

# 科濟藥業控股有限公司 CARSGEN THERAPEUTICS HOLDINGS LIMITED

(Incorporated in the Cayman Islands with limited liability) Stock Code : 2171.HK





# CONTENTS

Corporate Information	2
Chairman's Statement	3
Financial Highlights	5
Business Highlights	6
Management Discussion & Analysis	8
Directors and Senior Management	28
Directors' Report	34
Corporate Governance Report	69
Environmental, Social and Governance Report	88
Independent Auditor's Report	137
Consolidated Statement of Profit or Loss and Other Comprehensive Income	142
Consolidated Statement of Financial Position	143
Consolidated Statement of Changes in Equity	145
Consolidated Statement of Cash Flows	146
Notes to the Consolidated Financial Statements	148
Financial Summary	212
Forward-Looking Statements	213
Definitions	214
Glossary	217

# **Corporate Information**

# **BOARD OF DIRECTORS**

#### **Executive Directors**

Dr. Zonghai LI *(Chairman)* Dr. Huamao WANG Dr. Hua JIANG

#### **Non-executive Directors**

Mr. Bingsen GUO Mr. Ronggang XIE Mr. Huaqing GUO

#### **Independent Non-executive Directors**

Dr. Chunhai FAN (resigned on January 11, 2023) Dr. Guangmei YAN Mr. Tak Young SO (resigned on June 30, 2023) Dr. Huabing LI (appointed on March 9, 2023) Ms. Xiangke ZHAO (appointed on July 4, 2023)

#### **CORPORATE HEADQUARTERS**

1F, Building 2, No. 466 Yindu Road Xuhui District Shanghai PRC

# PRINCIPAL PLACE OF BUSINESS IN HONG KONG

5/F, Manulife Place, 348 Kwun Tong Road, Kowloon Hong Kong

#### **REGISTERED OFFICE**

P.O. Box 31119 Grand Pavilion Hibiscus Way 802 West Bay Road Grand Cayman KY1-1205 Cayman Islands

# PRINCIPAL SHARE REGISTRAR AND TRANSFER OFFICE

Maples Fund Services (Cayman) Limited P.O. Box 1093, Boundary Hall Cricket Square Grand Cayman KY1-1102 Cayman Islands

#### LEGAL ADVISERS AS TO HONG KONG LAW

Davis Polk & Wardwell 10th Floor, The Hong Kong Club Building 3A Chater Road, Hong Kong

## **COMPANY SECRETARY**

Mr. Wing Yat Christopher LUI

## **AUTHORIZED REPRESENTATIVES**

Dr. Zonghai Ll Mr. Wing Yat Christopher LUI

## **AUDIT COMMITTEE**

Ms. Xiangke ZHAO *(Chairman)* Dr. Huabing LI Mr. Huaqing GUO

#### **REMUNERATION COMMITTEE**

Dr. Huabing LI *(Chairman)* Dr. Zonghai LI Dr. Guangmei YAN

#### NOMINATION AND CORPORATE GOVERNANCE COMMITTEE

Dr. Zonghai LI *(Chairman)* Dr. Huabing LI Dr. Guangmei YAN

## HONG KONG SHARE REGISTRAR

Computershare Hong Kong Investor Services Limited Shops 1712-1716 17th Floor, Hopewell Centre 183 Queen's Road East Wanchai Hong Kong

## **STOCK CODE**

02171

## AUDITOR

Ernst & Young Certified Public Accountants Registered Public Interest Entity Auditor 27/F, One Taikoo Place 979 King's Road Quarry Bay, Hong Kong

## **COMPANY WEBSITE**

www.carsgen.com

#### **COMPLIANCE ADVISER**

Rainbow Capital (HK) Limited No. 710, 7/F, Wing On House 71 Des Voeux Road Central Hong Kong

#### **PRINCIPAL BANKER**

Bank of Hangzhou Co., Ltd. No. 46, Qingchun Road Hangzhou PRC

# **Chairman's Statement**

Dear shareholders,

On behalf of the CARsgen Board of Directors, I extend our sincere gratitude for your continuous trust and support to CARsgen. I am pleased to report our significant achievements of the Company for the year ended December 31, 2023 and provide an outlook for 2024.

In 2023, CARsgen remained dedicated to our vision, "Making Cancer Curable" and were committed to reinforcing our team and improving operational efficiency. We made substantial progresses in the regulatory and clinical development of our innovative products and the advancement of new technology platforms. Multiple important milestones for different product candidates across clinical, regulatory, and business development were achieved:

The NMPA approved the NDA application for zevor-cel for the treatment of adult patients with relapsed or refractory multiple myeloma in February 2024, an important milestone that kicked off the commercialization of zevor-cel in China together with Huadong Medicine. The pivotal phase 2 trial in North America is near enrollment completion.

For CT041, globally the first-in-class CLDN18.2 CAR-T, with the ongoing enrollment of patients, we anticipate the completion in the first half of 2024 and NDA submission at the end of 2024. In April 2023, CT041 IND was additionally approved in China for post-operative adjuvant therapy of Claudin18.2 positive patients in pancreatic cancer by the NMPA. In May 2023, the Phase 2 clinical trial in the U.S. and Canada was initiated for the treatment of advanced gastric cancer/gastroesophageal junction cancer (GC/GEJ) in patients who have failed at least 2 prior lines of systemic therapies.

In the published articles, we are pleased to report several cases of patients with hepatocellular carcinoma (HCC) or pancreatic cancer (PC) having demonstrated encouraging efficacy after being treated with GPC3 or CLDN18.2 CAR T therapies. Notably, two HCC patients treated with a combination of local therapy and GPC3 CAR-T cells achieved disease-free survival exceeding 7 years. Based on these encouraging results, we believe that advancing our innovative CAR-T products to adjuvant setting may further benefit the patients with solid tumors. In April, CT041 received IND clearance from the National Medical Products Administration (NMPA) for the postoperative adjuvant therapy of Claudin18.2 positive PC. In January 2024, CT011, an GPC3 CAR T product for patients with hepatocellular carcinoma, received IND clearance from the NMPA for patients with GPC3-positive stage IIIa hepatocellular carcinoma who are at high risk of recurrence after surgical resection.

We developed a proprietary CARcelerate<sup>™</sup> platform shorten the manufacturing time to around 30 hours and therefore yields younger and possibly more potent CAR T cells compared to conventional manufacturing. The improved manufacturing efficiency also enhances the supply capacity, reduces the manufacturing costs, and expedites the availability of the product to the patients. The platform has been utilized for CT071, an autologous CAR T-cell therapy candidate targeting GPRC5D or the treatment of R/R MM or R/R primary plasma cell leukemia, which achieved IND clearance from the FDA in November 2023.

# Chairman's Statement

In January 2023, we reached a collaboration agreement with Huadong Medicine Co., Ltd. (SZ. 000963) ("**Huadong Medicine**") for commercialization of zevorcabtagene autoleucel (zevor-cel, CT053) in mainland China. In August 2023, we and Moderna, Inc. (Nasdaq: MRNA, "Moderna") initiated a collaboration agreement to investigate CT041 in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine. A series of *in vitro* and *in vivo* studies have been conducted to evaluate the anti-tumor activity of the combination.

2023 brought challenges as well. In December 2023, the U.S. Food and Drug Administration ("FDA") placed a clinical hold on zevor-cel, satricabtagene autoleucel and CT071 pending resolution of the findings following an inspection of the manufacturing site located in Durham, North Carolina. We are conducting a thorough review and taking comprehensive actions to enhance CGMP compliance and are collaborating closely with the FDA to resolve these issues.

Despite these hurdles, the observed efficacy and safety profiles in clinical trials reinforce our belief in the transformative potential of our CAR T-cell products, especially in earlier therapy lines. We remain committed to enhancing patient access and benefits and fostering further collaborations to advance our innovative cell therapies.

We are optimistic that we will navigate and overcome the challenges ahead with resilience and determination. Your continued support is invaluable to our mission and successes. Thank you once again for your trust and support to CARsgen.

Sincerely, Dr. Zonghai Ll Chairman of the Board of Directors, CARsgen Therapeutics.

# **Financial Highlights**

	Year ended December 31	
	2023 <i>RMB'000</i>	2022 RMB′000
Net loss Net loss per share (RMB)	(747,794) (1.34)	(892,247) (1.62)
Non-IFRSs Measures		
Adjusted net loss <sup>(1)</sup> Adjusted net loss per share (RMB) <sup>(1)</sup>	(733,336) (1.31)	(848,252) (1.54)

	As at December 31	
	<b>2023</b> 22 <i>RMB'000 RMB</i>	
Cash and bank balances	1,849,752	2,268,036
Total	1,849,752	2,268,036

Our net loss was RMB748 million for the year ended December 31, 2023, representing a decrease of RMB144 million from RMB892 million for the year ended December 31, 2022. The decrease was primarily due to (i) the decrease in share-based compensation ("**Adjusted Items**"), which totaled RMB14 million for the year ended December 31, 2023, representing a decrease of RMB30 million from RMB44 million for the year ended December 31, 2022; (ii) lower research and development expenses and lower administrative expenses; and (iii) foreign exchange losses of RMB30 million for the year ended December 31, 2023, representing a net impact of RMB67 million from foreign exchange losses of RMB97 million for the year ended December 31, 2023.

Our adjusted net loss<sup>(1)</sup> was RMB733 million for the year ended December 31, 2023, representing a decrease of RMB115 million from RMB848 million for the year ended December 31, 2022. The decrease was primarily due to lower research and development expenses, lower general and administrative expenses and foreign exchange losses.

Cash and bank balances were RMB1,850 million as of December 31, 2023, representing a decrease of RMB418 million from RMB2,268 million as of December 31, 2022. The decrease mostly resulted from payments of research and development expenses, administrative expenses and capital expenditure on long-term assets. During the Reporting Period, we received RMB200 million (including VAT) from Huadong Medicine according to the collaboration agreement for the commercialization of zevor-cel in mainland China.

(1) Adjusted net loss and adjusted net loss per share are non-IFRSs measures. They exclude the impact of the Adjusted Items. For details of non-IFRSs measures, please refer to "Non-IFRSs Measures" subsection for details.

# **Business Highlights**

As of the date of this report, we have made significant progress in advancing our technology innovations, product pipeline and business operations in the U.S. and China.

#### Zevorcabtagene autoleucel (CT053)

Zevorcabtagene autoleucel is an autologous fully human CAR T-cell product candidate against B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma (R/R MM).

As informed by the NMPA on March 1, 2024, zevorcabtagene autoleucel was granted conditional approval on February 23, 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). Over 100 patients have been enrolled in the Phase 2 trial (NCT03915184) for R/ R MM in North America. The study has been placed on clinical hold by the FDA due to CMC observations related to our Research Triangle Park (RTP) Manufacturing Facility in Durham, North Carolina.

An update from the Phase I study in China (NCT03975907) with 3 years term follow-up was presented as a poster at the 2023 American Society of Hematology ("**ASH**") Annual Meeting in December 2023.

#### Satricabtagene autoleucel (CT041)

Satricabtagene autoleucel is an autologous humanized CAR T-cell product candidate against Claudin18.2 (CLDN18.2), a membrane protein highly expressed in certain cancers. As of the date of this report, satricabtagene autoleucel, based on our information, is the world's first CAR T-cell candidate for the treatment of solid tumors entering a Phase II clinical trial.

In April 2023, satricabtagene autoleucel IND was approved by the National Medical Products Administration (NMPA) for the postoperative adjuvant therapy of Claudin18.2 positive pancreatic cancer (PC) (CT041-ST-05, NCT05911217). In May 2023, the Phase 2 part of the Phase 1b/2 clinical trial (NCT04404595) in the U.S. and Canada was initiated for the treatment of Claudin18.2 positive advanced gastric cancer/gastroesophageal junction cancer (GC/GEJ) in patients who have failed at least 2 prior lines of systemic therapies. The study is currently under a clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility.

Updates from the Phase 1b study in the U.S. (NCT04404595) were presented as a poster at the 2024 American Society of Clinical Oncology Gastrointestinal Cancers Symposium ("**ASCO GI**").

## **CT011**

CT011 is an autologous CART-cell product candidate against Glypican-3 (GPC3). In January 2024, CT011 IND was approved by the NMPA for GPC3-positive stage IIIa hepatocellular carcinoma at high risk of recurrence after surgical resection.

## **CT071**

CT071 is an autologous fully human CAR T-cell therapy candidate against G protein-coupled receptor class C group 5 member D (GPRC5D) developed utilizing CARsgen's proprietary CARcelerate<sup>™</sup> platform for the treatment of R/R MM and relapsed/refractory primary plasma cell leukemia (R/R pPCL). The IND was cleared by the FDA on November 30, 2023 for R/R MM and R/R pPCL. An investigator-initiated trial (IIT) is ongoing in China to assess the safety and efficacy of CT071 in treating R/R MM and relapsed/refractory plasma cell leukemia (R/R PCL) (NCT05838131).

# **Business Highlights**

#### **Manufacturing Capacity**

We have established in-house, vertically integrated manufacturing capabilities for the three key stages of CAR T manufacturing, including the production of plasmids, lentiviral vectors, and CAR T cells.

We have expanded our global manufacturing capacity in China and the U.S. to support both clinical trials and subsequent commercialization of our pipeline. With the clinical manufacturing facility in Xuhui, Shanghai and commercial GMP manufacturing facility in Jinshan, Shanghai ("**Jinshan Manufacturing Facility**"), we manufacture CAR T-cell products in-house to support clinical trials in China and manufacture the lentiviral vectors in-house to support clinical trials globally. Our Research Triangle Park (RTP) CGMP manufacturing facility in Durham, North Carolina ("**RTP Manufacturing Facility**") has commenced operations of GMP production of autologous CAR T cell products, which will provide CARsgen additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually to support clinical studies and early commercial launch in the United States, Canada and Europe.

In December 2023, during its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing Practices (CGMP) or other procedural controls and requirements associated with the manufacturing facility, and a clinical hold was subsequently initiated for zevorcabtagene autoleucel, satricabtagene autoleucel and CT071. We have already been conducting a comprehensive review and improvement on the CGMP and is working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications. A response with Corrective and Preventive Actions (CAPAs) plan with a timetable was submitted to FDA on December 28, 2023 local time. We are continuing to address any observations identified by FDA and will submit a complete response once ready. Then, the FDA has 30 days to determine if the clinical hold can be lifted. We are committed to working closely with the FDA to address the findings to ensure the smooth progress and launching applications.

#### **Commercialization and External Collaboration**

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZ. 000963) entered into a collaboration agreement for the commercialization of CARsgen's lead drug candidate, zevorcabtagene autoleucel, in mainland China.

In August 2023, CARsgen and Moderna, Inc. (Nasdaq: MRNA, "**Moderna**") have initiated a collaboration agreement to investigate CT041 in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine.

# I. OVERVIEW

CARsgen is a biopharmaceutical company with operations in China and the U.S. and is focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has established a comprehensive CAR T-cell research and development platform, encompassing target discovery, innovative CAR T-cell development, clinical trials, and commercialscale production. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. CARsgen's mission is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable.

#### **II. BUSINESS REVIEW**

#### **Our Products and Product Pipeline**

Since CARsgen's inception, our strategic business model has been centered around the in-house development of innovative and differentiated biopharmaceutical products, with a primary focus on CAR T-cell therapies. Our leading product candidate, zevorcabtagene autoleucel for the treatment of the hematologic malignancy R/R MM, is at the most advanced development stage among the product candidates in our pipeline. Another hematologic malignancy product candidate (CT071) is in Phase 1 clinical trial. In addition, solid tumor product candidates are in confirmatory Phase II (CT041), Phase I (CT011), and Pre-IND stages. The following chart summarizes the development status of each product candidate in our pipeline as of the date of this report. Our product candidates are developed in-house and protected by the global rights owned by CARsgen.

	Product Candidate	Technology	Target	Indication	<b>Pre-clinical</b>	Phase I	Phase II/III <sup>2</sup>	BLA/ NDA
	Zevor-cel (CT053) <sup>°</sup>		BCMA	R/R MM R/R MM R/R MM	LUMMICAR 1 (China) LUMMICAR 2 (US, Canada) IIT (China)			launched
pies	CT041	Conventional	Claudin18.2	GC/GEJ GC/PC PC (adjuvant) GC/GEJ, PC, etc.	ST-01 (China) ST-02 (US, Canada) ST-05 (China) IIT (China)			
era	СТ011		GPC3	HCC (adjuvant)	(China)			
T-cell therapies	СТ071	CARcelerate <sup>™</sup>	GPRC5D	R/R MM, R/R pPCL R/R MM, R/R PCL	(US) IIT (China)			
Ĕ	СТ0180	-F	GPC3	HCC	IIT (China)			
	СТ0181	sFv-ε	GPC3	HCC	IIT (China)			
CAR	СТ0590	THANK-uCAR®	BCMA	R/R MM	IIT (China)			
	СТ048	CycloCAR®	Claudin18.2	GC/GEJ and PC	IIT (China)			
	KJ -C2113	CycloCAR®	Mesothelin	Solid tumors				
	KJ -C2114	THANK-uCAR®	Undisclosed	Solid tumors				
	КЈ -C2320	Undisclosed	Undisclosed	AML				
mAb	AB011		Claudin18.2	GC/GEJ and PC	Mono & Combo ( AB011+CAP	OX) (China)		
						for hematolog	jic malignancies 📄 foi	r solid tumors

R/R MM: relapsed/refractory multiple myeloma; GC: gastric cancer; GEJ: gastroesophageal junction cancer; PC: pancreatic cancer; HCC: hepatocellular carcinoma; R/R pPCL: relapsed/refractory primary plasma cell leukemia; AML: acute myeloid leukemia

Notes:

- 1. All product candidates are self-developed with global rights.
- 2. Phase II trials of some indications are pivotal studies.
- 3. Core Product Candidate. Commercial rights in mainland China have been granted to Huadong Medicine (SZ: 000963). Rights in the South Korean market have been licensed out to HK Inno.N Corporation (KOSDAQ: 195940).

## Zevorcabtagene autoleucel (CT053) – Fully Human BCMA CAR T

Zevorcabtagene autoleucel is a fully human, autologous BCMA CAR T-cell product candidate for the treatment of R/R MM. It incorporates a CAR construct with a fully human BCMA-specific single-chain variable fragment (scFv) with low immunogenicity and increased stability which helps overcome the challenge of T-cell exhaustion by reducing the self-activation of CAR T cells in the absence of tumor-associated targets.

CARsgen developed zevorcabtagene autoleucel in-house with our integrated research and development platform. Zevorcabtagene autoleucel received Orphan Drug designation for the treatment of multiple myeloma from the U.S. FDA in 2019 and Orphan Medicinal Product designation for the treatment of multiple myeloma from the European Medicines Agency (EMA) in 2020. Also, zevorcabtagene autoleucel received Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of R/R MM from the FDA in October 2019, PRIority MEdicines (PRIME) eligibility for the treatment of R/R MM from the EMA in September 2019, Breakthrough Therapy designation for the treatment of R/R MM from the NMPA in 2020, and received the priority review from NMPA in October 2022.

As informed by the NMPA on March 1, 2024, zevorcabtagene autoleucel was granted conditional approval on February 23, 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). Over 100 patients have been enrolled in the Phase 2 trial (NCT03915184) for R/R MM in North America. The study has been placed on clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility based in Durham, North Carolina. Updated data for a total of 17 patients who received zevorcabtagene autoleucel infusion in the Phase 1b/2 trial in U.S. were presented orally at the 7th Annual CAR-TCR Summit in September 2022.

At the 65th ASH Annual Meeting in December, 2023, CARsgen presented a poster titled 'Three-Year Follow-up on Efficacy and Safety Results from Phase I Lummicar Study 1 of Zevorcabtagene Autoleucel in Chinese Patients with Relapsed or Refractory Multiple Myeloma ' highlighting the 3-year follow-up on efficacy and safety results from the Phase I portion of Phase I/II registrational study in China (LUMMICAR-1, NCT03975907).

Updated results for the investigator-initiated trials (NCT03302403, NCT03380039, NCT03716856) were published in *Haematologica* in August 2022 article titled 'A novel BCMA CAR-T-cell therapy with optimized human scFv for treatment of relapsed/refractory multiple myeloma: results from phase I clinical trials'.

Additional data from these clinical trials will be disclosed in academic journals or at scientific conferences in due course. CARsgen plans to conduct additional clinical trials to develop zevorcabtagene autoleucel as a treatment option in earlier lines of multiple myeloma.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that zevorcabtagene autoleucel will ultimately be successfully developed and marketed (outside China) by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

#### Satricabtagene autoleucel – Humanized Claudin18.2 CAR T

Satricabtagene autoleucel is an autologous CAR T-cell product candidate against the protein Claudin18.2 and has the potential to be first-in-class globally. Satricabtagene autoleucel targets the treatment of Claudin18.2-positive solid tumors with a primary focus on GC/GEJ and PC. Claudin18.2 is expressed in a range of solid tumors, including GC/GEJ, PC, colorectal, lung, and ovarian cancers. Leveraging our in-depth understanding in CAR T-cell therapy, as well as our integrated antibody platform, we were the first in the world to successfully identify, validate and report Claudin18.2 as a solid tumor-associated antigen and viable target for CAR T-cell therapy for solid tumors in which Claudin18.2 is prevalently or highly expressed. To further address the challenges of CAR T-cell therapies in treating solid tumors, we developed an innovative, patent-protected preconditioning regimen that is administered prior to infusion of satricabtagene autoleucel. This regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine (FNC).

Satricabtagene autoleucel received Orphan Drug designation from the U.S. FDA in September 2020 for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA in January 2021 for the treatment of advanced gastric cancer. Satricabtagene autoleucel was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in November 2021 and was granted RMAT Designation for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022.

As of the date of this report, satricabtagene autoleucel, based on our information, is the world's first CAR T-cell candidate for the treatment of solid tumors entering a Phase II clinical trial.

In May 2023, the Phase 2 part of the satricabtagene autoleucel Phase 1b/2 clinical trial was initiated in the U.S. and Canada for advanced GC/GEJ trial (CT041-ST-02, NCT04404595). The study is currently under a clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility. At the 2024 ASCO GI meeting, CARsgen presented a poster entitled 'CLDN18.2 chimeric antigen receptor T cell therapy for patients with advanced gastric and pancreatic adenocarcinoma: Results of ELIMYN18.2 phase 1b clinical trial' with updated study results for satricabtagene autoleucel in the Phase 1b trial in the U.S.

Trials of satricabtagene autoleucel conducted in CARsgen in China include investigator-initiated trials (NCT03874897), a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and a Phase I clinical trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217). The updated results from the Phase Ib/II satricabtagene autoleucel study in China were presented at the 2022 ASCO Annual Meeting with the poster titled 'Multicenter Phase 1b Trial of Salvage CT041 Claudin18.2 – specific Chimeric Antigen Receptor T Cell Therapy for Patients with Advanced Gastric and Pancreatic Adenocarcinoma'. CARsgen plans to submit an NDA to the NMPA in China at the end of 2024.

The results of the investigator-initiated trial of satricabtagene autoleucel (NCT03874897) were reported in the *Nature Medicine* article titled "Claudin18.2-specific CAR T cells in gastrointestinal cancers: Phase I trial interim results" in May 2022.

Two metastatic pancreatic cancer patients administrated with satricabtagene autoleucel after the failure of standard therapy (NCT04581473 and NCT03874897) were reported in *Journal of Hematology* & *Oncology* article titled "CT041 CAR T cell therapy for Claudin18.2-positive metastatic pancreatic cancer".

