on the working capital and/or the gearing position of our Group as compared with the position disclosed in this prospectus. However, our Directors do not propose to exercise the Repurchase Mandate to such an extent as would, in the circumstances, have a material adverse effect on the working capital requirements of our Group or the gearing levels which in the opinion of our Directors are from time to time appropriate for our Group.

The exercise in full of the Repurchase Mandate, on the basis of 838,892,874 Shares in issue immediately after the Listing, would result in up to 83,889,287 Shares being repurchased by our Company during the period in which the Repurchase Mandate remains in force.

(d) *General*

None of our Directors nor, to the best of their knowledge and belief having made all reasonable enquiries, any of their respective close associates currently intends to sell any Shares to our Company or its subsidiaries.

Our Directors have undertaken to the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules and the applicable laws of the Cayman Islands.

No core connected person of our Company has notified our Company that he has a present intention to sell his Shares to our Company, or has undertaken not to do so if the Repurchase Mandate is exercised.

If as a result of any securities repurchase pursuant to the Repurchase Mandate, a shareholder's proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purpose of the Takeovers Code.

Accordingly, a shareholder, or a group of Shareholders acting in concert (within the meaning of the Takeovers Code), depending on the level of increase of the shareholder's interest, could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code as a result of any such increase. Our Directors are not aware of any other consequences which may arise under the Takeovers Code if the Repurchase Mandate is exercised.

If the Repurchase Mandate is fully exercised immediately following completion of the Global Offering (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), the total number of Shares which will be repurchased pursuant to the Repurchase Mandate shall be 83,889,287 Shares, being 10% of the issued share capital of our Company based on the aforesaid assumptions. The percentage shareholding of our Single Largest Shareholders will be increased to approximately 22.80% of the issued share capital of our Company immediately following the full exercise of the Repurchase Mandate. Any repurchase of Shares which results in the number of Shares held by the public being reduced to less than the prescribed percentage of our Shares then in issue could only be implemented with the approval of the Stock Exchange to waive the Listing Rules requirements regarding the public float under Rule 8.08 of the Listing Rules. However, our Directors have no present intention to exercise the Repurchase Mandate to such an extent that, in the circumstances, there is insufficient public float as prescribed under the Listing Rules.

B. FURTHER INFORMATION ABOUT THE BUSINESS OF OUR GROUP

1. Summary of material contracts

The following material contracts (not being contracts in the ordinary course of business) have been entered into by members of our Group within the two years immediately preceding the date of this prospectus, and are or may be material:



- (a) the Hong Kong Underwriting Agreement;
- (b) the cornerstone investment agreement dated 23 June 2025 entered into between our Company, Wealth Strategy Holding Limited (“**WSH**”), CCB International Capital Limited and Huatai Financial Holdings (Hong Kong) Limited, pursuant to which WSH agreed to subscribe for Shares at the Offer Price in the aggregate amount of Hong Kong dollar equivalent of US\$20 million, in accordance with the terms of the cornerstone investment agreement; and

- (c) the cornerstone investment agreement dated 23 June 2025 entered into between our Company, The Reynold Lemkins Group (Asia) Limited (“**Reynold Lemkins**”), CCB International Capital Limited and Huatai Financial Holdings (Hong Kong) Limited, pursuant to which Reynold Lemkins agreed to subscribe for Shares at the Offer Price in the aggregate amount of Hong Kong dollar equivalent of US\$2.8 million, in accordance with the terms of the cornerstone investment agreement.

2. Intellectual property rights

(a) Trademarks

As of the Latest Practicable Date, our Group had registered the following trademarks in Hong Kong and the PRC which are material to our business:

Trademark	Registered owner	Class	Place of registration	Trademark registration number	Expiry Date
	Cloudbreak Pharma HK	5, 10, 16, 42	Hong Kong	305998808	29 June 2032
	Cloudbreak Pharma HK	5, 10, 16, 42	Hong Kong	305998817	29 June 2032
	Cloudbreak Pharma HK	5, 10, 16, 42	Hong Kong	306182965	2 March 2032
	Cloudbreak Pharma HK	5, 10, 16, 42	Hong Kong	305998150	28 June 2032
拨康视云	Cloudbreak Pharma HK	5	PRC	70017658	6 September 2033
拨康视云	Cloudbreak Pharma HK	10	PRC	70016299	6 September 2033
拨康视云	Cloudbreak Pharma HK	42	PRC	70003992	6 September 2033
Cloudbreak	Cloudbreak Pharma HK	5	PRC	70017677	6 September 2033
Cloudbreak	Cloudbreak Pharma HK	10	PRC	70002226	6 September 2033
Cloudbreak	Cloudbreak Pharma HK	42	PRC	70017847	6 September 2033

Trademark	Registered owner	Class	Place of registration	Trademark registration number	Expiry Date
 拔康视云 Cloudbreak Pharma	Cloudbreak Pharma HK	10	PRC	67403377	12 March 2034
 Cloudbreak Pharma	Cloudbreak Pharma HK	10	PRC	67396047	13 March 2034
 Cloudbreak Pharma	Cloudbreak Pharma HK	5	PRC	67377783	13 July 2034
 Cloudbreak Pharma	Cloudbreak Pharma HK	42	PRC	67382461	13 July 2034
 拔康视云 Cloudbreak Pharma	Cloudbreak Pharma HK	5	PRC	67401039	13 July 2034
 拔康视云 Cloudbreak Pharma	Cloudbreak Pharma HK	42	PRC	67377958	13 July 2034

(b) Domain names

As of the Latest Practicable Date, our Group had registered the following domain names which are material to our business:

Domain name	Registered owner	Registration date	Expiry date
www.cloudbreakpharma.com	Our Company	24 August 2022	29 June 2025 ^(Note)

Note: The relevant domain name will be automatically renewed upon expiry

(c) Patents

For a discussion of the details of the granted patents and filed patent applications by our Company which are material to our business, see “Business – Intellectual Property” in this prospectus.

C. FURTHER INFORMATION ABOUT DIRECTORS AND SUBSTANTIAL SHAREHOLDERS

1. Interests and short positions of Directors and the chief executive of our Company in the Shares, underlying Shares or debentures of our Company and its associated corporations

So far as is known to our Directors, immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), the interests and short positions of our Directors or chief executive of our Company in the Shares, underlying Shares or debentures of our Company and its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO) or which will be required pursuant to section 352 of the SFO to be entered in the register referred to therein, or which, once our Shares are listed, will be required to notify to our Company and the Stock Exchange pursuant to Appendix C3 of the Listing Rules, will be as follows:

Interests and/or short positions in the Shares

Name of Director or chief executive	Capacity/ Nature of interest	Number of Shares interested as of the date of this prospectus	Approximate percentage of shareholding as of the date of this prospectus	Number of Shares interested upon completion of the Global Offering ⁽⁸⁾	Approximate percentage of shareholding upon completion of the Global Offering ⁽⁸⁾
Dr. Ni	Interest in a controlled corporation ⁽²⁾ , founder of a discretionary trust ⁽³⁾ , interest of spouse ⁽⁴⁾	245,235,661 Shares (L)	31.60%	245,235,661 Shares (L)	29.23%
Mr. Dinh	Interest in a controlled corporation ⁽⁵⁾ , founder of a discretionary trust ⁽⁶⁾	67,273,176 Shares (L)	8.67%	67,273,176 Shares (L)	8.02%
Dr. Li	Beneficial owner	32,159,598 Shares (L)	4.14%	32,159,598 Shares (L)	3.83%
Dr. Yang	Interest in a controlled corporation ⁽⁷⁾	25,564,598 Shares (L)	3.29%	25,564,598 Shares (L)	3.05%

Notes:

1. The letter “L” denotes a long position in the shareholder’s interest in the share capital of our Company.
2. Water Lily Consultants has a long position of 221,149,197 Shares. Water Lily Consultants is wholly-owned by Dr. Ni. Therefore, Water Lily Consultants is a controlled corporation of Dr. Ni, hence Dr. Ni is deemed to be interested in the same number of Shares that Water Lily Consultants is interested in under the SFO.

Water Lily Consultants is entitled to receive up to 63,156,492 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

3. Ni Legacy Trust has a long position of 3,900,219 Shares. Ni Legacy Trust is a discretionary family trust established by Dr. Ni for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Dr. Ni’s family members and charities independent of Dr. Ni. IconTrust, LLC is the trustee of Ni Legacy Trust. Therefore, Dr. Ni is interested in the same number of Shares that are held by IconTrust, LLC under Ni Legacy Trust under the SFO.
4. Ms. Leng is the spouse of Dr. Ni. Dr. Ni is therefore deemed to be interested in the same number of Shares that Ms. Leng is interested in under the SFO.

Ice Tree LLC has a long position of 15,217,266 Shares. Ice Tree Consultants has a long position of 3,624,970 Shares. Each of Ice Tree LLC and Ice Tree Consultants is wholly-owned by Ms. Leng. Therefore, Ice Tree LLC and Ice Tree Consultants are controlled corporations of Ms. Leng, hence Ms. Leng is deemed to be interested in the same number of Shares that Ice Tree LLC and Ice Tree Consultants are interested in under the SFO.

Leng Legacy Trust has a long position of 1,344,009 Shares. Leng Legacy Trust is a discretionary family trust established by Ms. Leng for estate planning and controlled by her by virtue of being settlor and protector. The beneficiaries are Ms. Leng’s family members and charities independent of Ms. Leng. IconTrust, LLC is the trustee of Leng Legacy Trust. Therefore, Ms. Leng is interested in the same number of Shares that are held by IconTrust, LLC under Leng Legacy Trust under the SFO.