An article titled "Metastatic gastric cancer target lesion complete response with Claudin18.2-CAR T cells" was published in *Journal for ImmunoTherapy of Cancer* reporting a patient with metastatic GC, who had progressed on four lines of combined systemic chemotherapy and immunotherapy after receiving two satricabtagene autoleucel infusions achieved target lesion complete response and sustained an 8-month overall partial response with only minimal ascites.

Additional data from these global clinical trials will be disclosed in academic journals or at scientific conferences. CARsgen plans to conduct additional clinical trials to develop satricabtagene autoleucel as an earlier line of treatment for GC/GEJ and PC.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that satricabtagene autoleucel will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

## CT011 – Humanized GPC3 CAR T

CT011 is an autologous CAR T-cell product candidate with proof-of-concept clinical data for the treatment of hepatocellular carcinoma (HCC) and has the potential to be the first-in-class globally. Our co-founder, CEO and Chief Scientific Officer, Dr. Zonghai LI led the world's first successful effort in identifying, validating and reporting GPC3 as a tumor-associated target for the development of CAR T-cell therapies to treat HCC. We have completed enrollment of a Phase I trial in China.

In January 2024, CT011 achieved IND clearance from the NMPA for patients with GPC3-positive stage IIIa hepatocellular carcinoma at high risk of recurrence after surgical resection.

In July 2023, an article titled "Combined local therapy and CAR-GPC3 T-cell therapy in advanced hepatocellular carcinoma: a proof-of-concept treatment strategy" was published in *Cancer Communication (London, England)* demonstrating patients who received local therapy followed by sequential infusions of CAR-GPC3 T-cells achieved more than 7-year disease-free survival.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that CT011 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

## CT071 – GPRC5D CAR T

CT071 is an autologous CAR T-cell therapy candidate targeting GPRC5D developed utilizing CARsgen's proprietary CARcelerate<sup>™</sup> platform of for the treatment of R/R MM and R/R pPCL. It incorporates a fully-human single-chain variable fragment (scFV) developed by CARsgen.

CARsgen's proprietary CARcelerate<sup>™</sup> platform may shorten CT071's manufacturing time to around 30 hours and therefore, resulting CAR-T cells are younger and possibly more potent compared to conventional manufacturing. The improved manufacturing efficiency aims to expedite the availability of the product to the patients, enhances the supply capacity and reduces the manufacturing costs.

CT071 IND was cleared by the FDA in November 2023 for the treatment of patients with R/R MM and R/R pPCL. The Phase 1 clinical trial of CT071 in the U.S. is currently on clinical hold by the FDA due to CMC observations at our RTP Manufacturing Facility. An investigator-initiated trial (IIT) is already under way in China to assess the safety and efficacy of CT071 in treating R/R MM and R/R PCL (NCT05838131). Preliminary clinical data from the IIT shows an acceptable safety profile with preliminary efficacy.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that CT071 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

### IND-Enabling or Preclinical Stage Product Candidates

In addition to the above clinical-stage product candidates currently in clinical phase, we have internally developed seven IND-enabling or preclinical product candidates as described below. Three of these products, CT0180, CT0181 and CT0590, are already in the IIT clinical stage.

**CT0180** is an autologous T-cell product engineered to express a fusion protein of GPC3-targeted antibody and T-cell receptor. An IIT trial has been initiated in China to evaluate the efficacy and safety of CT0180 in the treatment of hepatocellular carcinoma. The results from the IIT in China were presented at the 2023 ASCO Annual Meeting with the poster titled 'Phase I trial of Chimeric Anti-GPC3 scFv-CD3ε Engineered T Cells (CT0180) in Patients with Advanced Hepatocellular Carcinoma'.

**CT0181** is an autologous T-cell product engineered with a GPC3-targeted antibody-fused T-cell receptor co-expressing the interleukin (IL)-7 cytokine. An IIT trial has been initiated in China to evaluate the efficacy and safety of CT0181 in the treatment of hepatocellular carcinoma.

**CT0590** is an allogeneic CAR T-cell product candidate deploying our THANK-uCAR<sup>®</sup> technology that targets BCMA. We are developing CT0590 for the treatment of R/R MM. We have initiated an IIT trial to evaluate the efficacy and safety of CT0590 for the treatment of R/R MM.

**CT048** (KJ-C1807) is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR<sup>®</sup> technology being developed to treat patients with GC/GEJ and PC targeting Claudin18.2. We anticipate that by co-expressing cytokine IL-7 and chemokine CCL21, KJ-C1807 potentially has a greater clinical efficacy and reduced requirement for lymphodepletion conditioning. CARsgen has initiated an IIT trial to evaluate the efficacy and safety of CT048 for the treatment of GC/GEJ and PC.

**KJ-C2112** is a next-generation autologous CAR T-cell product candidate for the treatment of patients with EGFR/EGFRvIII-overexpressing glioblastoma. Preclinical studies have demonstrated the efficacy of KJ-C2112. We plan to collaborate with an experienced principal investigator and study KJ-C2112 in an investigator-initiated trial.

**KJ-C2113** is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR<sup>®</sup> technology that targets mesothelin, a tumor differentiation antigen normally restricted to the body's mesothelial surfaces, that is significantly overexpressed in a broad range of solid tumors. We are developing KJ-C2113 for the treatment of various types of solid tumors.

**KJ-C2114** is an allogeneic CAR T-cell product candidate deploying our THANK-uCAR<sup>®</sup> technology with an undisclosed target for the treatment of certain solid tumors.

#### **Continuous Discovery and Technology Development**

Despite the approval of some CAR T-cell products for the last-line treatment of hematologic malignancies, significant challenges remain, such as limited efficacies against solid tumors, undesirable safety concerns, and high manufacturing and treatment costs. We strive to explore and develop innovative technology platforms to address these challenges to generate better cell therapy products for global cancer patients.

We have established an integrated research and development platform covering the full CAR T development cycle including target discovery, antibody development, vector design, manufacturing, quality assurance, and quality control. Our integrated cell therapy platform is composed of target discovery, hybridoma and antibody humanization platform, fully human phage display antibody library platform, antibody identification platform, immune cell function evaluation platform, plasmid and lentiviral vector preparation platforms, cell therapy process development platform, analytical platforms with molecular, flow cytometry, biochemical, physical-chemical, and cell-based analytical capabilities, biological samples tests platform, clinical-scale and commercial-scale CAR T manufacturing platform, and platform for clinical studies. This platform enables us to efficiently and effectively develop a product candidate from early discovery to clinical trials and potentially to commercialization.

We continue to dedicate ourselves to advancing innovative CAR T technologies to address major challenges in the industry. Our four strategic pillars include:

(1) Efficacy: To enhance efficacy against solid tumors, we continue to develop next-generation CAR T technologies, such as CycloCAR<sup>®</sup>. CycloCAR<sup>®</sup> features the co-expression of cytokine IL-7 and chemokine CCL21 in CAR T cells to potentially improve clinical efficacy and reduce the requirement of lymphodepletion conditioning. Our preclinical studies showed that IL-7 enhanced the proliferation and survival of CAR T cells and inhibited the apoptosis of CAR T cells, and CCL21 could drive infiltration of T cells and dendritic cells into tumor sites. The preclinical CycloCAR T cells improved the therapeutic effects against solid tumors in mice compared to conventional CAR T cells. Moreover, even without preconditioning chemotherapy, the CycloCAR T cells could potently suppress the tumor growth with a significantly better efficacy than CAR T cells co-expressing IL-7 and CCL19 (7×19 CAR T, a previously reported design by other researchers). Our studies demonstrated that, independent of lymphodepletion chemotherapy, CycloCAR T cells exerted potent antitumor effects that were facilitated by infiltration of T cells and dendritic cells into tumor tissues, CycloCAR T cells experienced increased survival, and a potential anti-angiogenesis effect. We are using CycloCAR® to develop CAR T-cell therapies against several targets including Claudin18.2, GPC3, and mesothelin. We continue to explore potential combination approaches to boost the therapeutic effects of single agents and identify new targets and approaches to tackle new indications.

To improve the manufacturing efficiency, we developed a proprietary platform that can shorten the manufacturing time for the CAR T cells to around 30 hours, as compared to the conventional CAR T manufacturing process. The CARcelerate<sup>™</sup> platform produces CAR T cells that are younger and more likely to remain in a 'naïve' state and less likely to be exhausted. As such, these CAR T cells from the CARcelerate<sup>™</sup> platform are expected to exhibit more potent tumor killing activity. The improved manufacturing efficiency is expected to enhance the supply capacity, reduce the manufacturing costs, and expedite the availability of the product to the patients. We are using CARcelerate<sup>™</sup> to manufacture an autologous CAR T-cell therapy candidate targeting GPRC5D, CT071, for the treatment of patients with R/R MM or R/R pPCL.

(2) Safety: To minimize safety concerns, we continue to develop innovative technologies that can help reduce the risk of CRS, neurotoxicity and on-target off-tumor toxicities and to improve applicability of adoptive cell therapies. We leverage our in-house antibody platform, powered by a fully human phage display library and improved hybridoma technology, to identify and optimize antibody fragments with higher specificity for tumor targets and increased stability, which lead to reduced auto-activation of CAR T cells in the absence of tumor targets and controlled levels of cytokine release.

To improve the applicability of adoptive cell therapies, we developed the sFv- $\varepsilon$ -based T-cell therapy powered by a full T-cell receptor (TCR) complex comprising a GPC3-targeted scFv and a CD3 $\varepsilon$  subunit, which can form a functional TCR complex with other TCR subunits (TCR $\alpha$ , TCR $\beta$ , CD3 $\gamma$ , CD3 $\delta$  and CD3 $\zeta$ ) and redirect T cells to kill tumor cells in an MHC-independent manner. Our preclinical studies showed that sFv- $\varepsilon$ -based T-cell therapies could effectively recognize and kill carcinoma cells and significantly inhibit tumor growth in mouse xenograft models with reduced cytokine release in vitro and in vivo, which could improve the safety and applicability of adoptive cell therapies. In addition, the co-expressed IL-7 is a cytokine that could enhance the proliferation and survival of T cells. Our preclinical studies showed that sFv- $\varepsilon$ -based T-cell therapies displayed superior antitumor efficacy, T-cell persistence, and immunological memory in solid tumors xenografts with low cytokine release.

Patient accessibility: To reduce the cost and increase the accessibility of CAR T-cell therapies, (3) we continue to develop our market-differentiating allogeneic THANK-uCAR® technology. THANK-uCAR<sup>®</sup> is our proprietary technology to generate allogeneic CAR T cells with improved expansion and persistence by modifying donor-derived T cells. To minimize graft versus host disease (GvHD) and host versus graft response (HvGR) from allogeneic T cells, we disrupt the genomic loci encoding TCR and B2 microglobulin (B2M) to eliminate surface expression of the TCR or the human leukocyte antigen (HLA), an approach that has been validated by previous research. However, natural killer (NK) cells attack T cells without HLA expression, which then limits the expansion and persistence of the allogeneic CAR T cells. To protect the allogeneic CAR T cells from the patient's NK cells, we arm these TCR-/HLA- CAR T cells with a CAR that recognizes NKG2A to hinder the NKG2A-positive NK cell rejection of the CAR T cells and therefore allow the THANK-uCAR T cells to resist the attack by NK cells. Our in vitro and in vivo studies demonstrated that the armoring the TCR-/HLA- CAR T cells with the anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. We are developing allogeneic CAR T-cell product candidates using THANK-uCAR<sup>®</sup> technology, which we believe could potentially increase CAR T cell expansion, persistence and efficacy. We believe the successful application of THANK-uCAR® technology would significantly lower the cost of CAR T-cell therapy and increase patient accessibility.

(4) Target availability: In the development of cancer therapies, the expression of tumor-associated antigens in normal tissues poses a significant challenge, as this expression pattern leads to on-target off-tumor toxicities. To resolve the challenge with target availability, we continue to explore innovative technologies to enhance drug target availability and therefore turn undruggable antigens into promising targets. We developed LADAR® technology (local action driven by artificial receptor), in which an artificial receptor is triggered by a LADAR Ligand to induce the transcription of the gene(s) of interest (eg, the tumor antigen-targeted CAR, plus any cytokines or other therapeutic mediators). Through the LADAR® artificial receptor, the antitumor CAR transcription is only triggered when the LADAR binds to a LADAR Ligand, making it possible to precisely control when and where immune cells act against cancer cells.

The LADAR-CAR signaling circuits require both antigens for LADAR<sup>®</sup> and CAR recognition to kill target cells, thus reducing on-target off-tumor effects when these two antigens are not simultaneously expressed in the same normal tissues. In our in vitro studies, the LADAR<sup>®</sup> system induced strong therapeutic gene expression in response to antigen engagement and, importantly, negligible leakage expression in resting cells. LADAR-CAR T cells executed killing function only if both antigens were present.

We are also working on other applications of LADAR<sup>®</sup> system, such as LADAR-cytokine circuits. We believe that the establishment of LADAR<sup>®</sup> system is the key step to developing CAR T cells with powerful and precise killing of cancer.

To develop effective CAR T-cell products for more cancer types and further enhance the antitumor effect, we have been expanding our research to more promising oncology targets for cell therapies. In addition, leveraging our proprietary antibody platforms, we have successfully developed humanized or fully human antibodies against these targets, such as GPRC5D, B7-H3, etc. These antibodies, together with our CAR T-cell technology platforms, will help further enhance the product pipeline.

These technologies are currently being developed in-house with global rights and can be used alone or in combination to upgrade our existing product candidates and to generate future pipeline product candidates.

Utilizing these technologies, we strive to further enrich our product pipeline and subsequently advance these pipeline product candidates to clinical and commercial stage.

As of December 31, 2023, we had more than 300 patents of which 104 patents had been issued globally including China, the United States, Europe and Japan. This status is an increase of 22 issued patents and 29 patent applications from the end of 2022. Our R&D activities would continue to generate substantial intellectual property in our areas of expertise.

#### Manufacturing

We have established in-house GMP-compliant manufacturing capabilities to support vertically integrated CAR T manufacturing, including plasmids, lentiviral vectors, and CAR T-cell production. The vertically integrated production contributes to increased efficiency and enhanced control, resulting in improved drug product consistency and faster turnaround times for patients. The integrated manufacturing is also expected to significantly reduce costs and improve margins for more advantageous commercialization. To further improve the manufacture efficiency, we developed a proprietary platform CARcelerate<sup>™</sup> that can shorten the manufacturing time for the CAR T cells to around 30 hours, as compared to the conventional CAR T manufacturing process. The CARcelerate<sup>™</sup> platform produces CAR T cells that are younger and are more likely to remain in a 'naïve' state and less likely to be exhausted; as such, these CAR T cells from the CARcelerate<sup>™</sup> platform are expected to exhibit more potent tumor killing activity.

We have expanded our manufacturing capacity in China and the U.S. to support both the clinical trials and the subsequent commercialization of our products. A total of three production sites have been put into full operation, with the one in Xuhui, Shanghai, supporting clinical development and the ones located in Jinshan, Shanghai, and Research Triangle Park, Durham, North Carolina, United States supporting both clinical development and commercialization manufacture.

With the clinical manufacturing facility in Xuhui, Shanghai, and the commercial manufacturing facility in Jinshan, Shanghai, we can produce the lentiviral vectors and CAR T cells in-house to support clinical trials and CAR T-cell commercialization in China. We also provide the lentiviral vectors to clinical trials outside of China. Our clinical manufacturing facility in Xuhui, Shanghai with a total gross floor area (GFA) of approximately 3,000 sq.m. and an annual CAR T production capacity to support the CAR T-cell treatment of 200 patients has been used for clinical manufacturing of CAR T-cell products in supporting multiple clinical studies of our leading assets. Since establishment, our Xuhui facility has achieved over 95% manufacturing success rate for all product candidates. We have also completed the construction of our commercial-scale manufacturing facility located in Jinshan, Shanghai with a total GFA of approximately 7,600 sq.m. and an estimated manufacturing capacity to support CAR T-cell treatment of up to 2,000 patients annually. The Jinshan Manufacturing Facility passed the on-site inspection conducted by the Shanghai Medical Products Administration (SHMPA) and obtained the first Manufacture License for Pharmaceutical Products ("**Manufacturing License**") issued in China for CAR T-cell therapy.

The RTP Manufacturing Facility, with a total GFA of approximately 3,300 sq.m, was put into full operation in September 2022 with technology transfer completed and provides CARsgen with additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually. In December 2023, during its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing facility, and a clinical hold was subsequently initiated for zevorcabtagene autoleucel, satricabtagene autoleucel and CT071. We have already been conducting a comprehensive review and improvement on the CGMP and is working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications. A response with Corrective and Preventive Actions (CAPAs) plan with a timetable was submitted to FDA on December 28, 2023. We are continuing to address any observations identified by FDA and will submit a complete response once ready. Then, the FDA has 30 days to determine if the clinical hold can be lifted. We are committed to working closely with the FDA to address the findings to ensure smooth progress and production relative for clinical trials and provention if the clinical hold can be lifted. We are committed to working closely with the FDA to address the findings to ensure smooth progress and production quality for clinical trials and launching applications.

By building vertically integrated manufacturing capabilities in-house, we expect to significantly increase manufacturing sustainability, reduce manufacturing costs, and shorten the vein-to-vein time. In addition, we have an in-house GMP-compliant manufacturing facility capable of high yield production of lentiviral vectors. To accelerate the clinical production at the RTP Manufacturing Facility, CARsgen Jinshan Manufacturing Facility will provide the lentiviral vector to support CAR T-cell production for zevorcabtagene autoleucel and satricabtagene autoleucel clinical studies in the United States and Canada. With large scale lentiviral vectors production, we expect to reduce the CAR T manufacturing costs noticeably.

#### **Commercialization and External Collaboration**

In formulating our strategies for the commercialization and development of our innovative CAR T-cell products, we have been carefully evaluating the different available options while considering the Company's strategic development goals at different stages, the resources, the capabilities, and the financial implications.

# *Collaboration to evaluate satricabtagene autoleucel in combination with an mRNA cancer vaccine with MODERNA, INC.*

CARsgen and Moderna, Inc. (Nasdaq: MRNA, "**Moderna**") have initiated a collaboration agreement (the "**Agreement**") to investigate CARsgen's Claudin18.2 CAR T-cell product candidate (satricabtagene autoleucel) in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine.

Moderna is developing an investigational off-the-shelf mRNA cancer vaccine that encodes for the Claudin18.2 protein, a tumor associated antigen. Pursuant to the Agreement, the collaboration contemplates conducting preclinical studies and a Phase I clinical trial to evaluate satricabtagene autoleucel in combination with Moderna's Claudin18.2 mRNA cancer vaccine. Since reaching the agreement, CARsgen has collaborated with Moderna in conducting a series of in vitro and in vivo studies to evaluate the combination of satricabtagene autoleucel and Claudin18.2 mRNA cancer vaccine.

# *Collaboration for zevorcabtagene autoleucel commercialization in mainland China with Huadong Medicine*

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZ. 000963) entered into a collaboration agreement for the commercialization of zevorcabtagene autoleucel in mainland China. Under the terms of the agreement, CARsgen received an upfront payment of RMB200 million and is eligible to receive regulatory and commercial milestone payments up to RMB1,025 million. CARsgen will continue to be responsible for the development, regulatory approval, and manufacturing of zevorcabtagene autoleucel in mainland China.

Huadong Medicine's extensive commercialization experience in mainland China along with their strategic goal of being a leader in the oncology therapeutic area created the opportunity for a strong, strategic and mutually beneficial partnership between our two companies. We believe that the partnership with Huadong Medicine, through leveraging the respective strengths of the two companies, can significantly maximize the commercial successes of zevorcabtagene autoleucel in the market while reduce the risk and associated cost. Since reaching the agreement, teams from CARsgen and Huadong Medicine have been working together closely to implement this collaboration and prepare for the approval and commercialization of zevorcabtagene autoleucel in China.

## License Agreement for zevorcabtagene autoleucel in the Republic of Korea with HK Inno.N Corporation

CARsgen has entered into a licensing agreement with HK Inno.N Corporation (KOSDAQ: 195940), a fully-integrated pharmaceutical company, to develop and commercialize CT032 and zevorcabtagene autoleucel, targeting CD19 and BCMA respectively, for the potential treatment of various cancers in the Republic of Korea. Under the terms of the agreement, CARsgen will receive upfront and additional milestone payments totaling up to USD50 million as well as up to double digit royalties on net sales in the Republic of Korea.

#### **Expansion and Retention of Talent**

As of December 31, 2023, we had a total of 516 employees.

CARsgen continuously invests in talent development. New employees from various subsidiaries and departments completed new hire orientation training and new employees have buddies assigned to. The training and buddies expedited the new employee's integration into CARsgen. Performance management workshops were organized, mainly targeting management personnel. Through case discussions and other activities, the participants deepened their understanding and insights into strategic goal decomposition, cross-department goal alignment, and setting challenging objectives. CARsgen accelerated the development of talents with global experience and perspective offering English training, job rotations and overseas assignments. CARsgen also supports new managers' role transition and leadership development by offering trainings and organized experience sharing salon.

#### **Industry Overview**

As a novel treatment modality, CAR T-cell therapy offers breakthrough efficacy and curative potential for cancer patients. The global CAR T-cell therapy market has been experiencing strong growth since the approval of the first CAR T-cell therapy in 2017. The global CAR T-cell therapy market is further driven by the increases in global cancer incidence, the approval of more CAR T-cell therapies in more cancer types and indications, the improvements in manufacturing technology and capacities, and the availability of CAR T-cell products in more markets. As of the date of this report, there are six CAR T-cell products approved by U.S. FDA and five CAR T-cell products approved by NMPA in China. However, there are still significant unmet medical needs for the cancer patients worldwide, calling for more and better innovative CAR T-cell products, particularly for the treatment of solid tumors. With our pipeline products, including zevorcabtagene autoleucel, CT071, satricabtagene autoleucel, and innovative technology platforms, including CycloCAR<sup>®</sup>, THANK-uCAR<sup>®</sup>, LADAR<sup>®</sup> and CARcelerate<sup>TM</sup>, we are committed to increasing the efficiency and developing the innovative therapies to fulfill these unmet medical needs.

#### **Future and Outlook**

With the mission of "making cancer curable", we will continue to develop innovative product candidates for the treatment of cancer patients worldwide. Building on the milestones we have achieved, we will focus on rapid clinical development of zevorcabtagene autoleucel and satricabtagene autoleucel in both China and overseas, CT071 in overseas and CT011 in China. We will advance the clinical development to earlier line of treatment and continue to develop other product candidates in clinical and preclinical stages and to develop innovative CAR T technologies to further optimize the efficacy, safety and affordability of the CAR T-cell products. We will complete the rectification according to the requirements given by the FDA as fast as we can and continue to expand our manufacturing capacity in China and the United States to support the clinical trials and future commercialization of our product candidates and to make CAR T-cell treatments more accessible and affordable. We will continue to establish additional external partnerships with leading research institutes and pharmaceutical companies on technology and product licenses as means to maximize the application of our technology platform and the value of our product pipeline, bringing more innovative cell therapy products to cancer patients worldwide and ultimately creating more value for our investors and the society.

# **FINANCIAL REVIEW**

#### Overview

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in every year since inception, with operating losses of RMB768 million and RMB881 million for the years ended December 31, 2023 and 2022, respectively. Substantially all of our operating losses resulted from research and development expenses and administrative expenses.