Ice Tree LLC is entitled to receive up to 9,929,127 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

5. VD&TL has a long position of 65,329,167 Shares. VD&TL is wholly-owned by Mr. Dinh. Therefore, VD&TL is a controlled corporation of Mr. Dinh, hence Mr. Dinh is deemed to be interested in the same number of Shares that VD&TL is interested in under the SFO.

VD&TL is entitled to receive up to 9,929,127 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

6. Dinh Legacy Trust has a long position of 1,944,009 Shares. Dinh Legacy Trust is a discretionary family trust established by Mr. Dinh for estate planning and controlled by him by virtue of being settlor and protector. The beneficiaries are Mr. Dinh’s family members and charities independent of Mr. Dinh. IconTrust, LLC is the trustee of Dinh Legacy Trust. Therefore, Mr. Dinh is interested in the same number of Shares that are held by IconTrust, LLC under Dinh Legacy Trust under the SFO.

7. YDD Consulting is wholly-owned by Dr. Yang. Therefore, YDD Consulting is a controlled corporation of Dr. Yang, hence Dr. Yang is deemed to be interested in the same number of Shares that YDD Consulting is interested in under the SFO.

YDD Consulting is entitled to receive up to 11,873,136 Shares pursuant to the RSUs granted to it under the Equity Incentive Arrangements, subject to the conditions (including vesting conditions) of those RSUs.

8. Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).

2. Interests and/or short positions of Substantial Shareholders in our Shares

For information on the persons who will, immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), have an interest or a short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of the SFO or which would be recorded in the register of our Company as required under section 336 of the SFO or who will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other members of our Group, see “Substantial Shareholders” in this prospectus.

Save as set out above, as of the Latest Practicable Date, our Directors were not aware of any persons who will, immediately following the completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements), be directly or indirectly interested in 10% or more of the nominal of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Company or any other members of our Group.

3. Particulars of service agreements and letters of appointment

Each of Dr. Ni, Mr. Dinh and Dr. Yang, all being our executive Directors, has entered into a service agreement with our Company for an initial term of three years commencing from the Listing Date, and will continue thereafter until terminated by not less than three months’ notice in writing served by either party on the other. Each of our executive Directors is entitled to their respective basic salary set out below and a discretionary bonus.

Each of Dr. Li, Mr. Cao Xu and Mr. Xia Zhidong, our non-executive Directors, has entered into a letter of appointment with our Company. The terms and conditions of each of such letters of appointment are similar in all material respects. Each of them is appointed with an initial term of one year commencing from the Listing Date and will continue thereafter, unless terminated in certain circumstances as stipulated in the relevant letters of appointment.

Each of Mr. Lai Hin Wing Henry Stephen, Mr. Liu Chung Mun and Ms. Nie Sijiang, our independent non-executive Directors, has entered into a letter of appointment with our Company. The terms and conditions of each of such letters of appointment are similar in all material respects. Each of them is appointed with an initial term of three years commencing from the Listing Date and will continue thereafter, unless terminated in certain circumstances as stipulated in the relevant letters of appointment.

Save as aforesaid, none of our Directors has or is proposed to have a service agreement with our Company or any of our subsidiaries (other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation)).

The remunerations for each of the Directors is determined by our Company with reference to duties and level of responsibilities of each Director and the remuneration policy of our Company and the prevailing market conditions.

The appointments of our Directors are subject to the provisions of retirement and rotation of Directors under the Articles of Association.

4. Directors' emoluments

- (i) For the years ended 31 December 2022, 2023 and 2024, the aggregate emoluments paid and benefits in kind granted by our Group to our Directors were approximately US\$1.7 million, US\$11.6 million and US\$9.2 million, respectively.
- (ii) Under the arrangements currently in force, the aggregate amount of emoluments (including share-based payment and excluding any discretionary benefits or bonus) payable by our Group to our Directors for the financial year ending 31 December 2025 is expected to be approximately US\$20.8 million.
- (iii) None of our Directors or any past directors of any member of our Group has been paid any sum of money during the Track Record Period, (1) as an inducement to join or upon joining our Company or (2) for loss of office as a director of any member of our Group or of any other office in connection with the management of the affairs of any member of our Group.
- (iv) There has been no arrangement under which a Director has waived or agreed to waive any emoluments during the Track Record Period.

- (v) Under the arrangements currently proposed, conditional upon the Listing, the basic annual emoluments (excluding payment pursuant to any discretionary benefits or bonus or other fringe benefits) payable by our Group to each of our Directors will be as follows:

Executive Directors

Dr. Ni	US\$785,120
Mr. Dinh	US\$416,160
Dr. Yang	US\$416,160

Non-executive Directors

Dr. Li	Nil
Mr. Cao Xu	Nil
Mr. Xia Zhidong	Nil

Independent Non-executive Directors

Mr. Lai Hin Wing Henry Stephen	US\$30,000
Mr. Liu Chung Mun	US\$30,000
Ms. Nie Sijiang	US\$25,000

- (vi) Each of our Directors is entitled to reimbursement of all necessary and reasonable out-of-pocket expenses properly incurred in relation to all business and affairs carried out by our Group from time to time or in discharge of his/her duties to our Group under his/her service agreement or letter of appointment.

5. Related party transactions

We had no material related party transactions during the Track Record Period.

6. Disclaimers

Save as disclosed in this prospectus:

- (i) without taking into account any Shares which may be allotted and issued or repurchased by our Company under the Issuing Mandate and the Repurchase Mandate, our Directors are not aware of any person who immediately following the completion of the Global Offering will have an interest or short position in the Shares and underlying Shares which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is, either directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group;

- (ii) none of our Directors has for the purpose of Divisions 7 and 8 of Part XV of the SFO or the Listing Rules, nor is any of them taken to or deemed to have under Divisions 7 and 8 of Part XV of the SFO, any interests and short positions in the Shares, underlying Shares, and debentures of our Company or any associated corporations (within the meaning of Part XV of the SFO) or any interests which will have to be entered in the register to be kept by our Company pursuant to section 352 of the SFO or which will be required to be notified to our Company and the Stock Exchange pursuant to Appendix C3 of the Listing Rules, once the Shares are listed on the Stock Exchange;
- (iii) none of our Directors or the experts named in “E. Other Information – 6. Qualifications of experts” in this appendix has been interested in the promotion of, or has any direct or indirect interest in any assets acquired or disposed of by or leased to, any member of our Group within the two years immediately preceding the date of this prospectus, or which are proposed to be acquired or disposed of by or leased to any member of our Group, nor will any Director apply for the Offer Shares either in his/ her own name or in the name of a nominee;
- (iv) none of our Directors or the experts named in “E. Other Information – 6. Qualifications of experts” in this appendix is materially interested in any contract or arrangement subsisting at the date of this prospectus which is significant in relation to the business of our Group taken as a whole; and
- (v) none of the experts named in “E. Other information – 6. Qualifications of experts” in this appendix has any shareholding in any company in our Group or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any company in our Group.

D. EQUITY INCENTIVE ARRANGEMENTS

1. Series B Equity Incentive Arrangement

In 2020, pursuant to the amended and restated shareholders agreement of Cloudbreak Cayman entered into by and among certain subsidiaries of the Company and certain shareholders of the Company in connection with the Series B Financing, it was agreed that Cloudbreak Cayman shall offer equity incentives to certain directors and senior management personnel of Cloudbreak Cayman subject to certain vesting conditions relating to the clinical trial progress of a certain drug candidate.

At the same time of the Share Swap (as defined and details set out in “History, Development and Corporate Structure – Major Shareholding Changes in our Group – Our Company – (4) Share swap with Cloudbreak USA and allotment of shares in connection with Series B Equity Incentive Arrangement” in this prospectus) to establish our Company as the holding company of all Group companies, on 24 November 2021, an unanimous written resolution was passed by the then Shareholders of our Company to approve the adoption of Cloudbreak Cayman’s employee incentive arrangement in connection with the Series B Financing, such that share awards representing 9,732,246

Class A Ordinary Shares will be granted and issued to those directors and senior management personnel in replacement of the equity incentive in Cloudbreak Cayman referred in the paragraph above.

As of the Latest Practicable Date, our Company has granted and issued an aggregate of 7,788,237 Class A Ordinary Shares to Water Lily Consultants, Ice Tree LLC and VD&TL, and granted RSUs (which have not yet vested or been issued) representing 1,944,009 Class A Ordinary Shares to YDD Consulting as part of the Series B Employee Incentive Arrangement. Details of the outstanding RSUs granted under the Series B Equity Incentive Arrangement are as follows:

Name of grantee/ holding entity nominated by the grantee	Beneficial owner and position held within our Group	Grant Date	Award type	Vesting Period	Number of shares underlying the award as of the Latest Practicable Date	Number of Shares underlying the award immediately following the completion of the Global Offering	Approximate percentage of shareholding of the Shares underlying the awards immediately following the completion of the Global Offering ⁽¹⁾
YDD Consulting	Dr. Yang, our Executive Director and chief scientific officer	1 April 2022	RSUs	5 years ⁽²⁾	1,944,009 Class A Ordinary Shares	1,944,009 Shares	0.23%

Notes:

- (1) Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).
- (2) 40%, 30% and 30% of the RSUs will vest on 2 April 2025, 2 April 2026 and 2 April 2027, respectively, provided that the grantee remains in continuous employment or service with our Company or its affiliates. The grantee is required to stay in the appointed position for at least one more year after the vesting of each of the RSUs.