#### Loss for the years

Our net loss was RMB748 million for the year ended December 31, 2023, representing a decrease of RMB144 million from RMB892 million for the year ended December 31, 2022. The decrease was primarily due to (i) the decrease in share-based compensation ("**Adjusted Items**"), which totaled RMB14 million for the year ended December 31, 2023, representing a decrease of RMB30 million from RMB44 million for the year ended December 31, 2022; (ii) lower research and development expenses and lower administrative expenses; and (iii) foreign exchange losses of RMB30 million for the year ended December 31, 2023, representing a net impact of RMB67 million from foreign exchange losses of RMB97 million for the year ended December 31, 2022.

#### Non-IFRSs Measures

To supplement the Group's consolidated net loss and net loss per share which are presented in accordance with the IFRSs, the Company has provided adjusted net loss and adjusted net loss per share as additional financial measures, which are not required by, or presented in accordance with, the IFRSs.

Adjusted net loss for the periods and adjusted net loss per share for the periods represent the net loss and net loss per share respectively excluding the effect of share-based compensation. The terms adjusted net loss and adjusted net loss per share are not defined under the IFRSs.

The table below sets forth a reconciliation of the loss to adjusted loss during the years indicated:

	Year ended D	Year ended December 31,	
	2023	2022	
	RMB'000	<i>RMB'000</i>	
	(Audited)	(Audited)	
Loss for the years	(747,794)	(892,247)	
Add:			
Share-based compensation	14,458	43,995	
Adjusted net loss	(733,336)	(848,252)	

	Year ended December 31,	
	2023	2022
	RMB	RMB
	(Audited)	(Audited)
Loss per share for the years	(1.34)	(1.62)
Add:		
Share-based compensation per share	0.03	0.08
Adjusted net loss per share	(1.31)	(1.54)

The Company believes that the adjusted non-IFRSs measures are useful for understanding and assessing the underlying business performance and operating trends, and that the Company's management and investors may benefit from referring to these adjusted financial measures in assessing the Group's financial performance by eliminating the impact of certain unusual, non-recurring, non-cash and/or non-operating items that the Group does not consider indicative of the performance of the Group's core business. These non-IFRSs measures, as the management of the Group believes, is widely accepted and adopted in the industry in which the Group is operating. However, the presentation of these non-IFRSs measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with the IFRSs. Shareholders of the Company and potential investors should not view the adjusted results on a stand-alone basis or as a substitute for results under IFRSs, and these non-IFRSs measures may not be comparable to similarly-titled measures represented by other companies.

## **Research and Development Expenses**

	Year ended Dece	Year ended December 31,	
	2023	2022	
	RMB'000	RMB'000	
	(Audited)	(Audited)	
Employee benefit expenses	253,480	273,297	
Testing and clinical expenses	249,638	252,470	
Depreciation of property, plant and equipment	55,817	47,208	
Research and development consumables	54,632	51,494	
Utilities	19,178	19,070	
Depreciation of right-of-use assets	12,266	20,160	
Amortization of intangible assets	6,144	5,846	
Travelling and transportation expenses	5,793	4,952	
Office expenses	1,861	2,392	
Short term lease and low value lease expenses	1,623	814	
Professional service fees	270	1,191	
Other expenses	957	1,407	
Total	661,659	680,301	

Research and development expenses decreased to RMB662 million for the year ended December 31, 2023, representing a decrease of RMB18 million from RMB680 million for the year ended December 31, 2022, primarily due to lower employee benefit expenses.

# Administrative Expenses

	Year ended Dece	Year ended December 31,	
	2023 <i>RMB'000</i> (Audited)	2022 <i>RMB'000</i> (Audited)	
Employee benefit expenses	71,857	79,931	
Professional service fees	20,356	23,216	
Office expenses	7,841	13,041	
Depreciation of property, plant and equipment	6,411	4,411	
Depreciation of right-of-use assets	5,499	2,837	
Auditors' remuneration	4,191	3,445	
– audit service	4,191	3,260	
– non-audit service	-	185	
Short term lease and low value lease expenses	3,847	723	
Travelling and transportation expenses	3,112	2,036	
Utilities	1,399	991	
Amortization of intangible assets	1,258	1,071	
Other expenses	5,918	4,093	
Total	131,689	135,795	

Administrative expenses decreased to RMB132 million for the year ended December 31, 2023, representing a decrease of RMB4 million from RMB136 million for the year ended December 31, 2022, primarily due to lower employee benefit expenses.

Details of employee benefit expenses and share-based compensation included in the above administrative expenses and research and development expenses are as below:



## Employee benefit expenses

	Year ended Dee	Year ended December 31,	
	2023 <i>RMB'000</i> (Audited)	2022 <i>RMB'000</i> (Audited)	
Wages and salaries Pension costs	276,243 20,582	250,072	
Share-based compensation Other employee benefits	14,458 14,054	21,472 43,995 37,689	
Total	325,337	353,228	
Amount included in Research and Development Expenses Amount included in Administrative Expenses	253,480 71,857	273,297 79,931	

The decrease of employee benefit expenses is mainly due to lower share-based compensation and other employee benefits.

#### Share-based payments

Expenses for the share-based compensation have been charged to the consolidated statements of comprehensive loss as follows:

	Year ended Dece	Year ended December 31,	
	2023	2022	
	RMB'000	RMB'000	
	(Audited)	(Audited)	
Research and development expenses	13,910	36,310	
Administrative expenses	548	7,685	
Total	14,458	43,995	

The decrease of share-based compensation expenses is mainly due to the forfeiture of immature restricted shares and stock options of departing employees.

# LIQUIDITY AND CAPITAL RESOURCES

Management monitors and maintains a level of cash and bank balances deemed adequate to finance our operations and mitigate the effects of fluctuations. In addition, management monitors our borrowings and, from time to time, evaluates operations to renew our borrowings upon expiry based on our actual business requirements. We rely on equity financing and debt financing as our major sources of liquidity.

The following table sets forth our cash flows for the periods indicated:

	Year ended December 31,	
	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
	(Audited)	(Audited)
Net cash used in operating activities	(454,935)	(643,048)
Net cash generated from investing activities	39,251	2,386,990
Net cash used in financing activities	(22,142)	(236,514)
Net (decrease)/increase in cash and cash equivalents	(437,826)	1,507,428
Cash and cash equivalents at beginning of the years	2,268,036	691,284
Exchange gains on cash and cash equivalents	19,542	69,324
Cash and cash equivalents at end of the years	1,849,752	2,268,036

## **Net Cash Used in Operating Activities**

During the Reporting Period, we incurred negative cash flows from operations, and substantially all of our operating cash outflows resulted from our research and development expenses and administrative expenses.

Our operating activities used RMB455 million and RMB643 million for the year ended December 31, 2023 and 2022, respectively. During the Reporting Period, we received RMB200 million (including VAT) from Huadong Medicine according to the collaboration agreement for the commercialization of zevor-cel in mainland China.

We are currently a pre-income company. We believe our pipeline products have promising global market potential in the future. We intend to continue investing in our research and development efforts and aim to obtain marketing approvals for our product candidates as soon as feasible. As we launch and commercialize our product candidates, we expect to generate operating income and improve our net operating cash outflow position.

## **Net Cash Generated from Investing Activities**

Our cash generated from investing activities mainly reflects our cash generated from redemption of investment of term deposit and partially offset by purchase of property, plant and equipment.

For the year ended December 31, 2023, our net cash generated from investing activities was RMB39 million, which was primarily redemption of investment of term deposit and partially offset by purchase of property, plant and equipment. For the year ended December 31, 2022, our net cash generated from investing activities was RMB2,387 million, which was primarily redemption of investment of term deposit and partially offset by purchase of property, plant and equipment.

### Net Cash Used in Financing Activities

During the Reporting Period, our cash outflow from financing activities primarily due to payments of lease expenses and repayments of bank borrowings.

For the year ended December 31, 2023, our net cash used in financing activities was RMB22 million, primarily attributable to payment of lease expenses of RMB23 million, net repayments of bank borrowings of RMB5 million and payment of interest expenses of RMB0.3 million. For the year ended December 31, 2022, our net cash used in financing activities was RMB237 million, primarily attributable to net repayments of bank borrowings of RMB219 million and payment of interest expenses of RMB10 million.

## **Cash and Bank Balances**

	As at	As at
	December 31,	December 31,
	2023	2022
	RMB'000	RMB'000
	(Audited)	(Audited)
Cash at banks		
– USD	1,058,394	1,357,360
– RMB	779,122	906,855
– HKD	12,236	3,821
Subtotal	1,849,752	2,268,036
Total	1,849,752	2,268,036

The Group's total cash and bank balances as at December 31, 2023 were RMB1,850 million, representing a decrease of RMB418 million compared to RMB2,268 million as at December 31, 2022. The decrease was primarily attributable to payments of research and development expenses, and administrative expenses.

#### **Borrowing and Gearing Ratio**

The Group's total borrowings, including interest-bearing borrowings, as at December 31, 2023 were RMB3 million, representing a decrease of RMB4 million compared to RMB7 million as at December 31, 2022.

As at December 31, 2023 and December 31, 2022, the Group's bank borrowings of approximately RMB3 million and RMB7 million respectively are pledged by property, plant and equipment and right-of-use assets of the Group.

The fair values of the borrowings approximate their carrying amounts as the discounting impact is not significant.

As at December 31, 2023, the Group's secured borrowings is mature within one year with the interest rate of 5.2250% (2022: 5.2250%). The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at December 31, 2023 and 2022 were 4.73% and 4.83%, respectively.

#### Lease liabilities

The Group leases offices and dormitory. Lease on offices and dormitory were measured at net present value of the lease payments to be paid during the lease terms.

Lease liabilities were discounted at incremental borrowings rates of the Group entities.

Our lease liabilities decreased to RMB83 million as at December 31, 2023 from RMB112 million as at December 31, 2022.

#### **OTHER FINANCIAL INFORMATION**

#### Significant Investments, Material Acquisitions and Disposals

As at December 31, 2023, we did not hold any significant investments. During the year ended December 31, 2023, we did not have any material acquisitions or disposals of subsidiaries, associates and joint ventures.

#### Foreign Exchange Risk

The Group has entities operating in the United States of America and in the People's Republic of China and there are certain cash and bank balances, other receivables, accruals and other payables denominated in a currency that is not the functional currency of the relevant group entities. As at December 31, 2023, the Group had no foreign exchange hedging instruments. The Group constantly reviews the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary.

As at December 31, 2023 and 2022, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years would have increased/decreased approximately RMB90 million and RMB78 million respectively.

#### **Capital Expenditure**

For the year ended December 31, 2023, the Group's total capital expenditure amounted to approximately RMB10 million, which was mostly used in purchase of property, plant and equipment, and software.

#### **Charge on Assets**

As at December 31, 2023 and 2022, the Group's building with carrying values of RMB29 million and RMB31 million respectively were pledged for certain of the Group's borrowings.

As at December 31, 2023 and 2022, the Group's land use right with carrying values of RMB6.5 million and RMB6.6 million respectively was pledged as collateral for the Group's borrowings.

## **Contingent Liability**

As at December 31, 2023, the Group did not have any material contingent liabilities.

#### **Employees and Remuneration Policies**

During the Reporting Period, we have scaled down our team from about 539 employees as at December 31, 2022 to 516 employees as at December 31, 2023. As at December 31, 2023, we had a total of 516 employees, with 61% of them are female.

In compliance with the applicable labor laws, we enter into standard confidentiality and employment agreements with our key management and research staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for up to two years after the termination of his or her employment. The agreements also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment.

During the Reporting Period, we did not experience any strikes, labor disputes or industrial action which had a material effect on our business. We believe we have not experienced any significant difficulty in recruiting staff for our operations. We have established a labor union that represents employees with respect to the promulgation of bylaws and internal protocols in China.

Our employees' remuneration consists of salaries, bonuses, share-based incentive plans, social insurance contributions and other welfare payments. In accordance with applicable laws, we have made contributions to social insurance funds (including pension plan, unemployment insurance, work-related injury insurance, medical insurance and maternity insurance, as applicable) and housing funds for our employees. During the Reporting Period, we had complied with all statutory social insurance fund obligations applicable to us under PRC & US laws in all material aspects, and housing fund obligations applicable to us under PRC laws.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to our employees, especially key employees.

#### **Future Investment Plans and Expected Funding**

The Group will continue to expand its markets in the PRC and globally in order to tap its internal potential and maximize shareholders' interest. The Group will continue to grow through self-development, mergers and acquisitions, and other means. We will employ a combination of financing channels to finance capital expenditures, including but not limited to internal funds, capital markets and bank loans. Currently, the bank credit lines available to the Group are adequate.

# **Directors and Senior Management**

The biography details of the Directors and senior management are set out as follows:

# **EXECUTIVE DIRECTORS**

**Dr. Zonghai LI (**李宗海), aged 50, was appointed as a Director in February 2018, and the Chief Executive Officer and the Chief Scientific Officer in February 2021. He was re-designated as an executive Director in February 2021.

Dr. Zonghai LI has also held positions at CARsgen Therapeutics (Shanghai). He has been a director and the chief executive officer since October 2014, and the chief scientific officer since December 2017.

Dr. Zonghai LI has approximately 20 years of work experience in the biopharmaceutical field. Dr. Zonghai LI worked at Shanghai Cancer Institute (上海市腫瘤研究所) from July 2005 to June 2018 and served as the leader of the biotherapy research team at the State Key Laboratory of Oncogenes and Related Genes of Shanghai Cancer Institute (上海市腫瘤研究所癌基因及相關基因國家重點實驗室) during such period. In light of the governmental policy to support and encourage scientific researchers to work in private technology companies conditional upon the requisite college or research institutes' approval, Dr. Zonghai LI decided to establish our Group in October 2014 to conduct R&D work and the commercialization of cellular immunotherapy, while continuing to work at Shanghai Cancer Institute. The arrangement was ratified and approved by the Shanghai Cancer Institute in January 2016. Before that, Dr. Zonghai LI was a project manager at Guilin Pavay Gene Pharmaceutical Co., Ltd. (桂林華諾威基因藥業有限公司) from July 2000 to April 2002.

Dr. Zonghai LI has dedicated himself to developing innovative treatment for the patients with cancer. One of his early career achievements is the identification of GE11, a peptide ligand of EGFR which has become a widely used unnatural peptide in antitumor study now. He is also the inventor of new technologies such as Hpd3cell, a new phage display technology; FR806, a new safety switch for T cell therapy; CycloCAR technology to increase the antitumor activities of chimeric antigen receptor (CAR) T cells. He has a leading role in the research on CAR T cell therapy against solid tumors by publishing the first paper of CAR T cell therapy against GPC3, Claudin 18.2 and EGFR/EGFRvIII worldwide. Dr. Zonghai LI was a professor in Shanghai Cancer Institute, Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬仁濟醫院上海市腫瘤研究所) and a doctoral supervisor at Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬仁濟醫院).

Dr. Zonghai LI obtained his bachelor's degree in preventive medicine and master's degree in pathology and pathogen biology from the Central South University (中南大學), formerly known as the Hunan Medical University (湖南醫科大學), the PRC, in June 1997 and July 2000 respectively. He obtained his Doctor of Philosophy degree in pathogen biology from Fudan University (復旦大學), the PRC, in June 2005. Dr. Zonghai LI was awarded the Leading Talents of Shanghai City (上海市領軍人物) in 2018 and the Shanghai Youth Science and Technology Award (上海市青年科技傑出貢獻獎) in 2019.

**Dr. Huamao WANG (王**華茂), aged 47, was appointed as a Director in September 2018 and the Chief Operating Officer in February 2021. He was re-designated as an executive Director in February 2021.

Dr. Wang has also held positions at other members of our Group. He has been a director and the Chief Operating Officer of CARsgen Therapeutics (Shanghai) since October 2014, the general manager of CARsgen Pharmaceuticals since November 2017 and the general manager of CARsgen Diagnostics since November 2020.

Prior to joining our Group, Dr. Wang served as the general manager of YIJIE Biotech (Shanghai) Holding Limited (上海益傑生物技術有限公司) from July 2013 to October 2014, and the deputy general manager of Shanghai Ruijin Biotechnology Co., Ltd. (上海鋭勁生物技術有限公司) from January 2011 to June 2013. Before that, Dr. Wang worked at Zhejiang Academy of Medical Sciences (浙江省醫學科學院) from July 2009 to January 2011.

Dr. Wang obtained his bachelor's degree in biochemistry from Sichuan University (四川大學), the PRC, in July 1999. He received his master's degree and Doctor of Philosophy degree in pathogenic organisms from Fudan University (復旦大學), the PRC, in June 2003 and June 2009, respectively.

**Dr. Hua JIANG (**蔣華), aged 45, was appointed as an executive Director on August 1, 2022, who has about 18 years of work experience in the field of cancer biotherapy, and also serves as Vice President of Early Discovery of CARsgen, and is responsible for formulating the strategy of early discovery and the construction of R&D pipeline.

Dr. Jiang joined the Company in April 2021 as Senior Director of Immune Cell Research and Development Department, and is responsible for the research work of Immune Cell Research and Development and Preclinical Pharmacology. Dr. Jiang has achieved outstanding outcomes, not only by strengthening the technology platform but also by expanding a number of candidate product pipelines.

Prior to joining the Company, from July 2007 to April 2021, Dr. Jiang was responsible for the research and development of antibody and CAR T-cells, as well as the related mechanism in Shanghai Cancer Institute (上海市腫瘤研究所). Dr. Jiang was a professor in Shanghai Cancer Institute (上海市腫瘤研究所) and a doctoral supervisor at Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院). Dr. Jiang has published more than 20 SCI papers, including JNCI, CCR, Molecular Therapy and other professional journals. She published the world's first paper about CLDN18.2 and EGFR/EGFRvIII CAR T Therapy as the first author and the world's first paper of small molecule inhibitor and CAR T combination therapy in solid tumors as the co-corresponding author.

Dr. Jiang earned her bachelor's degree in Clinical Medicine from Jining Medical College (濟寧醫學院) in 2001. She obtained her master's degree in Pathogen Biology from Shandong University (山東大學) in 2004 and Ph.D. in Pathogen Biology from Fudan University (復旦大學) in 2007.

# Directors and Senior Management

# **NON-EXECUTIVE DIRECTORS**

**Mr. Bingsen GUO (**郭炳森), aged 53, was appointed as a Director in September 2018 and re-designated as a non-executive Director in February 2021.

Mr. Guo had been a director of CARsgen Therapeutics (Shanghai) from April 2016 to April 2020.

Mr. Guo is an entrepreneur with expertise in plastic manufacturing industry. He was appointed as a supervisor from February 2017 to April 2019 and co-founded Quanzhou Hongcheng Precision Plastic Mould Ltd. (泉州弘晟精密塑膠模具有限公司) in February 2017. Mr. Guo was appointed as the vice president of the council of the Fifth Administrative Committee of Fujian Province Youth Commercial Association (福建省青年 商會第五屆管委會理事會) in 2016. In October 2009, Mr. Guo founded Hubei Xincheng Plastic Ltd. (湖北鑫晟 塑膠有限公司); established Xinsheng Precision Computer Mould (Fujian) Ltd. (鑫晟精密電腦模具(福建)有限 公司) in April 2006 and acts as its executive director. Mr. Guo cofounded Fujian Huian Xian Yide Plastic Co., Ltd. (福建惠安縣怡德塑膠有限公司) in March 1998 and acts as its director.

Mr. Guo was awarded the 12th Fujian Province Outstanding Entrepreneur (第十二屆福建省優秀企業家) in 2008. He was nominated as one of the National Villages Young Entrepreneurial Leaders (全國農村青年創業致富帶頭人) in 2008.

Mr. Guo is an uncle of another non-executive Director, Mr. Huaqing GUO (郭華清).

**Mr. Huaqing GUO (**郭華清), aged 35, was appointed as a Director in September 2020 and re-designated as a non-executive Director in February 2021.

Mr. Guo has been an executive Director, the general manager and legal representative at Xiamen Runtang Tianyi Investment Management Ltd. (廈門潤唐天一投資管理有限公司) since June 2020 and has been responsible for investment management in the secondary market. He served as general manager and legal representative at Fujian Dingwo Investment Management Ltd. (福建省鼎沃投資管理有限公司) from September 2015 to May 2020, during which he participated in equity investments projects, and as a vice president at Quanzhou Jiatai Footwear Ltd. (泉州嘉泰鞋業有限公司) from September 2011 to August 2015. With his experience in business administration and investment management, our Company believes that Mr. Guo can bring a unique perspective to the Board, in particular, in assisting our Company's business development and risk assessment of various investments.

Mr. Guo obtained his bachelor's degree in business administration from Jiageng College of Xiamen University (廈門大學嘉庚學院), the PRC, in July 2011.

Mr. Guo is a nephew of Mr. Bingsen GUO (郭炳森).

**Mr. Ronggang XIE (**謝榕剛), aged 38, was appointed as a Director in September 2020 and re-designated as a non-executive Director in February 2021.

Mr. Xie has been appointed as a non-executive director of InnoCare Pharma Limited (諾誠健華醫藥有限公司) (HKEX: 9969), a non-executive director of Akeso, Inc. (康方生物科技(開曼)有限公司) (HKEX: 9926) and a director of Shanghai Allist Pharmaceuticals Co., Ltd. (上海艾力斯醫藥科技股份有限公司) (SSE: 688578) since March 2021, August 2020 and November 2019, respectively. Mr. Xie is currently a partner of Shanghai Loyal Valley Investment Management Limited (上海正心谷投資管理有限公司) and was promoted to a managing director in November 2016 after joining as a senior investment manager in October 2015. Prior to joining Shanghai Loyal Valley Investment Management Limited, Mr. Xie was appointed as an investment director between June 2014 and June 2015 and served as an investment manager at Suzhou Kaifeng Zhengde Investment Management Co., Ltd (蘇州凱風正德投資管理有限公司) from June 2011 to June 2014.

Mr. Xie obtained his master's degree in biomedical engineering from Southeast University (東南大學), the PRC, in March 2011.

## INDEPENDENT NON-EXECUTIVE DIRECTORS

**Dr. Guangmei YAN (**顏光美**)**, aged 67, was appointed as an independent non-executive Director effective as of the Listing Date.

Dr. Yan has been appointed as an independent director of Medprin Regenerative Medical Technologies Co., Ltd. (廣州邁普再生醫學科技股份有限公司) (SZSE: 301033) since November 2018. Dr. Yan also served as an independent director of MGI Tech Co., Ltd (深圳華大智造科技股份有限公司) (SSE: 688114) from June 2020 to December 2022.

Dr. Yan served as the vice president of Sun Yat-sen University (中山大學) (previously known as Sun Yat-sen University of Medical Sciences (中山醫科大學)) from 2008 to 2017. He was appointed as a professor from December 1996 to November 1999 and an assistant professor from August 1989 to July 1992. He began to teach at the university in August 1989.

Dr. Yan obtained his bachelor's degree in medicine from the Central South University Xiangya School of Medicine (中南大學湘雅醫學院), formerly known as the Hunan Medical School (湖南醫學院), the PRC in December 1979 and completed a training course of the National College of Pharmacy Teaching (全國高 等學院校藥理學師資進修班) organized by the university in February 1982. Dr. Yan obtained his master's and doctorate degree in medicine from Sun Yat-sen University (中山大學), formerly known as Sun Yat-sen University of Medical Sciences (中山醫科大學), the PRC, in March 1985 and July 1989, respectively.