As of the Latest Practicable Date, under the Series B Equity Incentive Arrangement, none of the RSUs had yet become vested and all of the RSUs were outstanding.

Assuming full vesting and exercise of all outstanding RSU awards under the Series B Equity Incentive Arrangement, the shareholding of our Shareholders immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements) will be diluted by approximately 0.23%, representing unvested RSUs with 1,944,009 underlying Shares upon Listing. The Company will not grant further incentive awards under the Series B Equity Incentive Arrangement after the Listing.

2. Series C Equity Incentive Arrangement

On 24 November 2021, an unanimous written resolution was passed by the then Shareholders of our Company to approve the grant of share awards to personnel relating to our Company as an employee incentive arrangement in connection with the Series C Financing. An aggregate of 96,084,237 Class A Ordinary Shares have been reserved for grant (in whatever form) under the arrangement.

Details of the equity incentive (which include RSUs, share options and share grants) granted to relevant personnel (or their respective investment holding entities) under the Series C Equity Incentive Arrangement are as follows:

Name of grantee/ holding entity nominated by the grantee	Beneficial owner and position held within our Group	Grant Date	Award type	Exercise Price per option	Vesting Period	Number of shares underlying the award as of the Latest Practicable Date ⁽⁵⁾	Number of Shares underlying the award immediately following the completion of the Global Offering	Approximate percentage of shareholding of the Shares underlying the awards immediately following the completion of the Global Offering ⁽¹⁾
Water Lily Consultants	Dr. Ni, our Executive Director, Chairman of the Board and chief executive officer	3 April 2023	RSUs	–	5 years ⁽²⁾	22,335,969 Class A Ordinary Shares	22,335,969 Shares	2.66%
		3 April 2023	RSUs	–	5 years ⁽²⁾	12,188,531 Class A Ordinary Shares	12,188,531 Shares	1.45%
		3 April 2023	RSUs	–	5 years ⁽³⁾	3,515,214 Class A Ordinary Shares	3,515,214 Shares	0.42%
		24 May 2025	RSUs	–	5 years ⁽⁷⁾	5,012,186 Class A Ordinary Shares	5,012,186 Shares	0.60%
Ice Tree LLC	Ms. Leng, spouse of Dr. Ni and hence a connected person	3 April 2023	RSUs	–	5 years ⁽²⁾	1,944,009 Class A Ordinary Shares	1,944,009 Shares	0.23%
		3 April 2023	RSUs	–	5 years ⁽³⁾	2,585,118 Class A Ordinary Shares	2,585,118 Shares	0.31%
		24 May 2025	RSUs	–	5 years ⁽⁷⁾	1,400,000 Class A Ordinary Shares	1,400,000 Shares	0.17%
VD&TL	Mr. Dinh, our Executive Director and chief operations officer	3 April 2023	RSUs	–	5 years ⁽²⁾	1,944,009 Class A Ordinary Shares	1,944,009 Shares	0.23%
		3 April 2023	RSUs	–	5 years ⁽³⁾	2,585,118 Class A Ordinary Shares	2,585,118 Shares	0.31%
		24 May 2025	RSUs	–	5 years ⁽⁷⁾	1,400,000 Class A Ordinary Shares	1,400,000 Shares	0.17%
YDD Consulting	Dr. Yang, our Executive Director and chief scientific officer	3 April 2023	RSUs	–	5 years ⁽²⁾	1,944,009 Class A Ordinary Shares	1,944,009 Shares	0.23%
		3 April 2023	RSUs	–	5 years ⁽³⁾	2,585,118 Class A Ordinary Shares	2,585,118 Shares	0.31%
		24 May 2025	RSUs	–	5 years ⁽⁷⁾	1,400,000 Class A Ordinary Shares	1,400,000 Shares	0.17%
Wenkui Fang, our chief innovation officer		3 April 2025	RSUs	–	5 years ⁽²⁾	3,888,018 Class A Ordinary Shares	3,888,018 Shares	0.46%
Abu Abraham, our chief medical officer		3 April 2025	RSUs	–	5 years ⁽²⁾	11,202,180 Class A Ordinary Shares	11,202,180 Shares	1.34%
Elizabeth Capen, our chief patent officer and chief compliance officer		3 April 2025	RSUs	–	5 years ⁽²⁾	2,585,118 Class A Ordinary Shares	2,585,118 Shares	0.31%
Kimberley Root, director, clinical operations		3 April 2023	Share options ⁽⁶⁾	US\$0.58025	years ⁽⁴⁾	198,192 Class A Ordinary Shares	198,192 Shares	0.02%

Notes:

- (1) Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).
- (2) 50%, 20%, 15% and 15% of the RSUs will vest on the date which is one year after Listing, 2 April 2026, 2 April 2027 and 2 April 2028, respectively, provided that the grantee remains employed by our Company or its affiliate and have not resigned or been terminated by our Company or any reason on the relevant vesting date. If the grantee leaves our Company in any circumstance, unvested shares shall be forfeited.
- (3) 50%, 20%, 15% and 15% of the RSUs will vest on the date which is one year after Listing, 2 April 2026, 2 April 2027 and 2 April 2028, respectively, provided that (a) certain vesting conditions relating to the clinical trial progress of certain drug candidate are fulfilled, and (b) the grantee remains employed by our Company or its affiliate and have not resigned or been terminated by our Company or any reason on the relevant vesting date. If the grantee leaves our Company in any circumstance, unvested shares shall be forfeited.
- (4) 50%, 20%, 15% and 15% of the options will vest on the date which is one year after Listing, 2 April 2026, 2 April 2027 and 2 April 2028, respectively, provided that (a) certain vesting conditions relating to the clinical trial progress of certain drug candidate are fulfilled, and (b) the grantee remains employed by our Company or its affiliate and have not resigned or been terminated by our Company or any reason on the relevant vesting date. If the grantee leaves our Company in any circumstance, unvested and vested options not yet exercised shall be forfeited.
- (5) As of the Latest Practicable Date, 17,371,448 Class A Ordinary Shares had been granted as share awards and issued on 1 April 2022 to certain individuals who are not Directors (of which 17,234,122 Class A Ordinary Shares were issued to Ms. Chan Ching Chu, chief financial officer of the Company, and 137,326 Class A Ordinary Shares were issued to a consultant of the Company who provided certain legal advisory services). These share awards are not subject to vesting conditions.
- (6) All such share options representing 198,192 Class A Ordinary Shares were granted to Ms. Kimberly Root, an employee of our Company, for nil consideration. Her residential address is 23636 Kingdon Ct, Laguna Niguel, CA 92677-2094, USA.
- (7) 20% of the RSUs will vest on each of the next five anniversaries of the Listing Date, provided that the grantee remains employed by our Company or its affiliate and have not resigned or been terminated by our Company or any reason on the relevant vesting date. If the grantee leaves our Company in any circumstance, unvested RSUs shall be forfeited.

As of the Latest Practicable Date, under the Series C Equity Incentive Arrangement, 17,371,448 Class A Ordinary Shares have been issued, of which 17,234,122 Class A Ordinary Shares were issued to Ms. Chan Ching Chu, chief financial officer of the Company, and 137,326 Class A Ordinary Shares were issued to a consultant of the Company who provided certain business consultancy services relating to our Group's corporate restructuring. These share awards are not subject to vesting conditions. They were granted to Ms. Chan Ching Chu as part of her employee compensation package as chief financial officer, and to the consultant as employee incentive for taking up such consultant role for our Group. As at the Latest Practicable Date, and none of the RSUs or options had yet become vested and all of the RSUs and options were outstanding. Upon Listing, options representing 198,192 Shares and RSUs representing 78,514,597 Shares remain subject to vesting conditions under the Series C Equity Incentive Arrangement.

Assuming full vesting and exercise of all outstanding options and RSU awards under the Series C Equity Incentive Arrangement, the shareholding of our Shareholders immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements) will be diluted by approximately 9.38%, representing unvested RSUs with 78,514,597 underlying Shares and unexercised options with 198,192 underlying Shares upon Listing. The Company will not grant further incentive awards under the Series C Equity Incentive Arrangement after the Listing.

3. 2023 Equity Incentive Scheme

As of the Latest Practicable Date, equity incentive awards representing 85,674,265 Shares under the 2023 Equity Incentive Scheme have been granted. No equity incentive awards under the 2023 Equity Incentive Scheme will be further granted. All granted equity incentive have been granted to specific individuals under the 2023 Equity Incentive Scheme. Pursuant to Rule 17.02(1)(b) of the Listing Rules, the 2023 Equity Incentive Scheme does not need to be approved by the Shareholders after Listing. In addition, given the 2023 Equity Incentive Scheme will not involve the grant of new Shares or options over new Shares after Listing and given all material terms of the 2023 Equity Incentive Scheme have been clearly set out in this prospectus, the options and share awards granted to specified participants before Listing as set out above may continue to be valid after Listing (subject to the Stock Exchange granting approval for Listing of the Shares to be issued in respect of such options and share awards) although the terms of the 2023 Equity Incentive Scheme do not comply with the provisions of Chapter 17 of the Listing Rules, as provided for under Rule 17.02(1)(b) of the Listing Rules. An application has been made to the Listing Committee of the Stock Exchange for the listing of, and permission to deal in, all Shares to be issued under the 2023 Equity Incentive Scheme.