# Directors and Senior Management

**Dr. Huabing LI (李**華兵), aged 43, was appointed as an independent non-executive Director commencing from March 9, 2023.

He has rich working experiences in the field of biology, and has worked in Shanghai Jiaotong University School of Medicine Shanghai Institute of Immunology as a Researcher with main responsibilities of the research on epigenetic immunology from December 2017. Prior to this, he served as postdoctoral researcher in Yale University from September 2012 and was a postdoctoral research fellow in Rutgers, the State University of New Jersey from June 2011 to August 2012.

Dr. Huabing LI earned his Bachelor's degree in Science in Biological Science from College of Life Sciences, Nankai University in June 2002. He obtained Master's degree in Science in Genetics from Nankai University in July 2005 and Ph.D. in Biochemistry and Molecular Biology from Rutgers, The State University of New Jersey in May 2011.

**Ms. Xiangke ZHAO (**道向可), aged 38, was appointed as an independent non-executive Director commencing from July 4, 2023.

Ms. Zhao was the chief financial officer of Town Health International Medical Group Limited (康健國際醫療 集團有限公司) (HKEX: 3886) from 2 December 2019 to 25 March 2024. Ms. Zhao also served as an executive director of Town Health International Medical Group Limited from 26 March 2021 to 20 June 2023, and an associate director of the Investment Management Department of China Life Private Equity Investment Company Limited (國壽股權投資有限公司) from July 2018 till March 2021. Ms. Zhao had worked in the assurance department and financial advisory department of two international accounting firms and has extensive experience in the provision of financial, auditing and advisory professional services.

Ms. Zhao graduated from Renmin University of China (中國人民大學) with a bachelor's degree in economics in June 2008. She is also a member of CPA Australia.

#### **SENIOR MANAGEMENT**

**Dr. Zonghai LI (**李宗海), **Dr. Huamao WANG (**王華茂) **and Dr. Hua JIANG (**蔣華) are each an executive Director of our Company and also a member of our senior management team. For further details, please see "Directors and Senior Management – Executive Directors" for details of their biography.

Dr. Raffaele BAFFA, aged 63, joined the Group in April 2022 and is our Chief Medical Officer.

Dr. Baffa has rich experiences in pharmaceutical industry and research institutes, taking various leadership positions in multi-national corporations and biotech companies. Prior to joining our Group, Dr. Baffa served as Chief Medical Officer and Executive Vice President of Research & Development at Ziopharm Oncology (NASDAQ: ZIOP). Ziopharm Oncology was rebranded to Alaunos (NASDAQ: TCRT) in January 2022. Prior to Ziopharm Oncology, Dr. Baffa was the Head of Research & Development and Chief Medical Officer in Medisix Therapeutics, a company focused on developing novel immune cell therapies. Dr. Baffa was the Vice President, Therapeutic Area Head of Oncology, Global Clinical Development for Shire Pharmaceuticals, and following the acquisition of the oncology division by Servier Pharmaceuticals, Dr. Baffa served as the Chief Medical Officer of Servier Pharmaceuticals. Dr. Baffa has also held leadership positions at Pfizer and Sanofi.

Dr. Baffa earned an M.D. from University of Padova, School of Medicine and a Ph.D. in biology and molecular pathology from University of Parma in Italy.

**Dr. Jie JIA (**頁捷**)**, aged 46, joined our Group in December 2016 and is our Vice President, Strategic Alliances and Operations.

Dr. Jia has served in CARsgen Therapeutics Corporation, our wholly-owned subsidiary incorporated in the United States since joining our Group, including as the Vice President, Business Development, responsible for overseeing the corporate operations of the Group in the United States, leading the strategic alliances and managing CMC operations from December 2016 to July 2017, as the Vice President, Strategic Alliances, responsible for overseeing the corporate operations in the United States, leading strategic alliances, managing CMC operations from July 2017 to December 2018, and as the Vice President, Strategic Alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances, managing CMC operations from January 2019 to present.

Dr. Jia obtained his bachelor's degree in biochemistry from Sichuan University (四川大學), the PRC, in July 1999 and his doctorate degree in biochemistry and molecular biology from Shanghai Institutes for Biological Sciences, Chinese Academy of Sciences (中國科學院上海生命科學研究院), the PRC, in August 2004. He has been a member of The North American Vascular Biology Organization and Sigma Xi since 2006 and 2008, respectively. In 2014, he joined The Nitric Oxide Society as a member. He became a member of American Association for the Advancement of Science in 2016. Dr. Jia joined the American Society of Clinical Oncology as an allied physician and doctoral scientist in 2017. He has been a member of the American Society of Hematology and a full member of the American Society of Quality since 2019.

**Dr. Sylvie PELTIER**, aged 60, joined the Group in October 2022 and is our Senior Vice President, Global Regulatory Affairs.

Dr. Peltier has extensive global leadership and hands-on experiences in Clinical and CMC Regulatory Affairs across several multinational pharmaceutical and biopharmaceutical companies. Prior to joining CARsgen, Dr. Peltier served as Vice President, Head of US Regulatory Affairs at MorphoSys US Inc (NASDAQ: MOR) since 2020, and as Head of Regulatory Affairs at Servier Pharmaceuticals LLC from 2018. Before joining Servier Pharmaceuticals LLC, Dr. Peltier served at Cephalon since 2007, an international biopharmaceutical company which was acquired later by TEVA Pharmaceuticals Industries Ltd (NYSE: TEVA), holding various positions from Senior Director, Europe Regulatory Affairs, CNS/Pain and CMC, Senior Director, US Regulatory Affairs, to Senior Director, Clinical Search Evaluation and Due Diligence. Previously, Dr. Peltier worked at Pfizer Regulatory Affairs from 1995.

Dr. Peltier earned a Diploma of Pharmacy Doctorate and a Diploma of Graduated Specialized Studies (DESS) in Health Law from University of Paris XI in Paris, France.

# **Directors' Report**

# **REPORT OF THE DIRECTORS**

The Directors present their report and the audited consolidated financial statements (the "**Consolidated Financial Statements**") of the Group for the Reporting Period.

## **GENERAL INFORMATION**

The Company was incorporated in the Cayman Islands on February 9, 2018 as an exempted company with limited liability under the laws of the Cayman Islands. The Company's shares were listed on the Main Board of the Stock Exchange on June 18, 2021.

# **PRINCIPAL ACTIVITIES**

CARsgen is a biopharmaceutical company with operations in China and the U.S. and is focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has established a comprehensive CAR T-cell research and development platform, encompassing target discovery, innovative CAR T-cell development, clinical trials, and commercial-scale production. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. CARsgen's mission is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable. There was no significant change in the nature of the Group's principal activities during the Reporting Period.

Particulars of the Company's principal subsidiaries as at December 31, 2023 are set out in Note 1 to the Consolidated Financial Statements.

# **BUSINESS REVIEW**

A fair review of the business of the Group as well as a discussion and analysis of the Group's performance during the Reporting Period and the material factors underlying its financial performance and financial position as required by section 388(2) and Schedule 5 to the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) ("**Companies Ordinance**") can be found in the section headed "Management Discussion and Analysis" of this report.

## DIRECTORS

During the Reporting Period and up to the Latest Practicable Date, the Board consists of the following Directors:

#### **Executive Directors**

Dr. Zonghai LI *(Chairman)* Dr. Huamao WANG Dr. Hua JIANG

#### **Non-executive Directors**

Mr. Bingsen GUO Mr. Ronggang XIE Mr. Huaqing GUO

#### Independent Non-executive Directors

Dr. Chunhai FAN (resigned on January 11, 2023) Dr. Guangmei YAN Mr. Tak Young SO (resigned on June 30, 2023) Dr. Huabing LI (appointed on March 9, 2023) Ms. Xiangke ZHAO (appointed on July 4, 2023)

In accordance with Article 16.2 of the Articles of Association of the Company, Ms. Xiangke ZHAO, the Director appointed by the Board on July 4, 2023 to fill a casual vacancy or as an addition to the Board, shall hold office only until the next following general meeting of the Company and shall then be eligible for re-election at that meeting. As such, Ms. Xiangke ZHAO will retire from office at the forthcoming annual general meeting of the Company ("AGM") and, being eligible, will offer herself for re-election.

In accordance with Article 16.19 of the Articles of Association of the Company, Dr. Zonghai LI, Dr. Huamao WANG and Mr. Bingsen GUO will retire from office by rotation at the forthcoming AGM and, being eligible, will offer themselves for re-election.

#### **DIRECTORS AND SENIOR MANAGEMENT'S BIOGRAPHIES**

Biographical details of the Directors and senior management are set out in the section headed "Directors and Senior Management" of this report.

#### **CHANGES IN INFORMATION OF DIRECTORS**

Details of changes in Directors during the Reporting Period and up to the Latest Practicable Date are set out below:

Name	Position	Details of Change	Reasons of Change
Dr. Chunhai FAN	independent non- executive Director	resigned on January 11, 2023	other business commitments which require more of his attention and dedication
Dr. Huabing Ll	independent non- executive Director	appointed on March 9, 2023	_
Mr. Tak Young SO	independent non- executive Director	resigned on June 30, 2023	other business commitments which require more of his attention and dedication
Ms. Xiangke ZHAO	independent non- executive Director	appointed on July 4, 2023	_

Having made specific enquiry and as confirmed by Directors, save for the biography details as disclosed under the section headed "Directors and Senior Management" of this report, no other changes in the information of Directors which shall be subject to disclosure according to paragraphs (a) to (e) and (g) under Rule 13.51(2) of the Listing Rules shall be disclosed in accordance with Rule 13.51B(1) of the Listing Rules since the date of publication of the 2023 interim report of the Company.

#### INDEPENDENCE OF INDEPENDENT NON-EXECUTIVE DIRECTORS

The Company has received from each of the independent non-executive Directors an annual confirmation in writing of his independence pursuant to Rule 3.13 of the Listing Rules. The Company considers that, during the Reporting Period and as at the Latest Practicable Date, all of the independent non-executive Directors are independent.

#### DIRECTORS' SERVICE CONTRACTS

For more information about the service contracts entered into by the Company, please see the Corporate Governance Report in this report for further details.

#### PERMITTED INDEMNITY PROVISION AND DIRECTORS' AND OFFICERS' LIABILITY INSURANCE

A permitted indemnity provision (as defined in the Companies Ordinance (Chapter 622 of the Laws of Hong Kong)) in relation to the directors' and officers' liability insurance is currently in force and was in force during the Reporting Period and up to the Latest Practicable Date. The Company has arranged appropriate directors' liability insurance coverage for the Directors of the Group during the Reporting Period and up to the Latest Practicable Date.

#### SUFFICIENCY OF PUBLIC FLOAT

Based on the information that is publicly available to the Company and within the knowledge of the Directors, the Company had maintained the prescribed public float under Rule 8.08 of the Listing Rules during the Reporting Period and as at the Latest Practicable Date.

#### **KEY PERFORMANCE INDICATORS**

Details of the key performance indicators of the Group as at December 31, 2023 are set out in the section headed "Management Discussion & Analysis" of this report.

#### **CORPORATE GOVERNANCE**

Particulars of the Company's corporate governance practices are set out in the section headed "Corporate Governance Report" of this report.

#### **REVIEW BY AUDIT COMMITTEE**

The Audit Committee currently comprises two independent non-executive Directors, namely, Ms. Xiangke ZHAO and Dr. Huabing LI, and one non-executive Director, namely Mr. Huaqing GUO. The Audit Committee has reviewed the audited Consolidated Financial Statements for the year ended December 31, 2023 with the management and the auditor of the Company. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

#### PRINCIPAL RISKS AND UNCERTAINTIES

#### **Risks Relating to Our Financial Position and Need for Additional Capital**

- We have incurred significant net losses and net operating cash outflows since our inception, and we anticipate that we will continue to incur net losses and net operating cash outflows for the foreseeable future and may never become profitable;
- We have net operating cash outflow during the Reporting Period;
- We may need additional capital to meet our operating cash requirements, and financing may not be available on terms acceptable to us, or at all;
- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. The risks involved in our business may cause potential investors to lose substantially all of their investment in our business;
- We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates;
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

#### **Risks Relating to Our Business**

- We depend substantially on the success of our product candidates, all of which are in pre-clinical or clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;
- We operate in a rapidly changing industry and we face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or developing product candidates or treatments that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. As a result, our product candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete;
- Clinical development of biopharmaceutical products involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results;
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- We may not be successful in our efforts to build or in-license a pipeline of new product candidates. If we fail to do so, our commercial opportunity will be limited;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

#### **Risks Relating to Extensive Government Regulation**

- All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated. Any failure to comply with existing regulations and industry standards, or any adverse actions by the NMPA or other comparable regulatory authorities against us, could negatively impact our reputation and our business, financial condition, results of operations and prospects;
- The regulatory approval processes of the NMPA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain, or experience delays in obtaining, regulatory approval for our product candidates, our business will be substantially harmed;
- Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs;
- Even if we are able to commercialize any approved product candidates, the products may become subject to unfavorable pricing regulations, or to unfavorable changes in national or third-party reimbursement practices, which could harm our business.

#### **Risks Relating to Manufacturing of Our Product Candidates**

• Our product candidates are cell therapies. The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to development or scalingout of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

#### **Risks Relating to Commercialization of Our Product Candidates**

- The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect;
- We currently have a limited marketing and sales organization and have no experience as a company in launching and marketing products. If we are unable to establish marketing and sales capabilities to market and sell our product candidates, we may not be able to generate product revenue or commercialize future product candidates. We may not be able to effectively build and manage our sales network;
- Product liability claims or lawsuits could cause us to incur substantial liabilities, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur;
- The increasing use of social media platforms presents new risks and challenges.

#### **Risks Relating to Our Intellectual Property Rights**

- If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates and other intellectual property, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our product candidates or technologies may be adversely affected;
- If we determine that our intellectual property rights (including rights in-licensed from third parties) or other intangible assets are impaired, our results of operations and financial condition may be adversely affected;
- Even if we are able to obtain patent protection for our product candidates, the life of such protection, if any, is limited, and third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

For further details, please refer to the section headed "Risk Factors" in the Prospectus.

#### DIRECTORS' AND CHIEF EXECUTIVE'S INTERESTS AND SHORT POSITIONS IN SHARES, UNDERLYING SHARES AND DEBENTURES OF THE COMPANY AND ITS ASSOCIATED CORPORATIONS

As at December 31, 2023, the interests or short positions of the Directors and chief executive's of the Company in the Shares, underlying Shares and debentures of the Company or any associated corporation (within the meaning of Part XV of the SFO), which (a) were required to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she was taken or deemed to have under such provisions of the SFO); or (b) were required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein; or (c) were required to be notified to the Company and the Stock Exchange pursuant to the Model Code, were as follows:

#### Interest in Shares and Underlying Shares of the Company

Name of Director/ Chief Executive	Capacity	Total number of Shares/ underlying Shares held	Approximate Percentage of Interest in the Company <i>(Note 3)</i>
Dr. Zonghai LI <i>(Note 1) (Note 2)</i>	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Mr. Bingsen GUO (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Dr. Huamao WANG (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Mr. Huaqing GUO (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Dr. Hua JIANG	Beneficial owner	3,037,156/ Long position	0.53%

Notes:

- (1) YIJIE Biotech (BVI) holds 198,139,536 Shares of our Company, representing 34.42% of interest of our Company as at December 31, 2023. YIJIE Biotech (BVI) is owned as to 69.00%, 10.20%, 10.00%, 10.00% and 0.80% by CART Biotech, Redelle Holding, He Xi Holdings Limited, Candock Holdings Limited and Accure Biotech Limited (collectively, the "Intermediary Entities") respectively. The Intermediary Entities are wholly-owned by Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO and Mr. Haiou CHEN respectively.
- (2) Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO, Mr. Haiou CHEN, the Intermediary Entities, Ms. Xuehong YANG, Yeed Holdings, Ms. Xiaojing GUO and Quanzhou Dingwo (LP) entered into the Concert Party Agreement on February 22, 2021 and each party is deemed to be interested in the Shares that the other parties are interested in under section 317 of the SFO. Each of Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO and Mr. Haiou CHEN, through the Intermediary Entities and YIJIE Biotech (BVI), are interested in 198,139,536 Shares of our Company, representing 34.42% of interest in our Company as at December 31,2023. Ms. Xuehong YANG is interested in 8,888,888 Shares, representing 1.54% of interest in our Company through Yeed Holdings as at December 31, 2023. Ms. Xiaojing GUO is interested in 5,555,556 Shares, representing 0.97% of interest in our Company through Quanzhou Dingwo (LP) as of December 31, 2023. In addition, Mr. Haiou CHEN was granted RSUs equivalent to 248,977 Shares and options with respect to 2,739,773 Shares subject to vesting or exercising under share schemes of the Company, of which 67,905 RSUs have been vested as of December 31,2023. Therefore, Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Haiaqing GUO, Mr. Haiou CHEN, the Intermediary Entities, Ms. Xuehong YANG, Yeed Holdings, Ms. Xiaojing GUO and Quanzhou Dingwo (LP) are deemed to be interested in 4,885,888 Shares, representing 0.97% of interest in our Company through Quanzhou Dingwo (LP) as of December 31,2023. In addition, Mr. Haiou CHEN was granted RSUs equivalent to 248,977 Shares and options with respect to 2,739,773 Shares subject to vesting or exercising under share schemes of the Company, of which 67,905 RSUs have been vested as of December 31,2023. Therefore, Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO, Mr. Haiou CHEN, the Intermediary Entities, Ms. Xuehong YANG, Yeed Holdings, Ms. Xiaojing GUO and Quanzhou Dingwo (LP) are deemed to be interested in a total of 215,572,
- (3) As at December 31, 2023, the total issued share capital of the Company was 575,640,021 Shares.

Save as disclosed above, as at December 31, 2023, none of the Directors and chief executive of the Company had or was deemed to have any interest or short position in the Shares, underlying Shares or debentures of the Company or any of its associated corporations (within the meaning of Part XV of the SFO) which was required to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they were taken or deemed to have taken under such provisions of the SFO), or which were required to be recorded in the register to be kept by the Company under Section 352 of the SFO, or which were required to be notified to the Company and the Stock Exchange pursuant to the Model Code.

# SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES OF THE COMPANY

As at December 31, 2023, the persons, other than the Directors or the chief executive of the Company, who had interests or short positions in the Shares and underlying Shares as recorded in the register of interests required to be kept by the Company pursuant to Section 336 of Part XV of the SFO are as follows:

Name of Shareholders	Capacity	Number of securities/ Nature of Shares held	Approximate percentage of interest in the Company <i>(Note 5)</i>
CART Biotech (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Redelle Holding (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
He Xi Holdings (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
CANDOCK Holdings Limited (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Mr. Haiou CHEN <i>(Note 1) (Note 2)</i>	Beneficial interest, interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Accure Biotech Limited (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Ms. Xuehong YANG (Note 2) (Note 3)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Yeed Holdings (Note 2) (Note 3)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%
Ms. Xiaojing GUO (Note 2) (Note 4)	Interest of controlled corporations and interest of party acting in concert	215,572,730/ Long position	37.45%

#### Interest in Shares and Underlying Shares of the Company

Name of Shareholders	Capacity	Number of securities/ Nature of Shares held	Approximate percentage of interest in the Company <i>(Note 5)</i>
Quanzhou Dingwo (LP) (Note 2) (Note 4)	Beneficial interest and interest of party acting in concert	215,572,730/ Long position	37.45%
YIJIE Biotech (BVI) <i>(Note 1)</i>	Beneficial interest and interest of party acting in concert	215,572,730/ Long position	37.45%

Notes:

- (1) YIJIE Biotech (BVI) holds 198,139,536 Shares of our Company, representing 34.42% of interest of our Company as at December 31, 2023. YIJIE Biotech (BVI) is owned as to 69.00%, 10.20%, 10.00%, 10.00% and 0.80% by the Intermediary Entities respectively. The Intermediary Entities are wholly-owned by Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO and Mr. Haiou CHEN respectively.
- (2) Dr. Zonghai LI, Mr. GUO Bingsen, Dr. Huamao WANG, Mr. Huaqing GUO, Mr. Haiou CHEN, the Intermediary Entities, Ms. Xuehong YANG, Yeed Holdings, Ms. Xiaojing GUO and Quanzhou Dingwo (LP) entered into the Concert Party Agreement on February 22, 2021 and each party is deemed to be interested in the Shares that the other parties are interested in under section 317 of the SFO. Each of Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO and Mr. Haiou CHEN, through the Intermediary Entities and YIJIE Biotech (BVI), are interested in 198,139,536 Shares of our Company, representing 34.42% of interest in our Company as at December 31, 2023. Ms. Xuehong YANG is interested in 8,888,888 Shares, representing 1.54% of interest in our Company through Yeed Holdings as at December 31, 2023. Ms. Xiaojing GUO is interested in 5,555,556 Shares, representing 0.97% of interest in our Company through Quanzhou Dingwo (LP) as of December 31, 2023. In addition, Mr. Haiou CHEN was granted RSUs equivalent to 248,977 Shares and options with respect to 2,739,773 Shares subject to vesting or exercising under share schemes of the Company, of which 67,905 RSUs have been vested as of December 31,2023. Therefore, Dr. Zonghai LI, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO, Mr. Haiou CHEN, the Intermediary Entities, Ms. Xuehong YANG, Yeed Holdings, Ms. Xiaojing GUO and Quanzhou Dingwo (LP) are deemed to be interested in a total of 215,572,730 Shares, representing 37.45% of interest in our Company as at December 31, 2023.
- (3) Yeed Holdings holds 8,888,888 Shares in our Company, representing 1.54% of interest in our Company as at December 31, 2023. Yeed Holdings is wholly-owned by Ms. Xuehong YANG, the wife of our non-executive Director, Mr. Bingsen GUO.
- (4) Quanzhou Dingwo (LP) holds 5,555,556 Shares in our Company, representing 0.97% of interest in our Company as at December 31, 2023. The general partner of Quanzhou Dingwo (LP) is Ms. Xiaojing GUO, the daughter of our non-executive Director, Mr. Bingsen GUO.
- (5) As at December 31, 2023, the total issued share capital of the Company was 575,640,021 Shares.

Save as disclosed above and to the best knowledge of the Directors, as at December 31, 2023, the Company is not aware of any other person (other than the Directors or the chief executive of the Company) who had an interest or short position in the Shares or underlying Shares as recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO.

#### **DIRECTORS' INTERESTS IN COMPETING BUSINESSES**

During the Reporting Period, none of the Directors or their respective close associates (as defined in the Listing Rules) is considered to have interests in businesses which compete or are likely to compete, either directly or indirectly, with the businesses of the Group pursuant to the Listing Rules.

#### ARRANGEMENT FOR DIRECTORS TO ACQUIRE SHARES OR DEBENTURES

Save as disclosed in this report, at no time during the Reporting Period was the Company or any of its subsidiaries, the holding company, a party to any arrangement to enable a Director to acquire benefits by means of the acquisition of shares in, or debentures of, the Company or any other body corporate.

#### PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

During the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company's listed securities.

#### **PRE-EMPTIVE RIGHTS**

There is no provision for pre-emptive rights under the articles of association of the Company or the laws of the Cayman Islands which would oblige the Company to offer new shares on a pro-rata basis to its existing shareholders.

#### DIRECTORS' INTERESTS IN TRANSACTIONS, ARRANGEMENTS OR CONTRACTS

Save for the Contractual Arrangements as disclosed in this report, no Director nor an entity connected with him/her had a material interest, whether directly or indirectly, in any transaction, arrangement or contract of significance to the business of the Group to which the Company or any of its subsidiaries was a party during the Reporting Period.

#### CONTINUING DISCLOSURE OBLIGATIONS PURSUANT TO THE LISTING RULES

Save as disclosed in the annual report, the Company does not have any disclosure obligations under Rule 13.20, 13.21 and 13.22 of the Listing Rules.

#### COMPLIANCE WITH THE RELEVANT LAWS AND REGULATIONS

The Group has compliance policies and procedures in place to ensure adherence to applicable laws, rules and regulations, in particular, those that have a significant impact on it. The Group would seek professional legal advice from its legal advisers to ensure that transactions and business to be performed by the Group are in compliance with the applicable laws and regulations. During the Reporting Period and up to the Latest Practicable Date, save as disclosed in the report, the Group was not aware of any non-compliance with the laws, regulations and regulatory requirements of the places where the Group operates in all material respects, including the requirements under the Companies Ordinance, the Listing Rules, the SFO and the Corporate Governance Code for, among other things, the disclosure of information and corporate governance.

#### **EQUITY-LINK AGREEMENT**

Save as disclosed in this report, the Company had not entered into any equity-linked agreement for the year ended December 31, 2023, nor did any equity-linked agreement subsist as at December 31, 2023.

#### **CONTROLLING SHAREHOLDER'S INTERESTS IN SIGNIFICANT CONTRACTS**

Save as disclosed in this report, at no time during the Reporting Period had the Company or any of its subsidiaries, and any of the controlling shareholders (as defined in the Listing Rules) of the Company or any of their subsidiaries (as the case may be) entered into any contract of significance or any contract of significance for the provision of services by any such controlling shareholders or their subsidiaries (as the case may be) to the Company or any of its subsidiaries.

#### **MANAGEMENT CONTRACTS**

Save for the Directors' service contracts and appointment letters, no contract of significance concerning the management and administration of the whole or any substantial part of business of the Company or any of its subsidiaries was entered into or subsisted during the Reporting Period.

#### **MATERIAL LITIGATION**

The Company was not involved in any material litigation or arbitration for the year ended December 31, 2023. The Directors are also not aware of any material litigation or claims that are pending or threatened against the Group for the year ended December 31, 2023.

#### **CONTINUING CONNECTED TRANSACTIONS**

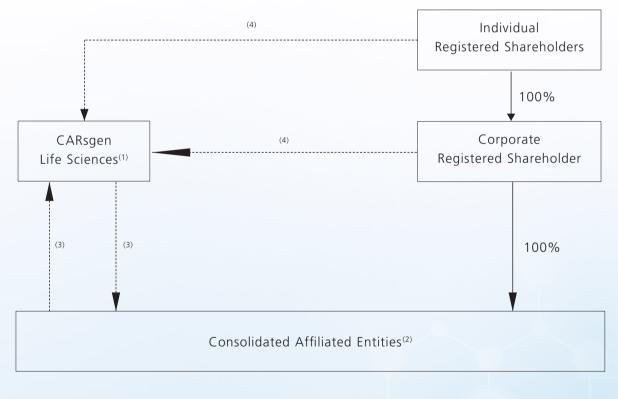
#### **Contractual Arrangement**

The Group entered into a series of Contractual Arrangements which would constitute non-exempt continuing connected transactions pursuant to Chapter 14A of the Listing Rules.

#### Background

In order to comply with the PRC laws and regulations and maintain effective control over all of our operations, we, through our wholly-owned subsidiary, CARsgen Life Sciences entered into the Contractual Arrangements with CARsgen Therapeutics (Shanghai), the Corporate Registered Shareholder (i.e. the shareholder of CARsgen Therapeutics (Shanghai)) and the Individual Registered Shareholders (i.e. the shareholders of the Corporate Registered Shareholder), pursuant to which CARsgen Life Sciences acquired effective control over the finance and operations of our Consolidated Affiliated Entities and is entitled to all the economic benefits derived from their operations.

The following simplified diagram illustrates the flow of economic benefits from our Consolidated Affiliated Entities to our Group stipulated under the Contractual Arrangements:



#### "\_\_\_\_\_" Denotes legal and beneficial ownership in the equity interest

#### "\_\_\_\_\_" Denotes the Contractual Arrangements

Note:

- (1) CARsgen Life Sciences is wholly-owned by CARsgen Pharma Holdings Limited, which is in turn wholly-owned by our Company.
- (2) Our Consolidated Affiliated Entities include CARsgen Therapeutics (Shanghai) and CARsgen Pharmaceuticals. CARsgen Pharmaceuticals is wholly-owned by CARsgen Therapeutics (Shanghai), which is in turn wholly-owned by the Corporate Registered Shareholder, which is in turn owned by the Individual Registered Shareholders, namely as to 69% by Dr. Zonghai Ll, 10.2% by Mr. Bingsen GUO, 10% by Dr. Huamao WANG, 10% by Mr. Huaqing GUO and 0.8% by Mr. Haiou CHEN.
- (3) CARsgen Life Sciences provides technology consultation services in exchange for service fees from CARsgen Therapeutics (Shanghai). See sub-section headed "Exclusive Business Cooperation Agreements" below.
- (4) The Corporate Registered Shareholder executed the Corporate Exclusive Option Agreement (as defined below) in favour of CARsgen Life Sciences for the acquisition of 100% equity interests and/or assets in CARsgen Therapeutics (Shanghai). See sub-section headed "Exclusive Option Agreements". The Individual Registered Shareholders in turn executed the Individual Exclusive Option Agreement (as defined below) in favour of CARsgen Life Sciences for the acquisition of 100% equity interests and/or assets in the Corporate Registered Shareholder.

The Corporate Registered Shareholder pledged as first charge all of its equity interests in CARsgen Therapeutics (Shanghai) to CARsgen Life Sciences as security for its and CARsgen Therapeutics (Shanghai)' s performance under the Exclusive Business Cooperation Agreements (as defined below), the Corporate Exclusive Option Agreement (as defined below), the Corporate Share Pledge Agreement (as defined below) and the Corporate Powers of Attorney (as defined below), as applicable. The Individual Registered Shareholders in turn pledged as first charge all of their respective equity interests in the Corporate Registered Shareholder to CARsgen Life Sciences as security for their respective performance and the performance of the Corporate Registered Shareholder and CARsgen Therapeutics (Shanghai) under the Exclusive Business Cooperation Agreement, Exclusive Option Agreements, Powers of Attorney, Share Pledge Agreements (as applicable). See subsection headed "Share Pledge Agreements."

The Corporate Registered Shareholder executed the Corporate Powers of Attorney in favour of CARsgen Life Sciences. The Individual Registered Shareholders in turn executed the Powers of Attorney in favour of CARsgen Life Sciences in respect of their respective rights as shareholders of the Corporate Registered Shareholder.

#### **Summary of Contractual Arrangements**

#### **Exclusive Business Cooperation Agreements**

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the exclusive business cooperation agreements on April 18, 2018 and the amended and restated exclusive business cooperation agreements on February 2, 2021 (collectively, the "**Exclusive Business Cooperation Agreements**"), pursuant to which CARsgen Therapeutics (Shanghai) agreed to engage CARsgen Life Sciences as its exclusive provider of technology consultation, technical services and other related services, including but not limited to (i) technological support in relation to product development and testing, (ii) design, develop, update and maintenance service in relation to technology system, (iii) technological support in relation to research and development activities, (iv) technological consultation service (including but not limited to viability testing, technology prediction, investigation into specific technologies and producing analytical valuation reports), (v) personnel training services, (vi) onsite personnel supervision; and (vii) other related services requested by CARsgen Therapeutics (Shanghai) from time to time to the extent permitted under PRC law.

Pursuant to the Exclusive Business Cooperation Agreements, the service fee shall be paid annually to CARsgen Life Sciences. The annual service fees shall be reasonably determined by CARsgen Life Sciences based on certain factors, including, among other things, the complexity and difficulty of such services, time and commitment required to provide such services, actual service scope and the market value of comparable service.

The Exclusive Business Cooperation Agreements are for an initial term of 10 years and is automatically extended upon expiry for a term provided by CARsgen Life Sciences in writing unless terminated by CARsgen Life Sciences in the same manner, or otherwise terminated pursuant to the terms of the Exclusive Business Cooperation Agreements.

#### Powers of Attorney

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the powers of attorney with the Corporate Registered Shareholder and other related parties on April 18, 2018 and the amended and restated powers of attorney on February 2, 2021 with Corporate Registered Shareholder (the "**Corporate Powers of Attorney**") pursuant to which the Corporate Registered Shareholder irrevocably and exclusively granted CARsgen Life Sciences or its designee(s) (being the directors of the offshore parent company of CARsgen Life Sciences and liquidators and other successors replacing such directors) the power to exercise all rights of the shareholders as set out in the then valid articles of association of CARsgen Therapeutics (Shanghai) and relevant laws and regulations.

The Corporate Powers of Attorney shall remain effective from the date of signing until the Corporate Registered Shareholder (including its successor(s)) ceases to be the shareholder of CARsgen Therapeutics (Shanghai) or otherwise terminated pursuant to the terms of the Corporate Powers of Attorney.

On the other hand, CARsgen Life Sciences also entered into the powers of attorney (the "Individual Powers of Attorney", and together with the Corporate Powers of Attorney, the "Powers of Attorney") on February 2, 2021 with the Individual Registered Shareholders, pursuant to which the Individual Registered Shareholders irrevocably and exclusively granted CARsgen Life Sciences or its designee(s) (being the directors of the offshore parent company of CARsgen Life Sciences and liquidators and other successors replacing such directors) the power to exercise all rights of the shareholders as set out in the then valid articles of association of the Corporate Registered Shareholder on similar terms as the Corporate Powers of Attorney.

#### Exclusive Option Agreements

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into an exclusive option agreement with the Corporate Registered Shareholder and other related parties on April 18, 2018 and an amended and restated exclusive option agreement on February 2, 2021 (collectively the "**Corporate Exclusive Option Agreement**") with the Corporate Registered Shareholder, pursuant to which CARsgen Life Sciences (or a third party designated by it, the "**designee**") will be granted an irrevocable and exclusive right to acquire 100% of the equity interest in and/or assets of CARsgen Therapeutics (Shanghai), in whole or in part at the sole and absolute discretion of CARsgen Life Sciences, to the extent permitted under the PRC laws and regulations.

On the other hand, CARsgen Life Sciences also entered into an exclusive option agreement on February 2, 2021 (the "**Individual Exclusive Option Agreement**", and together with the Corporate Exclusive Option Agreement, the "**Exclusive Option Agreements**") with the Individual Registered Shareholders pursuant to which CARsgen Life Sciences will be granted an irrevocable and exclusive right to acquire 100% of the equity interest in and/or assets of the Corporate Registered Shareholder, in whole or in part at the sole and absolute discretion of CARsgen Life Sciences to the extent permitted under the PRC laws and regulations, on similar terms as the Corporate Exclusive Option Agreement.

The Exclusive Option Agreements shall remain effective for 10 years from the date of signing and shall extend at the election of CARsgen Life Sciences, except until (1) all of the equity interest in and the assets of CARsgen Therapeutics (Shanghai) have been transferred to CARsgen Life Sciences or its designees and (2) CARsgen Life Sciences could conduct the business operated by CARsgen Therapeutics (Shanghai) legally.

#### Share Pledge Agreements

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the share pledge agreement with the Corporate Registered Shareholder and other related parties on April 18, 2018 and the amended and restated share pledge agreement (the "**Corporate Share Pledge Agreement**") on February 2, 2021 with the Corporate Registered Shareholder, pursuant to which the Corporate Registered Shareholder agreed to pledge all of its equity interest in CARsgen Therapeutics (Shanghai) to CARsgen Life Sciences to secure performance of its and CARsgen Therapeutics (Shanghai)'s obligations under the Corporate Exclusive Business Cooperation Agreement, the Corporate Exclusive Options Agreement, the Corporate Share Pledge Agreement and the Corporate Powers of Attorney (as applicable).

On the other hand, CARsgen Life Sciences entered into the share pledge agreement (the "Individual Share Pledge Agreement", and together with the Corporate Share Pledge Agreement, the "Share Pledge Agreements") on February 2, 2021 with the Individual Registered Shareholders, pursuant to which the Individual Registered Shareholders agreed to pledge all of their respective equity interests in the Corporate Registered Shareholder to CARsgen Life Sciences to secure performance their respective performance and the performance of the Corporate Registered Shareholder and CARsgen Therapeutics (Shanghai) under the Exclusive Business Cooperation Agreement, Exclusive Option Agreements, Powers of Attorney, Share Pledge Agreements (as applicable), on similar terms as the Corporate Share Pledge Agreement. As of the Latest Practicable Date, we have registered the share pledges under the Individual Share Pledge Agreements with the relevant PRC governmental authority in accordance with PRC laws and regulations.

#### Spouse Undertakings

Each of the spouses of the Individual Registered Shareholders (as applicable) has executed an undertaking (collectively, the "**Spouse Undertakings**"), to the effect that (i) she acknowledges and consents to the execution of the Contractual Arrangements by the relevant Individual Registered Shareholder and acknowledges that she does not have any equity interest or rights with respect to the Contractual Arrangements; (ii) she undertakes not interfere with the performance of the Contractual Arrangements nor to make any assertions in connection with the equity interest of the Corporate Registered Shareholder held by the respective Individual Registered Shareholder; (iii) she has not participated and will not participate in the management of the Corporate Registered Shareholder and will not make any assertions in connection with the equity interest Shareholder; and (iv) in the event that she obtains any interests in the Corporate Registered Shareholder, she shall be bound by the Contractual Arrangements.

#### **Reasons for Adoption of Contractual Arrangements**

Foreign investment activities in the PRC are mainly governed by the Industry Guidelines on Encouraged Foreign Investment (2022) (《鼓勵外商投資產業目錄(2022年版)》) and the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2022) (《外商投資准入特別管理措施(負面清單) (2022 年版)》) (collectively, the "**Relevant PRC Regulations**") promulgated jointly by the MOFCOM and the NDRC, pursuant to which the industries listed therein are divided into four categories in terms of foreign investment, namely, "encouraged", "permitted", "prohibited" and "restricted". According to the Relevant PRC Regulations, foreign investment is prohibited in the development and application of human stem cells and genes diagnosis and treatment technologies.

Our Group engages in discovering, developing and commercializing innovative cell therapies for the treatment of hematological malignancies and solid tumors (the "**Relevant Business**"), which involves the development and application of gene therapeutic technologies and products, and therefore falls into the scope of the "prohibited" category of the Relevant PRC Regulations. In order to comply with the PRC laws and regulations and maintain effective control over the Relevant Business, our Group entered into the Contractual Arrangements with CARsgen Therapeutics (Shanghai), the Corporate Registered Shareholder (i.e. the shareholder of CARsgen Therapeutics (Shanghai)) and the Individual Registered Shareholders (i.e. the shareholders of the Corporate Registered Shareholder). Our Directors (including the independent non-executive Directors) are of the view that the Contractual Arrangements and the transactions contemplated therein are fundamental to our Group's legal structure and business.

#### **Risks Relating to the Contractual Arrangements**

There are certain risks that are associated with the Contractual Arrangements, including:

- If the PRC government finds that the agreements that establish the structure for operating our business in China do not comply with PRC laws and regulations, or if these regulations or their interpretations change in the future, we could be subject to severe consequences and the relinquishment of our interests in the Consolidated Affiliated Entities.
- There is substantial uncertainty with respect to the interpretation and implementation of the newly enacted Foreign Investment Law and how it may impact the viability of our current corporate structure, corporate governance and business operations.
- Our Contractual Arrangements may not be as effective in providing operational control as direct ownership, and the Registered Shareholders and the Consolidated Affiliated Entities may fail to perform their obligations under our Contractual Arrangements.
- We may lose the ability to use the permits and licenses held by the Consolidated Affiliated Entities that are important to the operation of our business if the Consolidated Affiliated Entities declares bankruptcy or becomes subject to a dissolution or liquidation proceeding.
- Our Contractual Arrangements may be subject to scrutiny by the PRC tax authorities and additional taxes may be imposed. A finding that we owe additional taxes could substantially reduce our consolidated net income and the value of your Shares.

- The Registered Shareholders of CARsgen Therapeutics (Shanghai) may potentially have a conflict of interest with us, and they may breach their contracts with us or cause such contracts to be amended in a manner contrary to our interests.
- Certain of the terms of the Contractual Arrangements may not be enforceable under PRC laws.
- If we exercise the option to acquire equity ownership of CARsgen Therapeutics (Shanghai) and/or the Corporate Registered Shareholder, the ownership transfer may subject us to certain limitations and substantial costs.

Our Group has adopted measures to ensure the effective operation of our Group's businesses with the implementation of the Contractual Arrangements and our compliance with the Contractual Arrangements, including:

- major issues arising from the implementation and compliance with the Contractual Arrangements or any regulatory enquiries from government authorities will be submitted to our Board, if necessary, for review and discussion on an occurrence basis;
- our independent non-executive Directors will review the overall performance of and compliance with the Contractual Arrangements annually;
- our Company will disclose the arrangements in place and compliance with the Contractual Arrangements in our annual reports; and
- our Company will engage external legal advisors or other professional advisors, if necessary, to assist the Board in reviewing the implementation of the Contractual Arrangements.

#### **Material Change**

As of the Latest Practicable Date, there were no material changes in the Contractual Arrangements and/or the circumstances under which the Contractual Arrangements were adopted.

#### **Unwinding of the Contractual Arrangements**

As of the Latest Practicable Date, there has not been any unwinding of any Contractual Arrangements, nor has there been any failure to unwind any Contractual Arrangements when the restrictions that led to the adoption of the Contractual Arrangements are removed.

#### Waiver from the Stock Exchange

In relation to the Contractual Arrangements, we have applied to the Stock Exchange for, and the Stock Exchange has granted, a waiver from strict compliance with (i) the announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules in respect of the transactions contemplated under the Contractual Arrangements pursuant to Rule 14A.105 of the Listing Rules, (ii) the requirement of setting an annual cap for the transactions under the Contractual Arrangements of limiting the term of the Contractual Arrangements to three years or less under Rule 14A.52 of the Listing Rules, for so long as the Shares are listed on the Stock Exchange subject however to the following conditions:

- (a) no change without independent non-executive Directors' approval;
- (b) no change without independent shareholders' approval;
- (c) the Contractual Arrangements shall continue to enable our Group to receive the entire economic benefits derived by CARsgen Therapeutics (Shanghai);
- (d) on the basis that the Contractual Arrangements provide an acceptable framework for the relationship between our Company and its subsidiaries in which our Company has direct shareholding, on the one hand, and CARsgen Therapeutics (Shanghai), on the other hand, that framework may be renewed and/or reproduced upon the expiry of the existing arrangements or in relation to any existing or new wholly foreign owned enterprise or operating company (including branch company) engaging in the same business as that of our Group which the Group might wish to establish when justified by business expediency, without obtaining the approval of the shareholders, on substantially the same terms and conditions as the existing Contractual Arrangements; and
- (e) our Group will disclose details relating to the Contractual Arrangements on an on-going basis.

For details, please refer to the section "Connected Transactions" in the Prospectus.

#### **Confirmation from Independent Non-executive Directors**

Our independent non-executive Directors have reviewed the Contractual Arrangements and confirmed that:

- (i) no transaction has been carried out during Reporting Period, which have not been entered into in accordance with the relevant provisions of the Contractual Arrangements;
- (ii) no dividends or other distributions have been made by the Consolidated Affiliated Entities to the holders of its equity interests which are not otherwise subsequently assigned or transferred to our Group, which is confirmed by the auditor of the Company;
- (iii) no new contract has been entered into, renewed or reproduced between our Group and the Consolidated Affiliated Entities during the Reporting Period; and
- (iv) the Contractual Arrangements had been entered into in the ordinary and usual course of business of our Group, and are on normal commercial terms and are fair and reasonable so far as our Group is concerned, and in the interest of our Company and its shareholders as a whole.

Further, the Consolidated Affiliated Entities undertakes that, for so long as the Shares are listed on the Hong Kong Stock Exchange, the Consolidated Affiliated Entities will provide our Group's management and our auditor with full access to its relevant records for the purpose of procedures to be carried out by our auditor on the connected transactions. For the year ended December 31, 2023, the net loss of Consolidated Affiliated Entities is approximately RMB226 million, and as at December 31, 2023, the total assets of Consolidated Affiliated Entities is approximately RMB231 million.

#### **Confirmations from Company's Independent Auditor**

The auditor of the Company confirmed that based on the foregoing, in respect of the disclosed continuing connected transactions (a) nothing has come to their attention that causes them to believe that the disclosed continuing connected transactions have not been approved by the Directors; (b) nothing has come to their attention that causes them to believe that the transactions were not entered into, in all material respects, in accordance with the relevant agreements governing such transactions; and (c) with respect of the disclosed continuing connected transactions with CARsgen Therapeutics (Shanghai) under the Contractual Arrangements, nothing has come to their attention that causes them to believe that dividends or other distributions have been made by CARsgen Therapeutics (Shanghai) to the holders of the equity interests of CARsgen Therapeutics (Shanghai) are not otherwise subsequently assigned or transferred to the Group.

#### **RELATED PARTY TRANSACTIONS**

Details of the related party transactions carried out in the normal course of business are set out in Note 33 to the Consolidated Financial Statements. Save as the related party transactions involving payment of remuneration to certain Directors, which constitute continuing connected transactions fully exempt from the connected transaction requirements under Rule 14A.76(1) or Rule 14A.95 of the Listing Rules, during the Reporting Period, none of these related party transactions constitutes a connected transaction or continuing connected transaction as defined under the Listing Rules. The Company has complied with the disclosure requirements under Chapter 14A of the Listing Rules and disclosed in this report.

#### FINANCIAL SUMMARY

Shares of the Company were listed on the Stock Exchange on June 18, 2021. A summary of the published results and of the assets, liabilities and equity of the Group for the last five financial years, as extracted from the published audited financial information and financial statements, is set out on page 212 of this report.

#### **USE OF PROCEEDS FROM THE GLOBAL OFFERING**

The Company's Shares were listed on the Stock Exchange on June 18, 2021 with a total of 94,747,000 offer shares issued and the net proceeds raised from the Global Offering were approximately HK\$3,008 million. The net proceeds from the Listing (adjusted on a pro rata basis based on the actual net proceeds) have been and will be utilized in accordance with the purposes set out in the Prospectus. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus as follows:

- approximately HK\$902.4 million (US\$115.7 million) (or approximately 30% of the net proceeds) to fund further development of our Core Product Candidate, BCMA CAR-T (CT053)
- approximately HK\$932.5 million (US\$119.6 million) (or approximately 31% of the net proceeds) to fund ongoing and planned research and development of our other pipeline product candidates

- approximately HK\$601.6 million (US\$77.2 million) (or approximately 20% of the net proceeds) for developing full-scale manufacturing and commercialization capabilities
- approximately HK\$300.8 million (US\$38.6 million) (or approximately 10% of the net proceeds) for continued upgrading of CAR-T technologies and early-stage research and development activities
- approximately HK\$270.7 million (US\$34.7 million) (or approximately 9% of the net proceeds) will be used for our working capital and other general corporate purposes.