The following is a summary of the principle terms of the 2023 Equity Incentive Scheme, which was adopted by the Company and took effect on 14 March 2025.

General

(a) Purpose

The purpose of the 2023 Equity Incentive Scheme is to promote the success of the Company and the interests of its Shareholders by providing a means through which the Company may grant equity-based incentives to attract, motivate, retain and reward certain officers, employees, directors, advisers, consultants and other eligible persons and to further link the interests of award recipients with those of the Shareholders generally.

(b) Eligibility

An officer, director or employee of the Company or any of its affiliates, any member of the Board or any director of one of the Company's affiliates, or any individual consultant or adviser who renders or has rendered bona fide services (other than services in connection with the offering or sale of securities of the Company or one of its affiliates, as applicable, in a capital raising transaction or as a market maker or promoter of that entity's securities) to the Company or one of its affiliates as determined by the Board in its absolute discretion.

(c) Maximum number of Shares

Under the 2023 Equity Incentive Scheme, the maximum number of Shares that may be delivered pursuant to options and share awards (the "**Awards**") granted under the 2023 Equity Incentive Scheme will not exceed the limit as duly approved by the shareholders of the Company from time to time. The maximum number of Shares the Company is authorised to issue under the 2023 Equity Incentive Scheme is 85,674,267 Shares, representing 10% of the total issued Shares as of the Latest Practicable Date and Shares reserved for grant but not yet issued under the Series B Equity Incentive Arrangement and Series C Equity Incentive Arrangement.

(d) Administration

The 2023 Equity Incentive Scheme shall be administered, and all Awards under the 2023 Equity Incentive Scheme shall be authorised, by the administrator. The "administrator" means the Board or one or more committees appointed by the Board or another committee (within its delegated authority) to administer all or certain aspects of the 2023 Equity Incentive Scheme. The administrator may delegate ministerial, non-discretionary functions to individuals who are officers or employees of the Company or any of its affiliates or to third parties.

(e) Awards

The 2023 Equity Incentive Scheme is divided into two separate equity programs: (1) the option grant program under which eligible persons may, at the discretion of the administrator, be granted options, and (2) the share award program under which eligible persons may, at the discretion of the administrator, be awarded restricted or unrestricted Shares or RSUs.

Options*(a) Award agreement and general*

Each option shall be evidenced by an award agreement (the "**Award Agreement**") in the form approved by the administrator. The Award Agreement evidencing an option shall contain the terms established by the administrator for that Award and any other terms, provisions, or restrictions that the administrator

may impose on the option or any Shares subject to the option. The administrator may require that the recipient of an option promptly execute and return to the Company his or her Award Agreement evidencing the Award. In addition, the administrator may require that the spouse of any married recipient of an option also promptly execute and return to the Company the Award Agreement evidencing the Award granted to the recipient or such other spousal consent form that the administrator may require in connection with the grant of the Award.

(b) Price

The administrator will determine the purchase price per share of the Shares covered by each option (the “exercise price” of the option) at the time of the grant of the option, which exercise price will be set forth in the applicable Award Agreement, with the following factors:

- (i) the par value of Share;
- (ii) subject to clause (iii) below, 100% of the fair market value of a Share on the date of grant; or
- (iii) in the case of an option granted to a participant, possessing more than 10% of the total combined voting power of all classes of shares of the Company, 110% of the fair market value of a Share on the date of grant.

(c) Vesting, term and exercise

An option may be exercised only to the extent that it is vested and exercisable. The administrator will determine the vesting and/or exercisability provisions of each option (which may be based on performance criteria, passage of time or other factors or any combination thereof), which provisions will be set forth in the applicable Award Agreement. Unless the administrator otherwise expressly provides, once exercisable an option will remain exercisable until the expiration or earlier termination of the option.

Each option shall expire not more than 10 years after its date of grant. Any exercisable option will be deemed to be exercised when (a) the applicable exercise procedures in the related Award Agreement have been satisfied (or, in the absence of any such procedures in the related Award Agreement, the Company has received written notice of such exercise from the participant), and (b) in the case of an option, the Company has received any required payment, and (c) in the case of an option, the Company has received any written statement.

(d) Termination of employment

Unless otherwise provided in the applicable Award Agreement, if a participant's employment by or service to the Company or any of its affiliates is terminated by such entity for cause, the participant's option will terminate on the participant's severance date, whether or not the option is then vested and/or exercisable.

Share Award Program

(a) General

Each share award shall be evidenced by an Award Agreement in the form approved by the administrator. The Award Agreement evidencing a share award shall contain the terms established by the administrator for that share award, as well as any other terms, provisions, or restrictions (if any) that the administrator may impose on the share award (including, but not limited to, the number of Shares subject to such share award); in each case subject to the applicable provisions and limitations of the 2023 Equity Incentive Scheme. The administrator may require that the recipient of a share award promptly execute and return to the Company his or her Award Agreement evidencing the share award. In addition, the administrator may require that the spouse of any married recipient of a share award also promptly execute and return to the Company the Award Agreement evidencing the share award granted to the recipient or such other spousal consent form that the administrator may require in connection with the grant of the share award.

(b) Price

The administrator will determine the purchase price per share (if any) of the Shares covered by each share awards at the time of grant of the Award.

(c) Vesting, settlement and term

Each share award may or may not be subject to restrictions. Such restrictions may in each case be based on performance criteria, passage of time or other factors or any combination thereof. In respect of each share award, the restrictions (if any) imposed on the Shares applicable to such share award will be set forth in the applicable Award Agreement. In respect of each RSU award, the restrictions and/or vesting conditions applicable to such RSU award will be set forth in the applicable Award Agreement. Unless otherwise set forth in an Award Agreement, a RSU award may, in the discretion of the administrator, be settled in Shares or cash (or a combination thereof).

Any payment of cash or delivery of shares in payment for a share award, if applicable, may be delayed until a future date if specifically authorised by the administrator in writing and by the participant.

(d) Dividend and voting rights

Unless otherwise provided in the applicable Award Agreement, with respect to the share awards, any dividends paid with respect to those shares underlying the share awards shall be subject to the same restrictions (if any) that apply to the shares to which the dividends relate.

With respect shares underlying the RSU awards, the Award Agreement relating to a RSU award may specify whether the holder thereof shall be entitled to receive, on a current or deferred basis, distributions or dividends during the restriction period (and, if determined by the administrator, interest on any such distributions or dividends). Prior to the settlement of a RSU award in Shares, the holder of such RSU award shall have no rights as a shareholder of the Company with respect to the Shares subject to such RSU award. Settlement herein refers to the delivery of Shares or cash (or a combination thereof) to the grantees at the discretion of the administrator after vesting.

(e) Termination of employment

Unless the administrator otherwise expressly provides, share awards or RSUs that in each case remain subject to vesting conditions (if any) that have not been satisfied by the time specified in the applicable Award Agreement (which may include, without limitation, the participant's severance date), will not vest and will be forfeited or reacquired by the Company, as applicable, in such manner and on such terms as the administrator provides, which terms shall include, with respect to those share awards or RSU awards, to the extent not prohibited by law, return or repayment of the lower of (a) the fair market value of the shares underlying such award at the time of the termination, or (b) if applicable, the original purchase price of the shares underlying such award, without interest.

Outstanding options and share awards granted

(a) Options

As of the date of this prospectus, no options have been granted under the 2023 Equity Incentive Scheme.

(b) Share awards

As of the date of this prospectus, our Company had granted outstanding RSU awards under the 2023 Equity Incentive Scheme to 22 grantees for an aggregate of 85,674,265 Shares, representing approximately 10.33% in the total number of Shares in issue immediately after completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).

(c) Dilution impact and earnings per Share

As of the Latest Practicable Date, under the 2023 Equity Incentive Scheme, none of the RSUs had yet become vested and all of the RSUs were outstanding. Assuming full vesting and exercise of all incentive awards under the 2023 Equity Incentive Scheme, the shareholding of our Shareholders immediately following completion of the Global Offering (assuming no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements) will be diluted by approximately 9.95%, representing unvested RSUs with 83,449,265 underlying Shares upon Listing.

There is no consequent impact on the earnings per share of our Company for the years ended 31 December 2022, 2023 and 2024 and immediately following completion of the Global Offering as the options and share awards would not be included in the calculation of diluted earnings per share due to anti-dilution.