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to December 31, 2023:

Use of proceeds	Planned allocation of Net Proceeds (HKD million)	Planned allocation of Net Proceeds (RMB million)	Utilized amount (as at December 31, 2022) (RMB million)	Utilized for the twelve months ended December 31, 2023 (RMB million)	Utilized amount (as at December 31, 2023) ( <i>RMB million</i> )	Remaining amount (as at December 31, 2023) (RMB million)
Further development of our Core						
Product Candidate, BCMA CAR-T						
(CT053)	902.4	817.8	302.3	279.4	581.7	236.1
Ongoing and planned research and development of our other pipeline						
product candidates	932.5	845.1	324.6	231.6	556.2	288.9
Developing full-scale manufacturing and commercialization capabilities	601.6	545.2	278.5	18.1	296.6	248.6
Upgrading of CAR-T technologies and early-stage research and						
development activities	300.8	272.6	68.0	70.2	138.2	134.4
Working capital and other general						
corporate purposes	270.7	245.3	93.9	136.1	230.0	15.3
Total	3,008.0	2,725.9	1,067.3	735.4	1,802.7	923.2

The unutilized amount of net proceeds is expected to be fully utilized by 2025, which is later than originally planned, due to cost savings achieved via improved operational efficiency and moving outsourced services internally.

#### **EMOLUMENT POLICY AND DIRECTORS' REMUNERATION**

Pursuant to Rule 3.25 of the Listing Rules and the Corporate Governance Code as set out in Appendix C1 to the Listing Rules, the Company has established the Remuneration Committee to formulate remuneration policies. The remuneration is determined and recommended based on the experience, qualification, position and seniority of each Director and senior management. As for the independent non-executive Directors, their remuneration is determined based on the recommendation from the Remuneration Committee. The Directors and the senior management are eligible participants of the applicable share incentive plans.

Details of the remuneration of the Directors and the five highest paid individuals are set out in Note 9 and Note 10 to the Consolidated Financial Statements of this report.

For the Reporting Period, (i) no emoluments were paid by the Group to any Directors, former directors of the Company or five highest paid individuals as an inducement to join, or upon joining the Group, or as compensation for loss of office; (ii) none of the Directors waived or agreed to waive any remuneration; (iii) save as disclosed in this report, there were no loans, quasi-loans and other dealings in favor of Directors, their controlled bodies corporate and connected entities; and (iv) no consideration provided to or receivable by third parties for making available Directors' services.

The table below shows the emolument of senior management by band:

	Year ended December 31, 2023
HK\$1,500,001 to HK\$2,000,000	1
HK\$2,000,001 to HK\$2,500,000	2
HK\$2,500,001 to HK\$3,000,000	1
HK\$3,000,001 to HK\$3,500,000	-
HK\$3,500,001 to HK\$4,000,000	1
HK\$4,000,001 to HK\$4,500,000	1
HK\$4,500,001 to HK\$5,000,000	-
HK\$5,000,001 to HK\$5,500,000	-
HK\$5,500,001 to HK\$6,000,000	-
HK\$6,000,001 to HK\$6,500,000	-
HK\$6,500,001 to HK\$7,000,000	-
HK\$7,000,001 to HK\$7,500,000	-
HK\$7,500,001 to HK\$8,000,000	1
Total	7

#### **DISTRIBUTABLE RESERVES**

The Company may pay dividends out of the share premium account, retained earnings and any other reserves provided that immediately following the payment of such dividends, the Company will be in a position to pay off its debts as and when they fall due in the ordinary course of business.

As of December 31, 2023, the Company did not have any distributable reserves.

Details of the movements in the reserves of the Company during the year ended December 31, 2023 are set out in the consolidated statement of changes in equity and Note 28 to the consolidated financial statements.

#### **RESULTS AND DIVIDEND**

Details of the consolidated loss of the Group for the year and the Group's financial position as at December 31, 2023 are set out in the Consolidated Financial Statements and their accompanying notes on pages 142 to 211.

No dividend was paid or declared by the Company or other members of the Group during the Reporting Period.

#### **PROPERTY, PLANT AND EQUIPMENT**

Details of the movements in the property, plant and equipment of the Group during the Reporting Period are set out in Note 14 to the Consolidated Financial Statements.

#### SHARE CAPITAL

Details of the movements in share capital of the Company during the Reporting Period are set out in Note 27 to the Consolidated Financial Statements of this report.

#### TAX RELIEF AND EXEMPTION

The Directors are not aware of any tax relief and exemption available to the shareholders by reason of their holding of the Company's securities.

#### BANK BORROWINGS AND OTHER BORROWINGS

Details of the bank borrowings of the Group as at December 31, 2023 are set out in Note 24 to the Consolidated Financial Statements.

Save as disclosed, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized banking facilities, bank overdrafts or other similar indebtedness, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

#### CHARITABLE CONTRIBUTIONS

During the Reporting Period, we donated a total of more than RMB30,000 worth of winter supplies such as sleeping bags, blankets, and water mats to the Xiadawu Township School in Maqin County, Guoluo Prefecture, Qinghai Province, to protect the healthy growth of rural children and convey social warmth.

#### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

On March 1, 2024, the Company announced that the National Medical Products Administration ("**NMPA**") of China has approved the New Drug Application ("**NDA**") of zevorcabtagene autoleucel, for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy. According to the contract with Huadong Medicine Co., Ltd., the Company has received the first commercial milestone payments of RMB75 million at the date of this report.

#### **MAJOR CUSTOMERS AND SUPPLIERS**

The Group values long-standing relationships with its suppliers, customers, medical experts, and other business associates are key to the Group's success. The Group aims at delivering high quality products to its potential customers and developing mutual trust and enhancing communication and commitment between the Group and its suppliers to maintain sustainable growth. For more information, please refer to the "Environmental, Social and Governance Report" as part of this report.

During the year ended December 31, 2023, the Group had no revenues.

Purchases attributable to the Group's five largest suppliers and the largest supplier accounted for 39% and 27%, respectively, of the Group's total purchases for the Reporting Period.

None of the Directors or any of their close associates (as defined in the Listing Rules) or any shareholders of the Company (whom, to the best knowledge and belief of the Directors, own more than 5% of the Company's total issued share capital) had any beneficial interest in the Group's five largest suppliers for the Reporting Period.

#### **INDEPENDENT AUDITOR**

PricewaterhouseCoopers ("**PwC**") resigned as the auditor of the Company with effect from January 12, 2024. The Board, with the recommendation of the Audit Committee, resolved to appoint Ernst & Young ("**E&Y**") as the auditor of the Company with effect from January 12, 2024 to fill the vacancy following the resignation of PwC and to hold office until the conclusion of the next AGM of the Company. For more details of the change of auditor of the Company, please refer to the announcement of the Company dated January 12, 2024.

The Consolidated Financial Statements for the Reporting Period have been audited by E&Y, who will retire and, being eligible, offer itself for re-appointment, at the forthcoming AGM. Having been approved by the Board upon the Audit Committee's recommendation, a resolution for the re-appointment of E&Y as auditors of the Company for the ensuing year will be put to the forthcoming AGM for shareholder's approval.

Save as disclosed above, there were no other changes in auditor of the Company during the past three years.

#### ENVIRONMENTAL POLICIES AND PERFORMANCE

The Group is highly aware of the importance of environment protection and has not noted any material incompliance with all relevant laws and regulations in relation to its business including environmental protection, health and safety, workplace conditions, employment and the environment.

The Group has established detailed internal rules regarding environmental protection and adopted effective measures to achieve efficient use of resources, waste reduction and energy saving. For further details of the Group's environmental policies and performance, please refer to the Environmental, Social and Governance Report of the Company for the Reporting Period set out on pages 88 to 136, which has been prepared in accordance with Rule 13.91 and the Environmental, Social and Governance Reporting Guide contained in Appendix C2 of the Listing Rules.

#### **RETIREMENT BENEFITS SCHEME**

Carsgen Therapeutics (Shanghai)'s full-time employees in the PRC, including some of our named executive officers, participate in a government mandated defined contribution plan, pursuant to which pension benefits, medical care, an employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that our PRC subsidiaries make contributions to the government for these benefits based on percentages of the employees' salaries which are capped at 300 percent of the average local wage.

For employees in the United States, CARsgen Therapeutics Corporation (Employer) is helping to make saving for retirement under our 401(k) Plan easier by offering an Employer safe harbor matching contribution, which is another defined contribution plan of the Group. Employee's combined elective contributions and Roth 401(k) contributions are subject to a calendar year limit even though the Plan Year may not be the calendar year. The limit for the 2023 calendar year is US\$22,500. The limit for catch-up contributions for the 2023 calendar year is US\$7,500. Employer will be matching both employee's pre-tax and/or Roth elective contributions, dollar for dollar, up to 6% of employee's eligible pay. This contribution is called a safe harbor matching contribution. This contribution will be made on behalf of all eligible employees. Employer may choose to revoke or suspend the safe harbor contribution during the year. If this occurs, employee will be given 30 days advance notice of the suspension and employee will be given an opportunity to change employee's elective contribution rate.

Details of the pension obligations of the Company are set out in Note 2.4 to the Consolidated Financial Statements in this report. During the Reporting Period, there was no forfeiture of contributions under the defined contribution plans of the Group, and there were no forfeited contributions had been used by the Group to reduce the existing level of contributions.

#### **RELATIONSHIPS WITH THE GROUP'S EMPLOYEES**

The Group believes that employees are important and valuable assets. The Group will provide trainings for employees to enhance their knowledge in corporate values and culture and to implement them thoroughly. Meanwhile, the Group encourages staff on continuous learnings by sponsoring recognized development trainings. The Group also aims to provide competitive and attractive remuneration packages to retain its employees. Management reviews annually the remuneration package offered to the employees of the Group. Meanwhile, for the purpose of providing incentives and rewards to eligible participants who have contributed to the success of the Group's operations, the Company has adopted the 2019 Equity Incentive Plan, Post-IPO Share Option Scheme and Post-IPO RSU Scheme. Details of such schemes are set out in the sub-sections headed "Share Incentivization Schemes" in this report. For more information, please also refer to the "Environmental, Social and Governance Report" as part of this report.

#### SHARE INCENTIVE SCHEMES

We have adopted three share incentive schemes, collectively referred to as Share Incentive Schemes.

#### **2019 EQUITY INCENTIVE SCHEME**

Our Company adopted the 2019 Equity Incentive Plan on January 22, 2019. The purpose of the 2019 Equity Incentive Plan is to attract, motivate, retain and reward certain employees, Directors, and certain other eligible persons of our Group. The 2019 Equity Incentive Plan (i) does not involve any grant of options of the Company to subscribe for new Shares after the IPO, and (ii) only involves the grant of restricted share units after the IPO.

On May 11, 2021, our Company allotted and issued 12,497,947 Shares to Carfa Unity Limited and 7,125,575 Shares to Carfe Unity Limited, both of which are wholly-owned by the 2019 Equity Incentive Plan Trustee. Such Shares have been held in trust by the 2019 Equity Incentive Plan Trustee to facilitate the transfer of Shares to the grantees upon vesting of the relevant options and share awards.

As of December 31, 2023, a total of 11,186,052 options were outstanding and 367,014 share awards (in the form of RSUs) were unvested under the 2019 Equity Incentive Plan. The numbers of share awards available for grant under the 2019 Equity Incentive Plan on January 1, 2023 and December 31, 2023 are 5,587,316 and 5,954,463, respectively. No option or share award was granted under the 2019 Equity Incentive Plan during the Reporting Period.

The table below shows the details of outstanding share options granted under the 2019 Equity Incentive Plan.

		Number	of options duri	ng the Reporti	ng Period					
	Number of					Number of				
	Shares					Shares				
	subject to					subject to				
	outstanding	Granted	Exercised	Cancelled	Lapsed	outstanding				
	options as at	during the	during the	during the	during the	options as at	Date of			Exercise
Name of	January 1,	Reporting	Reporting	Reporting	Reporting	December 31,	grant of	Exercise		price
Grantee	2023	Period	Period	Period	Period	2023	share options	Period	Vesting Period	per Share
1. Connected Per Mr. Haiou CHEN	r <b>son</b> 2,539,773	0	0	0	0	2,539,773	December 28, 2020	December 28, 2020 – December 27, 2028	March 31, 2017 – March 30, 2020	US\$0.04
2. Employees	10,356,450	0	1,474,856 <sup>Note</sup>	0	235,315	8,646,279	December 28, 2020	December 28, 2020 – December 27, 2028	Three or four years from the vesting commencement date stipulated in relevant grant letters	US\$0-1.40
Total:	12,896,223	0	1,474,856	0	235,315	11,186,052				

Note:

For employees of the Group, the weighted average closing price of the Shares immediately before the dates on which the options were exercised in 2023 was HK\$11.58 per Share.

		Numb	er of RSUs during	the Reporting F	Period			
	Number of					Number of		
	Shares					Shares		
	subject to					subject to		
	unvested	Granted	Vested	Cancelled	Lapsed	unvested		
	RSUs as at	during the	during the	during the	during the	RSUs as at		
Name of	January 1,	Reporting	Reporting	Reporting	Reporting	December 31,	Date of	
Grantee	2023	Period	Period	Period	Period	2023	grant of RSUs	Vesting Period
1. Connected Pers	son							
Mr. Haiou CHEN	11,001	0	4,662 Note (ii)	0	0	6,339	July 22, 2021	July 22, 2022-July 21, 2025
	232,977	0	58,244 Note (ii)	0	0	174,733	March 24, 2022	March 24, 2023-March 23, 2026
2. Employees	846,682	0	293,593 Note (iii)	0	367,147	185,942	July 22, 2021	July 22, 2022-July 21, 2025
Total:	1,090,660	0	356,499	0	367,147	367,014		

The table below shows the details of unvested share awards granted under the 2019 Equity Incentive Plan.

Notes:

(i) The purchase price of all share awards mentioned in the table above is nil, and there is no performance target attached to these RSUs granted.

(ii) For Mr. Haiou CHEN, the weighted average closing price of the Shares immediately before the dates on which the RSUs were vested in 2023 was HK\$14.27 per Share.

(iii) For employees of the Group, the weighted average closing price of the Shares immediately before the dates on which the RSUs were exercised in 2023 was HK\$13.67 per Share.

#### **POST-IPO RSU SCHEME**

Our Company adopted the Post-IPO RSU Scheme on April 30, 2021. The purpose of the Post-IPO RSU Scheme is to align the interests of the eligible persons with those of our Group through ownership of Shares to encourage and retain them to make contributions to the long-term growth and profits of our Group.

As of December 31, 2023, a total of 2,824,026 share awards (in the form of RSUs) were unvested under the Post-IPO RSU Scheme. The numbers of share awards available for grant under the Post-IPO RSU Scheme on January 1, 2023 and December 31, 2023 are 20,802,370 and 19,412,174 respectively. The numbers of Shares that may be issued in respect of share awards granted under the Post-IPO RSU Scheme during the Reporting Period divided by the weighted average number of Shares in issue for the Reporting Period is 0.36%.

The table below shows the details of unvested share awards granted under the Post-IPO RSU Scheme.

		Numb	per of RSUs during	the Reporting Pe	eriod			
	Number of					Number of		
	Shares					Shares		
	subject to					subject to		
	unvested	Granted	Vested	Cancelled	Lapsed	unvested		
	RSUs as at	during the	during the	during the	during the	RSUs as at		
Name of	January 1,	Reporting	Reporting	Reporting	Reporting	December 31,	Date of	
Grantee	2023	Period	Period	Period	Period	2023	grant of RSUs	Vesting Period
Employees	1,685,000	0	372,250 Note (iv)	0	248,500	1,064,250	October 21, 2022	October 22,
								2023-October 21,
								2026
	161,438	0	40,358 Note (iv)	0	1,125	119,955	March 24, 2022	March 24,
								2023-March 23,
								2026
	0	2,012,554	0	0	418,233	1,594,321	April 13,	April 13, 2024 –
							2023 Note (ii)	April 12, 2027
	0	45,500	0	0	0	45,500	November 28,	November 28, 2024
							2023 Note (iii)	-November 27, 2027
Total:	1,846,438	2,058,054	412,608	0	667,858	2,824,026		

Number of RSUs during the Reporting Period

Notes:

(i) The purchase price of all RSUs mentioned in the table above is nil, and there is no performance target attached to these RSUs granted.

- (ii) The closing price per ordinary share of the Company is HK\$14.18 on April 12, 2023, being the business day immediately before April 13, 2023. Fair value of RSUs granted on April 13, 2023 at the date of grant is HK\$14.46, and as for relevant accounting standard and policy adopted, please refer to Note 29 to the consolidated financial statements.
- (iii) The closing price per ordinary share of the Company is HK\$11.20 on November 27, 2023, being the business day immediately before November 28, 2023. Fair value of RSUs granted on November 28, 2023 at the date of grant is HK\$11.38, and as for relevant accounting standard and policy adopted, please refer to Note 29 to the consolidated financial statements.
- (iv) For employees of the Group, the weighted average closing price of the Shares immediately before the dates on which the RSUs were exercised in 2023 was HK\$9.76 per Share.
- (v) Please refer to the announcements of the Company dated April 13, 2023 and November 28, 2023 for details.

#### **POST-IPO SHARE OPTION SCHEME**

Our Company adopted the Post-IPO Share Option Scheme on April 30, 2021. The purpose of the Post-IPO Share Option Scheme is to reward employees for their past contribution to the success of the Company and to provide incentives to them to further contribute to the Company.

As of December 31, 2023, a total of 7,542,978 options were outstanding under the Post-IPO Share Option Scheme. The numbers of options available for grant under the Post-IPO Share Option Scheme on January 1, 2023 and December 31, 2023 are 39,501,654 and 37,754,639 respectively. The numbers of Shares that may be issued in respect of option granted under the Post-IPO Share Option Scheme during the Reporting Period divided by the weighted average number of Shares in issue for the Reporting Period is 0.70%.

The table below shows the details of outstanding options granted under the Post-IPO Share Option Scheme.

		Number	r of options durir	ng the Reporting	Period					
Name of Grantee	Number of Shares subject to outstanding options as at January 1, 2023	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled during the Reporting Period	Lapsed during the Reporting Period	Number of Shares subject to outstanding options as at December 31, 2023	Date of grant of share options	Exercise Period	Vesting Period	Exercise price per Share <i>HK\$</i>
1. Connected Person										
Dr. Hua JIANG	36,164	0	0	0	0	36,164	March 24, 2022		March 24, 2023 – March 23, 2026	HK\$16.32
	0	120,000	0	0	0	120,000	April 13, 2023 <sup>Note (ii)</sup>		April 13, 2024 – April 12, 2027	HK\$14.46
Mr. Haiou CHEN	0	200,000	0	0	0	200,000	April 13, 2023 <sup>Note (ii)</sup>	The Options may be	April 13, 2024 – April 12, 2027	HK\$14.46
2. Employees	972,000	0	0	0	0	972,000	October 21, 2022	exercised during the period from the date	April 7, 2023 – October 20, 2026	HK\$13.58
	4,108,723	0	0	0	1,383,461	2,725,262	March 24, 2022	of vesting to the 10th anniversary of	March 24, 2023 – March 23, 2026	HK\$16.32
	679,076	0	0	0	522,524	156,552	July 22, 2021	the grant date.	July 22, 2022 – July 21, 2025	HK\$31.00
	0	3,074,000	0	0	363,000	2,711,000	April 13, 2023 <sup>Note (ii)</sup>		April 13, 2024 – April 12, 2027	HK\$14.46
	0	622,000	0	0	0	622,000	November 28, 2023 <sup>Note (iii)</sup>		November 28, 2024 – November 27, 2027	HK\$11.39
Total:	5,795,963	4,016,000	0	0	2,268,985	7,542,978				

Notes:

(i) There is no performance target attached to above options granted.

(ii) The closing price per ordinary share of the Company is HK\$14.18 on April 12, 2023, being the business day immediately before April 13, 2023. Fair value of options granted on April 13, 2023 at the date of grant is HK\$6.46, and as for relevant accounting standard and policy adopted, please refer to Note 29 to the consolidated financial statements.

(iii) The closing price per ordinary share of the Company is HK\$11.20 on November 27, 2023, being the business day immediately before November 28, 2023. Fair value of options granted on November 28, 2023 at the date of grant is HK\$4.32, and as for relevant accounting standard and policy adopted, please refer to Note 29 to the consolidated financial statements.

(iv) Please refer to the announcements of the Company dated April 13, 2023 and November 28, 2023 for details.

The total numbers of Shares that may be issued in respect of options and awards granted under the 2019 Equity Incentive Scheme, Post-IPO RSU Scheme and Post-IPO Share Option Scheme during the Reporting Period divided by the weighted average number of Shares in issue for the Reporting Period is 1.06%.

#### SUMMARY OF THE SHARE INCENTIVE SCHEMES

The principal terms and details of the Share Incentive Schemes are set out below:

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
1. Purpose	to secure and retain the services of eligible participants, to provide incentives for such persons to exert maximum efforts for the success of our Company and our affiliates, and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Shares through the granting of the Share Awards.	to align the interests of the eligible persons with those of our Group through ownership of Shares to encourage and retain them to make contributions to the long-term growth and profits of our Group.	to reward employees for their past contribution to the success of the Company and to provide incentives to them to further contribute to the Company.
2. Eligible Participants	Eligible persons include any person employed by our Company or our affiliates, any director of our Company or any of its subsidiaries, any person, including a consultant, who is (i) engaged by our Company or our affiliates to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of our affiliates and is compensated for such services.	Any individual, being an employee, director (including executive Directors, non-executive Directors and independent non-executive Directors) or officer, consultant, advisor, distributor, contractor, customer, supplier, agent, business partner, joint venture business partner or service provider of any member of the Group or any affiliate who the Board or its delegate(s) considers, in its sole discretion, to have contributed or will contribute to the Group is eligible to receive an award granted by the Board, by way of RSUs, which may vest in the form of Award Shares or the actual selling price of the Award Shares of RSUs in cash in accordance with the Post-IPO RSU Scheme. However, no individual who is resident in a place where the grant, acceptance or vesting of an Award pursuant to the Post-IPO RSU Scheme is not permitted under the laws and regulations of such place or where, in the view of the Board or its delegate(s), compliance with applicable laws and regulations in such place makes it necessary or expedient to exclude such individual, shall be	Any individual, being an employee, director or officer of any member of our Group who the Board may in its absolute discretion select to grant an Option to subscribe for such number of Shares as the Board may determine at the Subscription Price.

RSU Scheme.

	2019 Equity		Post-IPO Share
Details	Incentive Plan	Post-IPO RSU Scheme	Option Scheme
3. Maximum number of Shares that can be awarded	Subject to capitalization adjustments, the aggregate number of Shares that may be issued pursuant to Share Awards shall not exceed 27,519,380 Shares. As at the Latest Practicable Date, the total number of Shares available for issue under the 2019 Equity Incentive Plan is 3,798,492, representing approximately 0.66% of the total issued Shares.	The aggregate number of Shares underlying all grants made pursuant to the Post-IPO RSU Scheme (excluding Award which have been forfeited in accordance with the Post-IPO RSU Scheme) will not exceed 5% of the issued share capital of the Company as of the date of approval of the Post- IPO RSU Scheme without shareholders' approval, being 22,648,808 Shares. As at the Latest Practicable Date, the total number of Shares available for issue under the Post-IPO RSU Scheme is 18,448,955, representing approximately 3.20% of the total issued Shares.	The maximum number of Shares in respect of which Options may be granted under the Post-IPO Share Option Scheme when aggregated with the maximum number of Shares in respect of which Options may be granted under any other option scheme over Shares shall not exceed 10% of the issued share capital of the Company as of the date of approval of the Post-IPO Share Option Scheme (or of the refreshing of the 10% limit) by the shareholders of the Company, being 45,297,617 Shares. As at the Latest Practicable Date, the total number of Shares available for issue under the Post-IPO Share Option Scheme is 45,297,617, representing approximately 7.87% of the total issued Shares.
4. Maximum entitlement of each participan under the scheme	N/A	Save as prescribed in the scheme or as otherwise restricted by the Listing Rules, for any 12-month period, the aggregate number of Shares granted to any Selected Participant shall not exceed 1% of the total number of the issued Shares at the relevant time, without Shareholders' approval.	Except with the approval of Shareholders in general meeting, no Option may be granted to any one person such that the total number of Shares issued and to be issued upon exercise of Options and any other option over the Shares (including exercised, cancelled and outstanding options) granted and to be granted to such person in any 12-month period up to the date of the latest grant exceeds 1% of the Shares in issue from time to time.
			nom time to time.

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
5. Vesting Period	The total number of Shares subject to a Share Option may vest and therefore become exercisable in periodic installments that may or may not be equal. The Share Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions (including the vesting period) of each Share Option may vary.	The Board or its delegate(s) may from time to time while the Post-IPO RSU Scheme is in force and subject to all applicable laws, determine such vesting criteria and conditions or periods for the Award to be vested.	The Board or its delegate(s) may from time to time while the Post-IPO Share Option Scheme is in force and subject to all applicable laws, determine such vesting criteria and conditions or periods for the Options to be vested.

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
6. Duration and remaining life	No Share Option shall be exercisable after the expiration of eight years from the date of its grant or such shorter period specified in a share award agreement. As at December 31, 2023, the remaining life of the 2019 Equity Incentive Plan was approximately three years.	<ul> <li>The Post-IPO RSU Scheme shall terminate on the earlier of:</li> <li>(i) the end of the period of ten years commencing on the date on which the Post-IPO RSU Scheme is adopted except in respect of any non-vested RSUs granted hereunder prior to the expiration of the Post-IPO RSU Scheme, for the purpose of giving effect to the vesting in the form of Award Shares of such RSUs or otherwise as may be required in accordance with the provisions of the Post-IPO RSU Scheme; and</li> <li>(ii) such date of early termination as determined by the Board provided that such termination shall not affect any subsisting rights of any selected participant under the rules of the Post-IPO RSU Scheme, provided further that for the avoidance of doubt, the change in the subsisting rights of a selected participant in this paragraph refers solely to any change in the rights in respect of the RSUs already</li> </ul>	The Post-IPO Share Option Scheme shall be valid and effective for a period of 10 years commencing on the date when the Post-IPO Share Option Scheme becomes unconditional, after which period no further Options will be granted by the provisions of the Post-IPO Share Option Scheme, but the provisions of this Post-IPO Share Option Scheme shall remain in full force and effect to the extent necessary to give effect to the extent necessary to give effect to the exercise of any Options granted prior thereto or otherwise as may be required in accordance with the provisions of the Post-IPO Share Option Scheme. As at December 31, 2023, the remaining life of the Post-IPO Share Option Scheme was approximately seven years and six months.
		As at December 31, 2023, the remaining life of the Post-IPO RSU Scheme was approximately seven years and six months.	

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
7. Exercise price/ purchase price	The exercise price (or strike price) of each Share Option shall be determined in good faith by the Administrator and as set forth in a share award agreement. The consideration, if any, to be paid by the participant upon delivery of each Share subject to the restricted share unit award will be determined by the Board at the time of grant of such award.	No purchase price is to be paid by the participant upon vesting of Awards granted under the Post-IPO RSU Scheme.	The amount payable for each Share to be subscribed for under an option in the event of the option being exercised shall be determined by the Board at its absolute discretion, but shall be not less than the greater of: (i) the closing price of a Share as stated in the daily quotations sheet issued by the Stock Exchange on the date of grant;
			<ul> <li>(ii) the average closing price of our Shares as stated in the daily quotations sheets issued by the Stock Exchange for the five business days immediately preceding the date of grant; and</li> </ul>
			(iii) the nominal value of a Share on the date of grant.
8. Exercise Period	No share option shall be exercisable after the expiration of eight years from the date of its grant or such shorter period specified in a share award agreement.	N/A	The period during which the option can be exercised as set forth in the relevant offer letters in accordance with the plan.

	2019 Equity		Post-IPO Share
Details	Incentive Plan	Post-IPO RSU Scheme	Option Scheme
<ol> <li>Consideration for Acceptance of Options or Awards</li> </ol>	Each Option shall be in such form and shall contain such terms and conditions (including but not limited to the consideration for acceptance of Option, if any) as the Administrator shall deem appropriate. All Options shall be separately designated Incentive Share Options or Nonstatutory Share Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for Shares purchased on exercise of each type of Option. Each Restricted Share Award will be evidenced by a Share Award Agreement that will specify the period of restriction, the number of Shares granted, and such other terms and conditions as the Administrator, in its sole discretion, will determine.	The Company shall issue a letter to each Selected Participant in such form as the Board or the committee of the Board or person(s) to which the Board has delegated its authority may from time to time determine, specifying the Grant Date, the number of Award Shares underlying the Award, the consideration for acceptance of grant of Award (if any), the vesting criteria and conditions, and the Vesting Date and such other details as the they may consider necessary.	An Option 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 duly signed by the Grantee together with a payment to the Company and/or any of its Subsidiaries of HK\$1 (or the equivalent of HK\$1 in the local currency of any jurisdiction where the company and/or its Subsidiaries operate, as the Board may in its absolute discretion determine) by way of consideration for the grant thereof is received by the Company within the time period specified in the offer of the grant of the Option. Such remittance shall not be refundable. To the extent that the offer of the grant of an Option is not accepted within 28 days after the Offer Date, it will be deemed to have been irrevocably declined and will lapse, unless the

Board in its absolute discretion determines otherwise.

On behalf of the Board CARsgen Therapeutics Holdings Limited Dr. Zonghai LI Chairman

## **Corporate Governance Report**

The Board hereby presents to the shareholders the corporate governance report for the year ended December 31, 2023 (the "**Corporate Governance Report**").

#### **CORPORATE PURPOSE, CULTURE AND STRATEGY**

We always adhere to achieving our purpose of "To become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable" by focusing on our strategy of "internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors and reducing treatment costs". The management team has put our corporate culture into practice by incorporating the four core values of "Innovation and Creation", "Truth-seeking and Pragmatism", "Proactiveness" and "People-Oriented" into our daily work.

The Board carries out consistently ensuring that all members of the Group are guided by our purpose and strategy, align the four core values and the corporate culture in their daily work, and work together as one to promote quality development led by an advanced culture. The Group's operating practices, internal policies and stakeholder relationships give us the opportunity to actively practices our corporate culture and values in a multi-dimensional and holistic manner, which may create stable and sustainable business development and growth and bring long-term value to shareholders, and benefit cancer patients around the world.

#### **CORPORATE GOVERNANCE PRACTICES**

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in Part 2 of the CG Code as contained in Appendix C1 to the Listing Rules as its own code of corporate governance practices.

The Board is of the view that during the Reporting Period, the Company has complied with all the applicable code provisions as set out in the CG Code, except for code provision C.2.1 described in the paragraph headed "C. Directors' Responsibilities, Delegation and Board Proceedings – C.2 Chairman and Chief Executive". The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

#### **BOARD OF DIRECTORS**

#### **Responsibilities**

The Board is responsible for the overall leadership of the Group, oversees the Group's strategic decisions and monitors business and performance. The Board has delegated the authority and responsibility for day-today management and operation of the Group to the senior management of the Group. To oversee particular aspects of the Company's affairs, the Board has established three Board committees including the audit committee (the "Audit Committee"), the remuneration committee (the "Remuneration Committee") and the nomination and corporate governance committee (the "Nomination and Corporate Governance Committee"). The Board has delegated to the Board Committees responsibilities as set out in their respective terms of reference.

### Corporate Governance Report

All Directors have carried out duties in good faith and in compliance with applicable laws and regulations, and have acted in the interests of the Company and the shareholders at all times.

All Directors have full and timely access to all the information of the Company as well as the services and advice from the company secretary and senior management. The Directors may, upon request, seek independent professional advice in appropriate circumstances, at the Company's expenses for discharging their duties to the Company.

The Company has arranged appropriate liability insurance in respect of legal action against the Directors. The insurance coverage will be reviewed on an annual basis.

#### Responsibility, Accountabilities and Contributions of the Board and Management

The Board should assume responsibility for leadership and control of the Company and is collectively responsible for directing and supervising the Company's affairs. The Board directly, and indirectly through its committees, leads and provides direction to the management by laying down strategies and overseeing their implementation, monitors the Group's operational and financial performance, and ensures that sound internal control and risk management systems are in place.

All Directors, including independent non-executive Directors, have brought a wide spectrum of valuable business experience, knowledge and professionalism to the Board for its efficient and effective functioning. The independent non-executive Directors are responsible for ensuring a high standard of regulatory reporting of the Company and providing a balance in the Board for bringing effective independent judgement on corporate actions and operations.

The Board reserves for its decisions on all major matters relating to policy matters, strategies and budgets, internal control and risk management, material transactions (in particular those may involve conflict of interests), financial information, appointment of directors and other significant operational matters of the Company. Responsibilities relating to implementing decisions of the Board, directing and coordinating the daily operation and management of the Company are delegated to the management.

The Board has clearly set out the circumstances under which the management should report to and obtain prior approval from the Board before making decisions or entering into any commitments on behalf of the Company. The Board regularly reviews the above said circumstances and ensures they remain appropriate.

The Company has arranged appropriate liability insurance in respect of legal action against the Directors. The insurance coverage will be reviewed on an annual basis.

#### **Continuous Professional Development of Directors**

The Company believes education and training are important for maintaining an effective Board. Every Director has received formal and comprehensive trainings to ensure appropriate understanding of the business and operations of the Company and full awareness of Director's responsibilities and obligations under the Listing Rules and relevant statutory requirements.

The Company arranges continuous professional development trainings to Directors to ensure Directors keep abreast of regulatory developments and changes in order to effectively perform their responsibilities and to ensure that their contribution to the Board remains informed and relevant. Directors also regularly meet with the senior management team to understand the Group's businesses, governance policies and regulatory environment. All Directors are also encouraged to attend relevant training courses. The Directors pursued continuous professional development to comply with C.1.4 of the CG Code and relevant details are summarised as follows:

	Participated in continuous professional
Name of Director	development*
Executive Directors	
Dr. Zonghai LI ( <i>Chairman</i> )	$\checkmark$
Dr. Huamao WANG	
Dr. Hua JIANG	V
Non-executive Directors	
Mr. Bingsen GUO	$\checkmark$
Mr. Ronggang XIE	$\checkmark$
Mr. Huaqing GUO	$\checkmark$
Independent Non-executive Directors	
Dr. Chunhai FAN (resigned on January 11, 2023)	$\checkmark$
Dr. Guangmei YAN	$\checkmark$
Mr. Tak Young SO (resigned on June 30, 2023)	$\checkmark$
Dr. Huabing LI (appointed on March 9, 2023)	$\checkmark$
Ms. Xiangke ZHAO (appointed on July 4, 2023)	$\checkmark$

\* During the Reporting Period, our Company arranged trainings for the Directors related to updates and changes in regulatory requirements, business and market environment in a variety of ways from time to time.

#### **Chairman and Chief Executive Officer**

We do not have separate Chairman of the Board and Chief Executive Officer ("**CEO**") and Dr. Zonghai LI, the Chairman of our Board and CEO, 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. Zonghai LI is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. Our Board also believes that the combined role of Chairman of the Board and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Board will continue to review and consider splitting the roles of Chairman of the Board and the CEO at a time when it is appropriate by taking into account the circumstances of our Group as a whole.

#### Composition

As at the Latest Practicable Date, the Board is comprised of nine Directors, with three executive Directors, three non-executive Directors and three independent non-executive Directors. During the Reporting Period and up to the Latest Practicable Date, (i) Dr. Chunhai FAN ceased to be an independent non-executive Director from January 11, 2023, (ii) Dr. Huabing LI was appointed as an independent non-executive Director from March 9, 2023, (iii) Mr. Tak Young SO ceased to be an independent non-executive Director from June 30, 2023, and (iv) Ms. Xiangke ZHAO was appointed to be an independent non-executive Director from July 4, 2023, and there is no other change to the composition of the Board. A list of Directors and their respective biographies are set out on pages 28 to 33 of this report. Save as disclosed in this report, to the best knowledge of the Company, there are no financial, business, family, or other material relationship among members of the Board.

The Board has established mechanisms to ensure independent views and input are available to the Board. The Board ensures the appointment of at least three independent non-executive directors and at least one-third of its members being independent non-executive directors. Further, independent non-executive directors will be appointed to committees of the Board as required under the Listing Rules and as far as practicable to ensure independent views and input are available. The Nomination and Corporate Governance Committee strictly adheres to the independence assessment criteria as set out in the Listing Rules with regard to the nomination and appointment of independent non-executive directors, and is mandated to assess annually the independence of independent non-executive directors to ensure that they can continually exercise independent judgement.

Following the resignation of Dr. Chunhai FAN on January 11, 2023, the number of the independent nonexecutive Directors has fallen below the minimum number required under Rules 3.10(1) and 3.10A of the Listing Rules, and following the appointment of Dr. Huabing LI on March 9, 2023, the number of the independent non-executive Directors has re-complied with the requirements as set out in Rules 3.10(1) and 3.10A of the Listing Rules. In addition, following the resignation of Mr. Tak Young SO on June 30, 2023, the Company failed to comply with (i) appointment of a sufficient number of independent nonexecutive Directors as required under Rule 3.10(1) and 3.10A of the Listing Rules, and (ii) appointment of an independent non-executive director with appropriate professional qualifications, or accounting or related financial management expertise as required under Rule 3.10(2) of the Listing Rules, and following the appointment of Ms. Xiangke ZHAO on July 4, 2023, the Company re-complied with Rule 3.10(1), 3.10(2) and 3.10A of the Listing Rules. Save for the non-compliance mentioned above, during the period from January 1, 2023 and up to the Latest Practicable Date, the Board's composition is in compliance with the requirement under Rules 3.10(1), 3.10(2) and 3.10A of the Listing Rules. The Board believes that the balance between the executive Directors and the non-executive Directors is reasonable and adequate to provide sufficient checks and balances that safeguard the interests of the shareholders and the Group.

The Board values the importance of professional judgment and advice provided by non-executive Directors to safeguard the interests of the shareholders. The non-executive Directors contribute diversified qualifications and experience to the Group by expressing their views in professional, constructive and informed manner, and actively participate in Board and committee meetings and to bring professional judgment and advice on issues relating to the Group's strategies, policies, performance, accountability, resources, key appointments, standards of conduct, conflicts of interests and management process, with the shareholders' interests being the utmost important factor. The non-executive Directors also exercise their professional judgment and utilise their expertise to scrutinise the Company's performance in achieving agreed corporate goals, and monitor performance reporting.

Further, in compliance with Rule 3.10 of the Listing Rules, one of the Company's independent non-executive Director (namely Ms. Xiangke ZHAO) has the appropriate professional qualifications of accounting or related financial management expertise, and provide valuable advice from time to time to the Board. The Company has also received from each independent non-executive Director an annual confirmation of his independence and the Nomination and Corporate Governance Committee has conducted an annual review and considers that all independent non-executive Director are independent, taking into account of the independence guidelines set out in Rule 3.13 of the Listing Rules in the context of the length of service of each independent non-executive Director.

As part of the Company's corporate governance practice to provide transparency to the investor community and in compliance with the Listing Rules and the CG Code, the independent non-executive Directors are clearly identified in all corporate communications containing the names of the Directors. In addition, an upto-date list of Directors identifying the independent non-executive Director and the roles and functions of the Directors is maintained on the Company's website and the Stock Exchange's website.

#### **Appointments and Re-election of Directors**

Each of our executive Directors and non-executive Directors has entered into a service contract with us under which the initial term of their service contracts shall be three years commencing from the date of their appointment until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other not less than one months' prior notice. Pursuant to the service contracts entered into with us, none of our executive Directors and non-executive Directors will receive any remuneration as director's fee.

Each of our independent non-executive Directors has entered into an appointment letter with us. The initial term of their appointment letters shall commence from the date of their appointment for a period of three years or until the third annual general meeting of our Company after their appointment, respectively, whichever is earlier (subject always to re-election as and when required under the Articles of Association) until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than one month's prior notice in writing.

None of the Directors has entered into a service contract which is not determinable by the Group within one year without payment of compensation (other than statutory compensation).

In accordance with the Articles of Association, all Directors are subject to retirement by rotation at least once every three years and any new Director appointed to fill a casual vacancy shall submit himself for re-election by the shareholders at the first general meeting of the Company after appointment and new Directors appointed as an addition to the Board shall submit himself for re-election by the shareholders at the next following general meeting of the Company after appointment.

#### **Director Nomination Policy**

The Company has adopted a director nomination policy (the "**Director Nomination Policy**") which sets out the selection criteria and procedures in relation to nomination and appointment of Directors of the Company and aims to ensure that the Board has a balance of skills, experience and diversity of perspectives appropriate to the Company and the continuity of the Board and appropriate leadership at Board level.

The Director Nomination Policy sets out the factors for assessing the suitability and the potential contribution to the Board of a proposed candidate, including but not limited to the following:

- Integrity and reputation;
- Educational background, professional qualifications and work experience (including part-time jobs);
- Whether or not they have the necessary skills and experience;
- Whether or not they are able to spend sufficient time and energy to handle the Company's affairs;
- Whether or not they will promote the diversity of the Board in all aspects, including but not limited to gender, age, cultural and educational background, ethnicity, professional experience, skills, knowledge and term of office;
- Whether or not the candidates for independent directors meet the requirements for independence under Rule 3.13 of the Listing Rules; and
- Any other relevant factors as determined by the Nomination and Corporate Governance Committee or the Board from time to time.

The Director Nomination Policy also sets out the procedures for the selection and appointment of new Directors and re-election of Directors at general meetings. The Nomination and Corporate Governance Committee and/or the Board may nominate candidates for directorship. Where the Board proposes a resolution to elect or re-elect a candidate as Director at the general meeting, the relevant information of the candidate will be disclosed in the circular to Shareholders and/or explanatory statement accompanying the notice of the relevant general meeting in accordance with the Listing Rules and/or applicable laws and regulations.

Shareholders who wish to propose a person for election as a Director at the general meeting shall follow the provisions in the Company's Articles of Association and the Company's policy on "Procedures for Shareholders to Propose a Person for Election as a Director of the Company".

During the year ended December 31, 2023, the Nomination and Corporate Governance Committee recommended to the Board the appointment of Dr. Huabing LI and Ms. Xiangke ZHAO as independent non-executive Directors, at the meeting of the Nomination and Corporate Governance Committee. The appointment was subject to a nomination process in accordance with the Director Nomination Policy and the Board Diversity Policy, to ensure the Board possesses the necessary skills, experience and knowledge in alignment with the Company's strategy.

The Nomination and Corporate Governance Committee will review the Director Nomination Policy, as appropriate, to ensure its effectiveness.

#### **Board Meetings**

The attendance of each Director at Board and committee meetings of the Company, whether in person or by means of electronic communication, is detailed in the table below:

#### Attendance/No. of Meetings held during the Reporting Period

				Nomination and Corporate	
		Audit	Remuneration	Governance	General
Name of Directors	Board	Committee	Committee	Committee	Meeting
Executive Directors					
Dr. Zonghai Ll	4/4	N/A	2/2	2/2	1/1
Dr. Huamao WANG	4/4	N/A	N/A	N/A	1/1
Dr. Hua JIANG	4/4	N/A	N/A	N/A	1/1
Non-executive Directors					
Mr. Bingsen GUO	4/4	N/A	N/A	N/A	1/1
Mr. Ronggang XIE	4/4	N/A	N/A	N/A	1/1
Mr. Huaqing GUO	4/4	6/6	N/A	N/A	1/1
Independent Non-executive Directors					
Dr. Chunhai FAN (resigned on January 11, 2023)	0/0	0/0	0/0	0/0	0/0
Dr. Guangmei YAN	4/4	N/A	2/2	2/2	1/1
Mr. Tak Young SO (resigned on June 30, 2023)	1/1	3/3	N/A	N/A	1/1
Dr. Huabing LI (appointed on March 9, 2023)	4/4	5/5	2/2	2/2	1/1
Ms. Xiangke ZHAO (appointed on July 4, 2023)	2/2	3/3	N/A	N/A	0/0

At the Board meetings held during the Reporting Period, the Board discussed a wide range of matters, including annual results announcement, interim results announcement, appointment and remuneration of senior management and an executive director, Auditors' reappointment and remuneration, etc.

During the Reporting Period, the Board considered the following corporate governance matters:

- approval of the corporate governance report of the Company;
- review of the results of the internal audit work on the Group's risk management and internal control systems; and
- approval of the new and revised versions of corporate governance documents of the Company.

The Chairman of the Board held one meeting with the independent non-executive Directors during the Reporting Period without the presence of other Directors.

On May 25, 2023, the Company held its annual general meeting to consider and approve the re-election of Directors, the grant of general mandates to issue and repurchase shares, the re-appointment of the Auditor, and the proposed amendments to the Articles of Association. All the proposed resolutions to the annual general meeting were taken by poll and the poll results were set out in the Company's announcement dated May 25, 2023. The Chairman as well as other members of the Board were available to respond to enquiries during the annual general meeting, which provided opportunities for communication between Directors, senior management and the Shareholders.

## **BOARD COMMITTEES**

The Company has established the following committees under the Board of Directors: an Audit Committee, a Remuneration Committee and a Nomination and Corporate Governance Committee. The committees operate in accordance with terms of reference established by our Board of Directors.

#### **Audit Committee**

Our Company has established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code.

During the Reporting Period, (i) Dr. Chunhai FAN ceased to act as a member of the Audit Committee with effect from January 11, 2023; (ii) Dr. Huabing LI was appointed to act as a member of the Audit Committee on March 9, 2023; (iii) Mr. Tak Young SO ceased to act as the chairman of the Audit Committee with effect from June 30, 2023; and (iv) Ms. Xiangke ZHAO was appointed to act as the chairman of the Audit Committee on July 4, 2023. Following the resignation of Dr. Chunhai FAN and Mr. Tak Young SO, respectively, the Company failed to comply Rule 3.21 of the Listing Rules, and following the appointment of Dr. Huabing LI and Ms. Xiangke ZHAO, respectively, relevant non-compliance issues were addressed. As at the Latest Practicable Date, the Audit Committee consisted of two independent non-executive Directors, namely Ms. Xiangke ZHAO, being the chairman of the Audit Committee, holds the appropriate professional gualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules.

The primary duties of the Audit Committee are to assist the Board 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 assigned by our Board of Directors.

During the Reporting Period, the Audit Committee scheduled six meetings, during which matters such as financial reporting, operational and compliance controls, effectiveness of the risk management and internal control systems and internal audit function were discussed.