Below is a list of the grantees of the outstanding incentive awards under the 2023 Equity Incentive Scheme:

Name of grantee/holding entity nominated by the grantee	Beneficial owner and position held within our Group	Grant date	Award type	Exercise price per option	Vesting Period	Number of shares underlying the award as of the Latest Practicable Date	Number of shares underlying the award immediately following the completion of the Global Offering	Approximate percentage of shareholding of the Shares underlying the awards immediately following the completion of the Global Offering ⁽¹⁾
SG182.1 Waterlily Consultants	Dr. Ni, our Executive Director, Chairman of the Board and chief executive officer	24 May 2025	RSUs	–	5 years ⁽²⁾	20,104,592 Class A Ordinary Shares	20,104,592 Shares	2.40%
SG182.2 Ice Tree LLC	Ms. Leng, spouse of Dr. Ni and hence a connected person	24 May 2025	RSUs	–	5 years ⁽²⁾	4,000,000 Class A Ordinary Shares	4,000,000 Shares	0.48%
SG182.3 V&T	Mr. Dinh, our Executive Director and chief operations officer	24 May 2025	RSUs	–	5 years ⁽²⁾	4,000,000 Class A Ordinary Shares	4,000,000 Shares	0.48%
SG182.4 YDD Consulting	Dr. Yang, our Executive Director and chief scientific officer	24 May 2025	RSUs	–	5 years ⁽²⁾	4,000,000 Class A Ordinary Shares	4,000,000 Shares	0.48%
Abu Abraham, our chief medical officer		26 May 2025	RSUs	–	5 years ⁽²⁾	5,400,000 Class A Ordinary Shares	5,400,000 Shares	0.64%
Elizabeth Capen, our chief patent officer and chief compliance officer		26 May 2025	RSUs	–	5 years ⁽²⁾	5,400,000 Class A Ordinary Shares	5,400,000 Shares	0.64%

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

Name of grantee/holding entity nominated by the grantee	Beneficial owner and position held within our Group	Grant date	Award type	Exercise price per option	Vesting Period	Number of shares underlying the award as of the Latest Practicable Date	Number of shares underlying the award immediately following the completion of the Global Offering	Approximate percentage of shareholding of the Shares underlying the awards immediately following the completion of the Global Offering ⁽¹⁾
Wenkui Fang, our chief innovation officer		26 May 2025	RSUs	–	5 years ⁽²⁾	2,000,000 Class A Ordinary Shares	2,000,000 Shares	0.24%
Cao Feng, senior vice president, business development (China)		26 May 2025	RSUs	–	5 years ⁽³⁾	4,269,673 Class A Ordinary Shares	4,269,673 Shares	0.51%
World Leader Investments Limited	Yang Mo, senior vice president, hospital use (eye care)	9 June 2025	RSUs	–	5 years ⁽⁴⁾	4,200,000 Class A Ordinary Shares	4,200,000 Shares	0.50%
Coining UN Limited	Ka Dung Kam, senior vice president, artificial intelligence and eye care	9 June 2025	RSUs	–	5 years ⁽⁴⁾	4,200,000 Class A Ordinary Shares	4,200,000 Shares	0.50%
Hyperion Consulting International Limited	Daniel Sun, senior vice president, business development (Europe and Middle East)	9 June 2025	RSUs	–	5 years ⁽⁴⁾	4,200,000 Class A Ordinary Shares	4,200,000 Shares	0.50%
Long Data Technology (China) Limited	Kong Chi Hung, senior vice president, business development (Asia except for China)	9 June 2025	RSUs	–	5 years ⁽⁴⁾	4,200,000 Class A Ordinary Shares	4,200,000 Shares	0.50%
Prosperity Capital Investment Limited	Cheuk Wai Thomas Lee, senior vice president, corporate risk management	9 June 2025	RSUs	–	5 years ⁽⁴⁾	3,600,000 Class A Ordinary Shares	3,600,000 Shares	0.43%
Falanni International Limited	Andy Lin, vice president, medical affairs (Asia except for China)	9 June 2025	RSUs	–	5 years ⁽⁴⁾	3,600,000 Class A Ordinary Shares	3,600,000 Shares	0.43%
Top Star Limited	Edward Lau, vice president, medical affairs (China)	9 June 2025	RSUs	–	5 years ⁽⁴⁾	3,600,000 Class A Ordinary Shares	3,600,000 Shares	0.43%
Silver Genius Development Limited	Wing Sang Lo, investment committee director	9 June 2025	RSUs	–	5 years ⁽⁴⁾	3,000,000 Class A Ordinary Shares	3,000,000 Shares	0.36%
Rich Linkage Holdings Limited	Hoi Wang Kwan, vice president, global capital market strategist	9 June 2025	RSUs	–	5 years ⁽⁴⁾	2,700,000 Class A Ordinary Shares	2,700,000 Shares	0.32%
Elements Form Limited	Greg Hansen, vice president, business intelligence	9 June 2025	RSUs	–	5 years ⁽⁴⁾	2,400,000 Class A Ordinary Shares	2,400,000 Shares	0.29%
Tao Zhang, research & development director		26 May 2025	RSUs	–	5 years ⁽⁵⁾	300,000 Class A Ordinary Shares	300,000 Shares	0.04%

Name of grantee/holding entity nominated by the grantee	Beneficial owner and position held within our Group	Grant date	Award type	Exercise price per option	Vesting Period	Number of shares underlying the award as of the Latest Practicable Date	Number of shares underlying the award immediately following the completion of the Global Offering	Approximate percentage of shareholding of the Shares underlying the awards immediately following the completion of the Global Offering ⁽¹⁾
Fung Nga Fong, financial controller and company secretary		26 May 2025	RSUs	–	5 years ⁽⁵⁾	200,000 Class A Ordinary Shares	200,000 Shares	0.02%
Xiaoqiang Qiu, manufacturing facility head		26 May 2025	RSUs	–	5 years ⁽⁵⁾	200,000 Class A Ordinary Shares	200,000 Shares	0.02%
Dongxue Fan, global human resources head		26 May 2025	RSUs	–	5 years ⁽⁵⁾	100,000 Class A Ordinary Shares	100,000 Shares	0.01%

- (1) Calculated based on 838,892,874 Shares in issue immediately after completion of the Global Offering (assuming that no Shares are further issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).
- (2) 20% of the RSUs will vest on each of the next five anniversaries of the Listing Date, conditional on a successful and Listing and provided that the grantee remains employed by our Company or its affiliate and have not resigned or been terminated by our Company or any reason on the relevant vesting date. If the grantee leaves our Company in any circumstance, unvested RSUs shall be forfeited.
- (3) RSUs with 120,000 underlying shares will immediately vest upon Listing and be automatically issued as Shares; RSUs with 3,969,673 underlying shares will vest on the date which is six months after Listing and be automatically issued as Shares, and RSUs with 36,000 underlying shares will vest on each of the next five anniversaries of the Listing Date and be automatically issued as Shares, provided that the grantee remains employed by our Company and/or our affiliate(s) and has not resigned or been terminated by our Company and/or our affiliate(s) for any reason on the relevant vesting date. If the grantee leaves our Company and/or our affiliate(s) in any circumstance, unvested RSUs shall be forfeited.
- (4) 5% of the RSUs will immediately vest upon Listing and be automatically issued as Shares; 5% of the RSUs will vest upon the expiration of each of three months, six months and nine months from the Listing Date and be automatically issued as Shares; whereas the remaining 80% of the RSUs will vest in five equal tranches of 16% each of the first five anniversaries of the date of grant and be automatically issued as Shares and subject to fulfilment of key performance indicator(s) or other performance criteria to be determined by the Board (or its delegate) in its sole discretion, provided that the grantee remains employed by our Company and/or our affiliate(s) and has not resigned or been terminated by our Company and/or our affiliate(s) for any reason on the relevant vesting date. If the grantee leaves our Company and/or our affiliate(s) in any circumstance, unvested RSUs shall be forfeited. If a certain specified event occurs according to the terms of such grant, shares issued under such grant shall be forfeited, or the grantee shall pay to our Company the equivalent value of such Shares in cash as at the Listing Date in lieu of the forfeiture within ten business days, and all unvested RSUs shall be unconditionally forfeited.

- (5) 40% of the RSUs will immediately vest upon Listing and be automatically issued as Shares; while 12% of the RSUs will vest on each of the next five anniversaries of the Listing Date and be automatically issued as Shares, provided that the grantee remains employed by our Company and/or our affiliate(s) and has not resigned or been terminated by our Company and/or our affiliate(s) for any reason on the relevant vesting date. If the grantee leaves our Company and/or our affiliate(s) in any circumstance, unvested RSUs shall be forfeited. If a certain specified event occurs according to the terms of such grant, shares issued under such grant shall be forfeited, or the grantee shall pay to our Company the equivalent value of such Shares in cash as at the Listing Date in lieu of the forfeiture within ten business days, and all unvested RSUs shall be unconditionally forfeited.

4. Post-IPO Equity Incentive Scheme

A summary of the principal terms of the Post-IPO Equity Incentive Scheme conditionally approved and adopted in compliance with Chapter 17 of the Listing Rules by resolution of our Shareholders on 14 March 2025 is as follows.

(a) Purpose

The purpose of the Post-IPO Equity Incentive Scheme is to incentivise and reward the Eligible Participants (as defined below) for their contribution to the Group and to align their interests with that of our Company so as to encourage them to work towards enhancing the value of our Company.

(b) Eligible Participants

The Board (which expression shall, for the purpose of this paragraph, include the Board or a duly authorised committee thereof) may, at its absolute discretion, offer to grant an option or a share award to subscribe for such number of Shares as the Board may determine to (a) an employee (whether full time or part-time) or an officer or director of our Company or any of its subsidiaries (the “**Eligible Employee(s)**”) and (b) a consultant or adviser who provides services to the Group on a continuing and recurring basis in its ordinary and usual course of business which are material to the long term growth of the Group (“**Service Provider(s)**”, together with the Eligible Employees referred as the “**Eligible Participant(s)**”).

For the avoidance of doubt, Service Providers shall exclude placing agents or financial advisers providing advisory services for fundraising, mergers or acquisitions, and any professional service providers such as auditors or valuers.

The eligibility of any Eligible Employees shall be determined by the Board from time to time on the basis of the Board’s opinion as to, among others, the participant’s individual performance, time commitment, responsibilities or employment conditions according to the prevailing market practice and industry standard, the length of engagement with the Group and the actual or potential contribution to the development and growth of the Group. The eligibility of any Service Providers shall be determined by the Board from time to time on the basis of the Board’s opinion as to, among others, their contribution to the development and growth of the Group, the prevailing market practice and industry standard, the

actual degree of involvement in and/or cooperation with the Group and length of collaborative relationship the Service Providers has established with the Group, and the amount of support, assistance, guidance, advice, efforts and contributions the Service Providers has exerted and given towards the success of the Group, and/or whether the person is regarded as a valuable consultant of the Group, taking into account the knowledge, experience, qualification, expertise and reputation of the Service Providers or other relevant factors (including without limitation technical know-how, market competitiveness, synergy between him/her and the Group and his/her strategic value).

(c) *Maximum number of Shares*

- (i) Subject to paragraphs (iv) and (v) below, the total number of Shares which may be issued upon exercise of all options and share awards to be granted under the Post-IPO Equity Incentive Scheme shall not in aggregate exceed 10% of the relevant class of Shares in issue on the day on which trading of the Shares commences on the Stock Exchange (the “**Scheme Mandate Limit**”), being 83,889,287 Shares (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements). Options and share awards lapsed in accordance with the terms of the Post-IPO Equity Incentive Scheme will not be counted for the purpose of calculating the Scheme Mandate Limit.
- (ii) Subject to paragraph (i) above, within the Scheme Mandate Limit, the total number of Shares which may be issued upon exercise of all options and share awards to be granted to Service Providers shall not exceed 1% of the relevant class of Shares in issue on the day on which trading of the Shares commences on the Stock Exchange, being 8,388,928 Shares (the “**Service Providers Sublimit**”) (excluding the Shares which may be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme, except for those RSUs that immediately become vested upon the Listing pursuant to the Equity Incentive Arrangements).
- (iii) Subject to paragraph (iv) below, the Scheme Mandate Limit and the Service Providers Sublimit may be refreshed at any time after three years from the date of Shareholders’ approval for the last refreshment (or the date on which the Post-IPO Equity Incentive Scheme is adopted, as the case may be) by approval of its Shareholders in general meeting provided that (1) any controlling shareholders and their associates (or if there is no controlling shareholder, directors (excluding independent non-executive directors) and the chief executive of our Company and their respective associates) must abstain from voting in favour of the relevant resolution at the general meeting; and (2) our Company must comply with the requirements under Rules 13.39(6), 13.39(7), 13.40,

13.41 and 13.42 of the Listing Rules. The requirements under (1) and (2) of this paragraph do not apply if the refreshment is made immediately after an issue of securities by our Company to the Shareholders on a pro rata basis as set out in Rule 13.36(2)(a) of the Listing Rules such that the unused part of the plan mandate (as a percentage of the relevant class of Shares in issue) upon refreshment is the same as the unused part of the plan mandate immediately before the issue of securities, rounded to the nearest whole Share.

- (iv) The total number of Shares which may be issued upon exercise of all options and share awards to be granted under the Post-IPO Equity Incentive Scheme and any other plans of our Company under the plan mandate as refreshed must not exceed 10% of the relevant class of Shares in issue as of the date of approval of the refreshed plan mandate.
- (v) Without prejudice to paragraph (iv) above, our Company may seek separate Shareholders' approval in a general meeting to grant options and/or share awards beyond the Scheme Mandate Limit to participants specifically identified by our Company before such approval is sought. In such event, our Company must send a circular to its Shareholders containing a general description of the specified participants, the number and terms of options and/or share awards to be granted, the purpose of granting options and/or share awards to the specified participants with an explanation as to how the terms of the options and/or share awards will serve such purpose and all other information required under the Listing Rules.

(d) Maximum entitlement of a grantee

Where any grant of options or share awards to a participant would result in the Shares issued and to be issued upon exercise of all options and/or share awards granted and to be granted to such participant (excluding any options and share awards lapsed in accordance with the terms of the Post-IPO Equity Incentive Scheme) in the 12-month period up to and including the date of such grant representing in aggregate over 1% of the relevant class of Shares in issue, such grant must be separately approved by the Shareholders in general meeting with such participant and his/her close associates (or his/her associates if the participant is a connected person) abstaining from voting. The number and terms (including the exercise price) of options and/or share awards to be granted to such participant must be fixed before Shareholders' approval.

(e) Grant and exercise of options and share awards

The Board or a duly authorised committee thereof may in its absolute discretion specify such event, time limit or conditions (if any) as it thinks fit when making such offer to the Eligible Participants, including, without limitation, conditions as to performance criteria (such as growth rate of revenue, earnings per

share and/or total shareholders' return) to be satisfied or achieved by the Eligible Participants and/or our Company and/or the Group which must be satisfied before an option or a share award can be exercised. An offer of the grant of an option or a share award shall be made to any Eligible Participants by letter in such form as the Board or a duly authorised committee thereof may from time to time determine specifying the number of Shares, the vesting period, the subscription price, the option period, the date by which the grant must be accepted and further requiring the Eligible Participants to hold the option or share award on the terms on which it is to be granted and to be bound by the provisions of the Post-IPO Equity Incentive Scheme. An option or a share award shall be deemed to have been granted and accepted and to have taken effect when the duplicate letter comprising acceptance of the offer of the grant of the option or share award duly signed by the grantee together with a payment to our Company and/or any of its subsidiaries of HK\$1 (or the equivalent of HK\$1 in the local currency of any jurisdiction where our Company and/or its subsidiaries operate, as the Board or a duly authorised committee thereof may in its absolute discretion determine) by way of consideration for the grant thereof is received by our Company within the time period specified in the offer of the grant of the option or share award.

An option or a share award shall be personal to the grantee and shall not be assignable and no grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest in favour of any third party over or in relation to any option or share award. Any breach of the foregoing by the grantee shall entitle our Company to cancel any outstanding entitlement of such grantee.

An option may be exercised in accordance with the terms of the Post-IPO Equity Incentive Scheme at any time during a period to be determined and notified by the Board to each grantee, which period may commence on a day falling at least 12 months after the date upon which the offer for the grant of options is made but shall end in any event not later than 10 years from the date on which an option is offered to a participant, subject to the provisions for early termination under the Post-IPO Equity Incentive Scheme. The minimum period for which an option or a share award must be held before it can be vested or exercised (if applicable) shall be 12 months from the date of grant of such option or share award, except that any options or share awards granted to an Eligible Employee may be subject to a short vesting period, including where:

- (i) grants of "make-whole" options or a share awards to new Eligible Employee(s) to replace options or share awards such Eligible Participant(s) forfeited when leaving their previous employers;
- (ii) grants to an Eligible Participant whose employment is terminated due to death or disability or event of force majeure;
- (iii) grants of options or share awards which are subject to fulfilment of performance targets as determined in the conditions of his/her grant;

- (iv) grants of options or share awards the timing of which is determined by administrative or compliance requirements, in which case the vesting date may be adjusted to take account of the time from which the options or share awards would have been granted if not for such administrative or compliance requirements;
- (v) grants of options or share awards with a mixed vesting schedule such as the options or share awards vest evenly over a period of 12 months; and
- (vi) grants of options or share awards with a total vesting and holding period of more than 12 months, such as where the options or share awards may vest by several batches with the first batch to vest within 12 months of the grant date and the last batch to vest 12 months after the date of grant of such options or share awards.

(f) Subscription price

The amount payable for each Share to be subscribed for under an option (the “**Subscription Price**”) in the event of the option being exercised shall be determined by the Board or a duly authorised committee thereof at its absolute discretion, which shall be not less than the highest of:

- (i) the nominal value of a Share;
- (ii) the closing price of the Shares as stated in the Stock Exchange’s daily quotations sheet on the date of grant, which must be a business day; and
- (iii) the average closing price of the Shares as stated in the Stock Exchange’s daily quotations sheets for the five business days immediately preceding the date of grant.

The amount payable for each Share to be subscribed for under a share award (the “**Purchase Price**”) shall be determined by the Board or a duly authorised committee thereof at its absolute discretion, based on considerations such as the prevailing closing price of the Shares, the purpose of the share award and the contribution of the Eligible Participant.

(g) Options and share awards granted to connected persons

- (i) Any grant of options or share awards to a director, chief executive or substantial shareholder of the Company, or any of their associates must be approved by the independent non-executive Directors (excluding any independent non-executive Director who is the grantee of the options or share awards).

- (ii) Where any grant of share awards (excluding grant of options) to a director (other than an independent non-executive Director) or chief executive of the Company, or any of their associates would result in the shares issued and to be issued in respect of all share awards granted (excluding any share awards lapsed in accordance with the terms of the Post-IPO Equity Incentive Scheme) to such person in the 12-month period up to and including the date of such grant, representing in aggregate over 0.1% of the Shares in issue, such further grant of share awards must be approved by the Shareholders at a general meeting of our Company, with voting to be taken by way of poll.
- (iii) Where any grant of options or share awards to an independent non-executive Director or a substantial shareholder of our Company or any of their respective associates would result in the Shares issued and to be issued in respect of all options and awards granted (excluding any options lapsed in accordance with the terms of the Post-IPO Equity Incentive Scheme) under the Post-IPO Equity Incentive Scheme and any other plans of our Company to such person in the 12-month period up to and including the date of such grant representing in aggregate over 0.1% of the Shares in issue, such further grant of options or share awards must be approved by the Shareholders at a general meeting of our Company, with voting to be taken by way of poll.

Our Company shall send a circular to the Shareholders containing all information as required under the Listing Rules in this regard. The grantee, his/her associates and all core connected persons (as defined in the Listing Rules) of our Company shall abstain from voting (except where any core connected person intends to vote against the proposed grant and his/her intention to do so has been stated in the aforesaid circular). Any change in the terms of an option or a share award granted to a Director, a chief executive, a substantial shareholder of our Company or an independent non-executive Director or any of their respective associates is also required to be approved by Shareholders in the aforesaid manner if the initial grant of the options or share awards requires such approval.

(h) Restriction of grant of options and share awards

No option or share awards shall be offered or granted:

- (i) to any Eligible Participant after a price sensitive event has occurred or a price sensitive matter has been the subject of a decision, until (and including) the trading day after the relevant price sensitive or inside information has been announced in accordance with the applicable provisions of law or the Listing Rules;
- (ii) to any Eligible Participant during the period commencing one month immediately before the following (whichever is earlier):

- (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of our Company's annual, quarterly (if any) or half-yearly results; and
- (b) the deadline for our Company to publish an announcement of its annual, quarterly (if any) or half-yearly results;

and ending on the date of the results announcement. No option or share award shall be granted during any period of delay in the publication of a results announcement;

- (iii) to any Director (except where the Subscription Price is to be determined by the Board or a duly authorised committee thereof at the time of exercise of the option):
 - (a) during the period of 60 days immediately preceding the publication of the annual results of our Company or, if shorter, the period from the end of the relevant financial year up to the publication date of the results; or
 - (b) during the period of 30 days immediately preceding the publication of the quarterly (if any) or half-yearly results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results.

(i) Lapse of options and share awards

Any option or share award shall elapse automatically and not be exercisable on the earliest of:

- (i) the expiry of the option period or other applicable exercisable periods under the Post-IPO Equity Incentive Scheme;
- (ii) the expiry of the periods or the occurrence of the relevant event referred to in paragraphs (m)(i) and (m)(iii) below;
- (iii) subject as provide in the Post-IPO Equity Incentive Scheme, the date of the commencement of the winding-up of our Company;
- (iv) the date on which the grantee commits a breach of relevant clauses that rights are personal to the grantee; or
- (v) the occurrence or non-occurrence of any event, expiry of any period, or non-satisfaction of any condition, as specified in the letter containing the offer or grant of the relevant option or share award.

(j) Voting and dividend rights

No grantee shall enjoy any of the rights of a Shareholder (including but not limited to voting, dividend, transfer rights or any other rights attached to a Share) by virtue of the grant of an option or a share award pursuant to the Post-IPO Equity Incentive Scheme, unless and until the registration of the grantee (or such other person as may succeed to the grantee's title by operation of applicable laws and in compliance with the terms of the Post-IPO Equity Incentive Scheme) as the holder thereof.

(k) Effects of alterations in the capital structure of our Company

In the event of a capitalisation issue, rights issue, subdivision or consolidation of Shares or reduction of capital of our Company whilst an option or a share award remains outstanding, such corresponding adjustment (if any) certified by the auditors for the time being of or an independent financial adviser to our Company as fair and reasonable will be made to (a) the number of Shares to which the option or the share award relates, so far as outstanding, and/or (b) the Subscription Price of any outstanding option and the Purchase Price of any share awards, provided that (i) any such alteration shall give a grantee the same proportion of the issued share capital (rounded to the nearest whole Share) to which the grantee was entitled prior to such alteration; (ii) any such adjustments shall be made on the basis that the aggregate Subscription Price and Purchase Price payable by a grantee on the full exercise of any option or share award shall remain as nearly as possible the same as it was before such event; and (iii) no adjustment shall be made the effect of which would be to enable a Share to be issued at less than its nominal value. In addition, in respect of any such adjustments, other than any adjustment made on a capitalisation issue, such auditors or independent financial adviser must confirm to the Board in writing that the adjustments comply with the relevant provisions of the Listing Rules (or any guideline or supplementary guideline as may be issued by the Stock Exchange from time to time).

(l) Rights on ceasing employment, death, or dismissal

- (i) If the grantee of an option or a share award is an employee and ceases to be an employee for any reason other than death, or for serious misconduct or other grounds referred to in sub-paragraph (iii) below before exercising his/her option or share award in full, the option or share award (to the extent not already exercised) will lapse automatically on the date of cessation of his/her employment or engagement with the Group.
- (ii) If the grantee of an option or a share award is an employee and ceases to be an employee by reason of his/her death, before exercising the option or share award in full, his/her legal personal representative(s), or, as appropriate, the grantee may exercise the option or share award (to the extent not already exercised) in whole or in part within a period of 12 months following the date of death of the grantee.

- (iii) If the grantee of an option or a share award is an employee and ceases to be an employee by reason that he has been guilty of serious misconduct or has committed any act of bankruptcy or has become insolvent or has made any arrangement or composition with his/her creditors generally, or has been convicted of any criminal offense involving his/her integrity or honesty or (if so determined by the Board) on any other ground on which an employer would be entitled to terminate his/her employment summarily, his/her option or share award will lapse automatically on the date of cessation of his/her employment with the Group.

(m) Rights on takeover and plans of compromise or arrangement

If a general or partial offer (whether by way of take-over offer, share repurchase offer or otherwise in like manner other than by way of a plan of arrangement) is made to all the holders of Shares (or all such holders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or in concert with the offeror) our Company shall use its best endeavors to procure that such offer is extended to all the grantees (on the same terms mutatis mutandis, and assuming that they will become, by the exercise in full of the options and/or share awards granted to them, Shareholders of our Company). If such offer becomes or is declared unconditional, the grantee (or his/her legal personal representative(s)) shall be entitled to exercise the grantee's outstanding entitlement in full at any time within 14 days after the date on which such general offer becomes or is declared unconditional.

(n) Rights on a voluntary winding-up

In the event of an effective resolution being passed for the voluntary winding-up of our Company or an order of the court being made for the winding-up of our Company, notice thereof shall be given by our Company to grantees with options and/or share awards outstanding in full or in part at such date. If a grantee immediately prior to such event had any outstanding entitlement, the grantee (or his legal personal representative(s)) may by notice in writing to our Company within 21 days after the date of such resolution elect to be treated as if the entitlement had been exercised immediately before the passing of such resolution either to its full extent or to the extent specified in the notice, such notice to be accompanied by a remittance for the full amount of the aggregate Subscription Price or Purchase Price for the Shares in respect of which the notice is given, whereupon the grantee shall be duly transferred with the relevant Shares (or treated as such by our Company) and entitled to receive out of the assets available in the liquidation pari passu with the holders of Shares such sum as would have been received in respect of the Shares that are the subject of such election.

(o) Ranking of Shares

The Shares underlying the options and the share awards will be subject to all the provisions of the Articles of Association of our Company for the time being in force and will rank pari passu with the fully paid Shares in issue on the date of such transfer and accordingly will entitle the holders to participate in all dividends and other distributions paid or made on or after the date of such transfer other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date therefor falls before the date of such transfer.

(p) Duration

The Post-IPO Equity Incentive Scheme shall be valid and effective for a period of 10 years commencing on the date when the Post-IPO Equity Incentive Scheme becomes unconditional, after which period no further options or share awards will be granted by the provisions of the Post-IPO Equity Incentive Scheme, but the provisions of the Post-IPO Equity Incentive Scheme shall remain in full force and effect to the extent necessary to give effect to the exercise of any options or share awards granted prior thereto or otherwise as may be required in accordance with the provisions of the Post-IPO Equity Incentive Scheme.

(q) Alteration of the Plan

The Board may subject to the rules of the Post-IPO Equity Incentive Scheme amend any of the provisions of the Post-IPO Equity Incentive Scheme at any time (but not so as to affect adversely any rights which have accrued to any grantee at that date).

Any alterations to the terms and conditions of the Post-IPO Equity Incentive Scheme which are of a material nature, and any change to the terms of any options or share awards granted to the advantage of Eligible Participants, shall be subject to the approval of the Shareholders in general meeting and, where required under the Listing Rules, the Stock Exchange.

Any change to the terms of options or share awards granted to a Eligible Participant must be approved by the Board, the remuneration committee, the independent non-executive Directors and/or the Shareholders (as the case may be) if the initial grant of the options or share awards was approved by the Board, the remuneration committee, the independent non-executive Directors and/or the Shareholders (as the case may be). Such requirement does not apply where the alterations take effect automatically under the existing terms of the Post-IPO Equity Incentive Scheme.

(r) Cancellation of options and share awards

Any cancellation of options or share awards granted may be effected on such terms as may be agreed with the relevant grantee, as the Board may in its absolute discretion sees fit and in a manner that complies with all applicable legal requirements for such cancellation. Where our Company cancels options and/or share awards granted to a participant and makes a new grant to the same participant, such new grant may only be made under the Post-IPO Equity Incentive Scheme with available Scheme Mandate Limit approved by the Shareholders. The options or share awards cancelled will be regarded as utilised for the purpose of calculating the Scheme Mandate Limit.

(s) Clawback

The Board may, at its absolute discretion, determine such malus and/or clawback provisions to be applied to an option and a share award or an offer of grant so as to provide, upon the occurrence of the applicable malus and/or clawback event(s) such as serious misconduct, a material misstatement in our Company's financial statements and fraud. If the Board exercises its discretion under this paragraph, it will give the relevant grantee written notice of such determination and the Board's interpretation of and determination pursuant to this paragraph shall be final, conclusive and binding.

(t) Termination

Our Company by resolution in general meeting or the Board may at any time terminate the operation of the Post-IPO Equity Incentive Scheme and in such event no further options or share awards will be offered but the provisions of the Post-IPO Equity Incentive Scheme shall remain in full force in all other respects. All options and share awards granted prior to such termination shall continue to be valid and exercisable in accordance with the terms of the Post-IPO Equity Incentive Scheme.

(u) Value of option and share awards

Our Directors consider it inappropriate to disclose the value of options and/or share awards which may be granted under the Post-IPO Equity Incentive Scheme as if they had been granted as of the Latest Practicable Date. Any such valuation will have to be made on the basis of a certain option and/or share awards pricing model or other method that depends on various assumptions including the exercise price, the exercise period, interest rate, expected volatility and other variables. As no options or share awards have been granted under the Post-IPO Equity Incentive Scheme, certain variables are not available for calculating the value of options or share awards. Our Directors believe that any calculation of the value of options and share awards granted as of the Latest Practicable Date would be based on a number of speculative assumptions that are not meaningful and would be misleading to investors.

(v) *General*

As of the Latest Practicable Date, no options or share awards had been granted or agreed to be granted under the Post-IPO Equity Incentive Scheme.

E. OTHER INFORMATION

1. Estate duty

Our Directors have been advised that no material liability for estate duty is likely to fall on any member of our Group in the Cayman Islands, Hong Kong and other jurisdictions in which the companies comprising our Group are incorporated.

2. Litigation

Save as disclosed in “Business – Legal and Regulatory Matters – Legal Proceedings and Compliance” in this prospectus, as of the Latest Practicable Date, neither our Company nor any of our subsidiaries was engaged in any litigation or arbitration of material importance, and no litigation or claim of material importance was known to our Directors to be pending or threatened against our Company or any of our subsidiaries, that would have a material adverse effect on our results of operations or financial conditions.

3. Joint Sponsors

The Joint Sponsors have made an application on behalf of our Company to the Listing Committee of the Stock Exchange for the listing of, and permission to deal in, our Shares in issue and to be issued as mentioned in this prospectus (including the Shares to be issued pursuant to the Equity Incentive Arrangements and the Post-IPO Equity Incentive Scheme).

The Joint Sponsors satisfy the independence criteria applicable to sponsors under Rule 3A.07 of the Listing Rules. The Joint Sponsors are entitled to the sponsor’s fee in the amount of US\$600,000.

4. Preliminary expenses

The preliminary expenses of our Company are approximately US\$1,000 and are payable by our Company.

5. Promoter

- (a) Our Company has no promoter for the purpose of the Listing Rules.
- (b) Save as disclosed herein, within the two years immediately preceding the date of this prospectus, no cash, securities or other benefit had been paid, allotted or given, nor are any such cash, securities or other benefit intended to be paid, allotted or given to the promoter in connection with the Global Offering or the related transactions described in this prospectus.

6. Qualifications of experts

The qualifications of the experts who have given opinions and/or whose names are included in this prospectus are as follows:

Name:	Qualifications
CCB International Capital Limited	A licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 4 (advising on securities), and Type 6 (advising on corporate finance) of the regulated activities under the SFO
Huatai Financial Holdings (Hong Kong) Limited	A licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 3 (leveraged foreign exchange trading), Type 4 (advising on securities), Type 6 (advising on corporate finance), Type 7 (providing automated trading services) and Type 9 (asset management) of the regulated activities under the SFO
Frost & Sullivan Limited	Industry consultant
Haiwen & Partners	Legal advisers to our Company as to PRC laws
Harney Westwood & Riegels	Legal advisers to our Company as to Cayman Islands laws
JunHe LLP Shanghai Office	Legal advisers to our Company as to PRC intellectual property laws

Jun He Law Offices P.C.

Legal adviser to our Company as to U.S. intellectual property laws

PricewaterhouseCoopers

Certified Public Accountants under Professional Accountants Ordinance (Chapter 50 of the Laws) and Registered Public Interest Entity Auditor under Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)

7. Consents of experts

Each of the experts named in “E. Other Information – 6. Qualifications of experts” in this appendix has given and has not withdrawn its respective written consent to the issue of this prospectus with copies of its reports and/or letters and/or opinions (as the case may be) and/or the references to its name included herein in the form and context in which they are respectively included.

None of the experts named in “E. Other Information – 6. Qualifications of experts” in this appendix has any shareholding interests in any member of our Group or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

8. Binding effect

This prospectus shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

9. Share registrar

Our Company’s principal register of members will be maintained in the Cayman Islands by our Principal Share Registrar, Harneys Fiduciary (Cayman) Limited, and a register of members will be maintained in Hong Kong by our Hong Kong Share Registrar, Tricor Investor Services Limited. Unless our Directors otherwise agree, all transfers and other documents of title of the Shares must be lodged for registration with and registered by our share registrar in Hong Kong and may not be lodged in the Cayman Islands.

10. Bilingual prospectus

The English language and Chinese language versions of this prospectus are being published separately in reliance upon the exemption provided by section 4 of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong). In case of any discrepancies between the English language version and the Chinese language version, the English language version shall prevail.

11. Miscellaneous

Save as disclosed in this prospectus:

- (a) within the two years immediately preceding the date of this prospectus:
 - (i) no share or loan capital of our Company or of any of our subsidiaries has been issued, agreed to be issued or is proposed to be issued fully or partly paid either for cash or for a consideration other than cash; and
 - (ii) save for commissions paid with respect to the Series C Financing and as disclosed in “Underwriting – Underwriting Arrangement and Expenses – International Offering – Commissions and expenses” in this prospectus, there are no commissions, discounts, brokerages or other special terms granted in connection with the issue or sale of any capital of any member of our Group;
 - (iii) no commission has been paid or payable (except commission to the Underwriters, but not including commission to sub-underwriters) for subscribing or agreeing to subscribe, or procuring or agreeing to procure subscriptions, for any Shares or any shares of our subsidiaries; and
 - (iv) no founder shares, management shares or deferred shares or any debentures in our Company or any of our subsidiaries have been issued or agreed to be issued;
- (b) no share, warrant or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
- (c) none of the equity and debt securities of our Company, if any, is listed or dealt with in any other stock exchange nor is any listing or permission to deal being or proposed to be sought;
- (d) all necessary arrangements have been made enabling the Shares to be admitted into CCASS;
- (e) our Company has no outstanding convertible debt securities or debentures;
- (f) our Directors confirm that none of them shall be required to hold any Shares by way of qualification and none of them has any interest in the promotion of our Company;
- (g) our Directors confirm that there has been no material adverse change in the financial or trading position or prospects of our Group since 31 December 2024 (being the date to which the latest audited combined financial statements of our Group were made up);

- (h) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months immediately preceding the date of this prospectus;
- (i) there is no restriction affecting the remittance of profits or repatriation of capital into Hong Kong and from outside Hong Kong;
- (j) there is no arrangement under which future dividends are waived or agreed to be waived; and
- (k) none of the persons named in “– E. Other Information – 6. Qualifications of experts” in this appendix is interested beneficially or otherwise in any shares of any member of our Group or has any right or option (whether legally enforceable or not) to subscribe for or nominate persons to subscribe for any securities in any member of our Group.

APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE FOR INSPECTION

1. DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this prospectus and delivered to the Registrar of the Companies in Hong Kong for registration were:

- (a) a copy of each of the material contracts referred to in “Statutory and General Information – B. Further Information about the Business of our Group – 1. Summary of material contracts” set out in Appendix IV to this prospectus; and
- (b) the written consents referred to in “Statutory and General Information – E. Other Information – 7. Consents of experts” set out in Appendix IV to this prospectus.

2. DOCUMENTS ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and our Company’s website at www.cloudbreakpharma.com during a period of 14 days from the date of this prospectus:

- (a) our Memorandum and Articles of Association;
- (b) the Accountant’s Report of our Group for the years ended 31 December 2022, 2023 and 2024 issued by PricewaterhouseCoopers, the text of which is set out in Appendix I to this prospectus;
- (c) the report on the unaudited pro forma financial information of our Group issued by PricewaterhouseCoopers, the text of which is set out in Appendix II to this prospectus;
- (d) the audited consolidated financial statements of our Company for the years ended 31 December 2022, 2023 and 2024;
- (e) the legal opinions issued by Haiwen & Partners, our PRC Legal Advisers, in respect of certain aspects of our Group in the PRC;
- (f) the legal opinions issued by JunHe LLP Shanghai Office and Jun He Law Offices P.C., our legal advisers as to PRC and U.S. intellectual property law, respectively, in respect of the intellectual property of our Group;
- (g) the letter of advice issued by Harney Westwood & Riegels, our Cayman Islands legal advisers, in respect of certain aspects of the Cayman Companies Act referred to set out in Appendix III to this prospectus;
- (h) the Cayman Companies Act;
- (i) the industry report prepared by Frost & Sullivan, as set out in “Industry Overview” in this prospectus;

APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE FOR INSPECTION

- (k) the material contracts referred to in “Statutory and General Information – B. Further Information about the Business of our Group – 1. Summary of material contracts” set out in Appendix IV to this prospectus;
- (l) the written consents referred to in “Statutory and General Information – E. Other Information – 7. Consents of experts” set out in Appendix IV to this prospectus;
- (m) the service contract and letters of appointment with our Directors referred to in “Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 3. Particulars of service agreements and letters of appointment” set out in Appendix IV to this prospectus;
- (n) terms of the 2023 Equity Incentive Scheme; and
- (o) terms of the Post-IPO Equity Incentive Scheme.



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