The attendance records of the members of the Audit Committee, during the Reporting Period, are as follows:

Name of Members of the Audit Committee	Attendance	
Ms. Xiangke ZHAO (appointed on July 4, 2023)	3/3	
Dr. Huabing LI (appointed on March 9, 2023)	5/5	
Mr. Huaqing GUO	6/6	
Mr. Tak Young SO (resigned on June 30, 2023)	3/3	
Dr. Chunhai FAN (resigned on January 11, 2023)	0/0	

#### **Remuneration Committee**

Our Company has established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code. During the Reporting Period, (i) Dr. Chunhai FAN ceased to act as the Chairman of the Remuneration Committee with effect from January 11, 2023; and (ii) Dr. Huabing LI was appointed to act as the Chairman of the Remuneration Committee on March 9, 2023. As at the Latest Practicable Date, the Remuneration Committee consisted of two independent non-executive Directors, namely, Dr. Guangmei YAN and Dr. Huabing LI, and one executive Director, namely Dr. Zonghai LI. Dr. Huabing LI was the chairman of the Remuneration Committee.

The primary duties of the Remuneration Committee include, without limitation, making recommendations to the Board of Directors on our policy and structure for the remuneration of all Directors and senior management and on the establishment of a formal and transparent procedure for developing the policy on such remuneration and determining the specific remuneration packages of all Directors and senior management.

During the Reporting Period, the Remuneration Committee scheduled two meetings, during which matters such as remuneration of senior management and individual executive directors, policy and structure for the remuneration of all directors and senior management were discussed.

During the Reporting Period, the Remuneration Committee reviewed and approved:

- (a) on April 13, 2023, the grant of a total of 375,000 Options to Mr. Haiou CHEN, Dr. Hua JIANG and a member of senior management of the Company, without a performance target attached and considered that (i) the grant of Options forms part of their remuneration package, (ii) the grant of Options is for recognition of their past contribution and enable them to benefit from the business success they are helping to create, (iii) the vesting period attached will ensure their and the Company's long term interests are aligned and they are motivated to continue contributing towards the Company's development, and (iv) the above grant of Options to them is in line with the purpose of the Post-IPO Share Option Scheme;
- (b) on April 13, 2023, the grant of a total of 163,558 RSUs to two members of senior management of the Company, without a performance target attached and considered that (i) the grant of RSUs forms part of their remuneration package, (ii) the grant of RSUs is for recognition of their past contribution and enable them to benefit from the business success they are helping to create, (iii) the vesting period attached will ensure their and the Company's long term interests are aligned and they are motivated to continue contributing towards the Company's development, and (iv) the above grant of RSUs to them is in line with the purpose of the Post-IPO RSU Scheme; and
- (c) on November 28, 2023, the grant of a total of 7,000 RSUs to one senior manager of the Company, without a performance target attached and considered that (i) the grant of RSUs forms part of his remuneration package, (ii) the grant of RSUs is for recognition of his past contribution and enable him to benefit from the business success he is helping to create, (iii) the vesting period attached will ensure his and the Company's long term interests are aligned and he is motivated to continue contributing towards the Company's development, and (iv) the above grant of RSUs to him is in line with the purpose of the Post-IPO RSU Scheme.

For more details, please refer to the announcements of the Company dated April 13 and November 28, 2023.

The attendance records of the members of the Remuneration Committee, during the Reporting Period, are as follows:

Name of Members of the Remuneration Committee	Attendance
Dr. Huabing LI (appointed on March 9, 2023)	2/2
Dr. Guangmei YAN	2/2
Dr. Zonghai Ll	2/2
Dr. Chunhai FAN (resigned on January 11, 2023)	0/0

#### **Nomination and Corporate Governance Committee**

Our Company has established the Nomination and Corporate Governance Committee with written terms of reference in compliance with the Corporate Governance Code. During the Reporting Period, (i) Dr. Chunhai FAN ceased to act as a member of the Nomination and Corporate Governance Committee with effect from January 11, 2023; and (ii) Dr. Huabing LI was appointed to act as a member of the Nomination and Corporate Governance Committee on March 9, 2023. As at the Latest Practicable Date, the Nomination and Corporate Governance Committee consisted of two independent non-executive Directors, namely, Dr. Guangmei YAN and Dr. Huabing LI, and one executive Director, namely Dr. Zonghai LI. Dr. Zonghai LI is the chairman of the Nomination and Corporate Governance Committee.

The primary duties of the Nomination and Corporate Governance Committee include, without limitation, reviewing the structure, size and composition of the Board of Directors, assessing the independence of the independent non-executive Directors, making recommendations to the Board of Directors on matters relating to the appointment of Directors, developing, reviewing and assessing the adequacy of our Company's policies and practices on corporate governance and reviewing our Company's compliance with the Corporate Governance Code and disclosure in the corporate governance report.

During the Reporting Period, the Nomination and Corporate Governance Committee scheduled two meetings, during which matters such as re-election of directors, appointment of senior management and executive director were discussed.

The attendance records of the members of the Nomination and Corporate Governance Committee, during the Reporting Period, are as follows:

Name of Members of the Nomination and Corporate Governance Committee	Attendance
Dr. Zonghai Ll	2/2
Dr. Guangmei YAN	2/2
Dr. Huabing LI (appointed on March 9, 2023)	2/2
Dr. Chunhai FAN (resigned on January 11, 2023)	0/0

## COMPANY SECRETARY

Mr. Wing Yat Christopher LUI has been appointed as the Company Secretary on February 23, 2021, has taken no less than 15 hours of relevant professional training during 2023 and has complied with Rule 3.29 of the Listing Rules in relation to the professional training requirements. The primary contact person of Mr. Wing Yat Christopher LUI at the Company is Mr. Haiou CHEN who is our executive vice president.

## SHAREHOLDERS RIGHTS

The Company encourages shareholders' active participation in annual general meetings and other general meetings or other proper means. To safeguard shareholders' interests and rights, a separate resolution will be proposed for each issue at general meetings, including the election of individual Directors. All resolutions put forward at general meetings will be voted by poll pursuant to the Listing Rules and poll results will be posted on the websites of the Company and the Stock Exchange in a timely manner after each general meeting.

#### **Convening of Extraordinary General Meeting**

Any one or more members holding as of date of deposit of the requisition not less than one-tenth of the paid-up capital of the Company carrying the right of voting at general meetings of the Company shall at all times have the right, by written requisition, to require an extraordinary general meeting of the Company to be called by the Board for the matter specified in such requisition. A written requisition shall be deposited at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong. If within 21 days of such deposit the Board fails to proceed to convene such meeting to be held within a further 21 days, the requisitionist(s) themselves or any of them representing more than one-half of the total voting rights of all of them, may do so in the same manner, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the Board shall be reimbursed to the requisitionist(s) by the Company.

#### **Putting Forward Proposals at General Meetings**

There are no provisions in the Articles of Association or in the Companies Law of the Cayman Islands for putting forward proposals or new resolutions by shareholders at general meetings. Shareholders who wish to move forward a resolution may request the Company to convene a general meeting in accordance with the procedures mentioned above.

## **COMMUNICATION WITH SHAREHOLDERS**

## **Shareholders Communication Policy**

To enable our shareholders to exercise their rights in an informed manner based on a good understanding of the Group's operations, businesses and financial information, the Company adopted the shareholders communication policy to provide effective communication with the Shareholders and other stakeholders. The policy sets out a number of ways to ensure effective and efficient communication with our shareholders and stakeholders is achieved, including but not limited to our corporate communications (in both English and Chinese, to facilitate shareholders' understanding) and posting of relevant information on the Company Website. To facilitate communication between the Company, our shareholders and stakeholders and solicit and understand the views of shareholders and stakeholders, investor and analyst briefings, roadshows, media interview and specialist industry forums are organized on a regular basis and are attended by our directors.

The Company has reviewed the implementation and is satisfied with the effectiveness of the shareholders' communication policy during the year ended December 31, 2023.

#### Enquiries to the Board

Shareholders who intend to put forward their enquiries or communicate their views about the Company to the Board could send written enquiries or materials to the Company. The Company will not normally deal with verbal or anonymous enquiries.

Shareholders may send their enquiries or requests as mentioned above to the following:

Address: 1F, Building 2, No. 466 Yindu Road Xuhui District Shanghai the PRC (For the attention of the Board of Directors)

Email: IR@carsgen.com

#### DIRECTORS' RESPONSIBILITY IN RESPECT OF THE FINANCIAL STATEMENTS

The Directors acknowledge their responsibility for preparing the financial statements of the Company for the year ended December 31, 2023, and are not aware of any material uncertainties relating to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern.

The statement of the Auditors about their reporting responsibilities on the financial statements is set out in the section headed "Independent Auditor's Report".

#### DIVERSITY

The Board has adopted a 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 measurable objectives, including but not limited to professional experience, skills, knowledge, gender, age, cultural and education background, ethnicity and length of service.

In recognizing the particular importance of gender diversity, our Company undertook in the Prospectus that our Nomination and Corporate Governance Committee would, within three years from the Listing Date, identify and recommend one female candidate to our Board for consideration on her appointment as Director of our Company. In 2023, the Nomination and Corporate Governance Committee has recommended, and the Board has appointed Ms. Xiangke ZHAO as an independent non-executive Director. The current Board comprises seven male members and two female members. The Board is of the view that the current composition of the Board is in line with the board diversity policy (including but not limited to gender diversity). The Company will continue to put effort into developing a pipeline of potential successors of the Board to maintain or achieve gender diversity via different channels, such as by engaging human resources agencies to identify potential successors for the Board.

We are also committed to adopting a similar approach to promote diversity within the management (including but not limited to the senior management) of our Company to enhance the effectiveness of corporate governance of our Company as a whole.

As at December 31, 2023, we hired 516 full-time employees, of which 201 were male and 315 were female. The Company is aiming to achieve a more balanced gender ratio in the workforce in the future and will continue to monitor and evaluate the diversity policy from time to time to ensure its continued effectiveness.

Nomination and Corporate Governance Committee will review the board diversity policy from time to time to ensure its continued effectiveness.

#### **DIVIDEND POLICY**

The Company has adopted a policy on payment of dividends pursuant to code provision F.1.1 of the CG Code taking into consideration of various elements including but not limited to, among other things, the Company's profitability, operation and development plans, external financing environment, costs of capital, the Company's cash flows and other factors that the Directors may consider relevant. The policy sets out the factors in consideration, procedures, methods and intervals of the payment of dividends with an objective to provide the shareholders with continuing, stable and reasonable returns on investment while maintaining the Company's business operation and achieving its long-term development goal. Distribution of any interim or final dividends will be formulated by the Board, and will be subject to shareholders' approval.

As at December 31, 2023, no arrangement was reached pursuant to which the Shareholders waived or agreed to waive their dividends.

#### **MODEL CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted the Insider Dealing Policy (the "**Policy**"), with terms no less exacting than the Model Code as set out in Appendix C3 to the Listing Rules as its own securities dealing policy to regulate all dealings by Directors and employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities.

Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Policy throughout the Reporting Period.

No incident of non-compliance of the Policy by the employees was noted by the Company for the Reporting Period.

## **CHANGE IN CONSTITUTIONAL DOCUMENTS**

Upon the Shareholders' approval on May 25, 2023, certain changes were made to the Articles of Association to, inter alia, bring the Articles of Association in line with the Core Shareholder Protection Standards set out in Appendix A1 to the Listing Rules. For more details, please refer to the circular of the Company dated April 19, 2023.

On March 26, 2024, the Board resolved to propose certain amendments to the seventh amended and restated memorandum and articles of association of the Company. For more details, please refer to the announcement of the Company dated March 26, 2024.

Save as disclosed above, there has not been any changes to the Articles of Association during the Reporting Period and up to the date of the Latest Practicable Date.

#### AUDITOR'S RESPONSIBILITY AND REMUNERATION

The Company appointed E&Y as the external auditor for the year ended December 31, 2023. A statement by E&Y about their reporting responsibilities for the financial statements is included in the Independent Auditors' Report on pages 137 to 141.

The remuneration for the audit and non-audit services provided by the Auditor to the Group during the year ended December 31, 2023 was approximately as follows:

Type of Services	Amount ( <i>RMB'000</i> )
Audit and audit related services Non-audit services	4,191
Total	4,191

## **RISK MANAGEMENT AND INTERNAL CONTROL**

#### **Risk Management**

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in general market conditions and the regulatory environment of the PRC, the United States and global biologics market, our ability to develop, manufacture and commercialize our product candidates, and our ability to compete with other pharmaceutical companies operating in the same markets as ours. See "Risk Factors" in the Prospectus for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to foreign exchange, cash flow and fair value interest rate, credit and liquidity risks that arise in the normal course of our business.

We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our approach to risk management:

- Our Audit Committee will oversee and manage the overall risks associated with our business operation, including (i) reviewing and approving our risk management policies to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iii) reviewing our corporate risk and (iv) monitoring and ensuring the appropriate application of our risk management framework across our Group.
- Our management team will be responsible for (i) formulating and updating our risk management policy and targets; (ii) reviewing and approving major risk management issues of our Group; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Group; (v) reviewing the relevant departments' reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Group; and (viii) reporting to our Audit Committee on our material risks.

• The relevant departments, including but not limited to the finance department, the internal audit department, the legal department and the human resources department, are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. In order to standardize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

#### **Internal Control**

Our Board is responsible for establishing and ensuring effective internal controls to safeguard our Shareholder's investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

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 protection of intellectual property, environmental protection, and occupational health and safety. For example, we maintain a list of positions that require a certificate to undertake and require that the corresponding personnel to participate in trainings and pass the necessary assessment to obtain the certificate before they are allowed to commence their work. We provide periodic trainings on these measures and procedures to our employees as part of our employee training programs. From time to time, we are inspected for our compliance with environmental, health and safety laws and regulations by authorities such as the Public Security Bureau and the Health Commission. As of the Latest Practicable Date, we had not been subject to any administrative penalties in connection with environmental, health and safety matters.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the Listing. We have established an Audit Committee in connection with the Listing, which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial information and renders advice in respect of financial reporting as well as oversee internal control procedures of our Group.
- We have engaged Rainbow Capital (HK) Limited as our compliance advisor to provide advice to our Directors and management team. Our compliance advisor is expected to, upon our consultation, provide advice and guidance in respect of compliance with the applicable laws and the Listing Rules including various requirements of the financial reporting directors' duties and internal control in a timely fashion.

- We have engaged a PRC law firm to advise us on and keep us abreast of PRC laws and regulations after the Listing. We will continue to arrange various trainings sessions to be provided by external legal advisors from time to time when necessary, and/or any appropriate accredited institution to update our Directors, senior management and relevant employees on the latest PRC laws and regulations.
- We have established procedures to protect the confidentiality of clinical trial data. We clearly define the scope of the personnel who can access data generated from clinical trials and the information about the enrolled participants. Access to such data has been strictly limited to the authorized personnel according to the GCP and relevant regulations. We have also implemented measures to secure patients' privacy. For example, we only use anonymized code as a basis for patient identification. We require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form, or the ICF. We will obtain consent from patients for use of genetic materials or if any use of data falls outside the scope of the previously signed ICF. With regard to the use of genetic materials, our biological sample analysis laboratory has formulated standard procedures and strictly follow such procedures for the storage, use and destruction of biological samples of the clinical trial participants. In addition, our clinical operations team has standardized procedures for handling human genetic materials in compliance with the relevant laws and regulations, such as the HGR Regulation.
- We have developed the policy on information disclosure management which provide a general guide to the Directors, senior management and relevant employees of the Company in handling and dissemination of confidential information, monitoring information disclosure and responding to enquiries. Control procedures have been implemented to ensure that unauthorized access and use of inside information are strictly prohibited. The Board is aware of its obligations to announce any inside information in accordance with the Listing Rules.
- Our compliance policies are standard for our industry and apply to all of our employees. We have established and maintained strict anti-corruption and anti-bribery policies, which sets forth our internal policies and procedures with regard to business entertainment, provision of gifts and financial reimbursement. We also require all of our employees to attend the trainings on the anti-corruption and anti-bribery polices. This year, we reviewed and updated our policies and provided training to our employees on these updates. For instance, departments are now required to complete a conference request form prior to hosting or attending a third-party conference. This is to assess the necessity of the conference and ensure compliance with relevant regulations. We will also ensure that our business development team complies with applicable promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities. Moreover, we have formulated an anti-corruption and anti-bribery integrity agreement which we require our suppliers, including CROs to execute before we enter into business relationship.

- We have complied with the Corporate Governance Code, except for the deviation from the code provision C.2.1 of the Corporate Governance Code. We have established three board committees, namely, the Audit Committee, the Nomination and Corporate Governance Committee and the Remuneration Committee, with respective terms of reference in compliance with the Corporate Governance Code.
- Our Directors believe that compliance creates value for us and dedicate to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across the organization, we regularly conduct internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.

During the Reporting Period, we have regularly reviewed and enhanced our internal control system. We believe that our Directors and senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control matters.

#### **Investment Risk Management**

We engage in short-term investments with surplus cash on hand. Our primary objective for short-term investments is to preserve principal and increase fund-using efficiency and liquidity as well. Our finance department, under the supervision of our senior officer of Finance, is responsible for managing our short-term investment activities. Before making a proposal to invest in wealth management products, our financial department must assess our cash flow and operational needs and capital expenditures.

We operate under a Board approved investment policy which governs the investment of our funds and is reviewed from time to time by our Board. We will make its investment decisions on a case-by-case basis after thoroughly considering a number of factors, including but not limited to macroeconomic environment, general market conditions and the expected profit or potential loss of the investment. Under the Company's investment policy, we are prohibited from investing in high risk products and the proposed investment must not interfere with its business operation or capital expenditure. As of the Latest Practicable Date, the Company's investment decisions did not deviate from its investment policy.

Our portfolio to date has been required to hold only instruments with an effective final maturity of 24 months or less, with effective final maturity being defined either as the obligation of the issuer to repay principal and interest or the discretionary ability of investor to put the security back in advance to the issuer. The initial target range for the average maturity of our portfolio is 24 months.

We believe that our internal investment policies and the related risk management mechanism are adequate. We may make investments that meet the above criteria after consultation and approval by our Board where we believe it is prudent to do so.

#### **FDA** inspection

Reference is made to the announcement of the Company dated December 12, 2023.

The Company submitted a response with Corrective and Preventive Actions (CAPAs) plan together with a timetable to the FDA at the end of December 2023. The Company has been implementing the CAPAs according to the plan, and has provided the FDA the first update with implementation progress and results for CAPAs. The remaining CAPAs progress will be updated to the FDA periodically. Once all CAPAs have been completed and submitted to the FDA, the Company will promptly apply to lift the clinical hold when appropriate.

In order to enhance the effectiveness and timeliness of the CAPAs implementation, the Company has engaged several third-party GMP consultants with diverse areas of expertise to provide advices and guidances.

Meanwhile, the Company has endeavoured to establish, enhance or update CAPA-related policies and procedures, train relevant personnel and maintain training records. Additionally, employees will also receive general CGMP training to continuously improve our quality culture and quality system management.

We believe we have taken sufficient actions to improve our internal control processes related to the FDA inspection findings. We will work closely with the FDA to ensure the smooth progress of return to production.

#### Process and main features of risk management and internal control system

The goal of the Group is to identify and manage the risks (including ESG Risks) which are inherent in the Group's business and its operating markets so that the risks can be reduced, mitigated, transferred or avoided.

The Board acknowledges that it is its responsibility to ensure that the Company establishes and maintains sound risk management and internal control systems within the Group and to review the effectiveness of the systems. Such systems are designed to manage and mitigate risks inherent in the Group's business faced by the Group to an acceptable level, but not to eliminate the risk of failure to achieve business objectives, and can only provide reasonable assurance against material misstatement, loss or fraud.

The Board oversees the Group's overall risk management and internal control process through the Audit Committee which forms an important part of the corporate governance regime of the Group. The Audit Committee, on behalf of the Board, continuously reviews the risk management and internal control systems. The review process has been conducted annually to confirm the effectiveness of management and internal control systems comprising, among other things, periodic assessment of key operational risks and control measures, meetings with management of business groups, internal audit team, and the external auditors, reviewing the relevant work reports and information of key performance indicators, and discussing the major risks with the senior management of the Company to aim at mitigating, reducing, transferring or avoiding such risks; the strengths and weaknesses of the overall internal control system, and action programs to address the control weaknesses or improve the assessment process. The Audit Committee will then report to the Board after properly reviewing the effectiveness of the Group's risk management and internal control systems. The Board has conducted a review over the risk management and internal control system of the Group for the year ended December 31, 2023, which covers financial, operational, compliance procedural and risk management functions, and considers them efficient and adequate. No significant area of concern that may affect the financial, operational, compliance, control and risk management of the Group has been identified during the year ended 31 December 2023.

#### Review of effectiveness of the risk management and internal control system

In addition, the Board believes that the Company's accounting and financial reporting functions have been performed by staff of the appropriate qualifications and experience and that such staff receives appropriate and sufficient training and development. Based on the audit report of the Audit Committee, the Board also believes that sufficient resources have been obtained for the Company's internal audit function and that its staff qualifications and experience, training programs and budgets are sufficient. The Board has reviewed through the work of its Audit Committee and was satisfied to the effectiveness of the Group's internal control and risk management systems for the year ended 31 December 2023.

#### **Inside Information**

With regard to the internal controls and procedures for the handling and dissemination of inside information, the Group is in compliance with provisions under the Part XIVA and relevant parts of the Securities and Future Ordinances and Listing Rules. To be certain that all the staff members of the Group are aware of the inside information handling, the Group's disclosure policy sets out guidance and procedures to ensure that the inside information of the Group is disseminated to the public completely, accurately and timely. The Group also has reasonable measures and procedures regarding keeping the sensitive information confidential and ensuring the confidentiality terms are in place in the significant agreements. Other procedures including sending blackout period and securities dealing restrictions notification to the relevant Directors timely have also been implemented by the Group against possible mishandling of inside information within the Group.

## **ABOUT THE REPORT**

CARsgen Therapeutics Holdings Limited ("**the Company**" or "**CARsgen Therapeutics**", stock code: 2171) has issued the 2023 Environmental, Social and Governance Report ("**ESG Report**") as the Company's third ESG report to introduce its management and performance concerning environmental protection, social responsibility and corporate governance to stockholders.

#### **REPORTING SCOPE**

Unless otherwise stated, the report scope is consistent with the scope of the consolidated financial statements of the Company's 2023 annual report, covering the Company and its wholly-owned and majority-owned subsidiaries, jointly referred to as "**the Group**" or "**We**". The Reporting Period is from 1 January 2023 to 31 December 2023 (the "**Reporting Period**"), and some content may trace back to previous years or extend to future years.

## **REPORTING STANDARDS**

The Report is prepared in compliance with the requirements of Appendix C2 *Environmental, Social and Governance Reporting Guide* (the "**ESG Reporting Guide**") to the Main Board Listing Rules ("**Listing Rules**") of Stock Exchange of Hong Kong Limited ("**HKEX**").

#### **REPORTING PRINCIPLES**

"**Materiality**": The ESG Report includes communication with stakeholders and a materiality assessment in the preparation process as the basis for determination of important ESG topics.

"Quantitative": The ESG Report adopts quantitative information to disclose the key performance indicators ("KPI") on environmental and social levels, accompanied by a narrative that explains their purposes and impacts.

"Balance": The ESG Report provides an unbiased picture of our ESG performance in compliance with the "Balance" principle.

"**Consistency**": The key performance indicators and statistical method used in this report are consistent with the ones used in the previous annual ESG Reports to ensure the comparability.

## **REPORT AVAILABILITY**

The Report is released in both print and online versions. The online version is available for viewing or download from the HKEX news website (http://www.hkexnews.hk) and the Company's official website (https://www.CARsgen.com).

#### **BOARD STATEMENT**

The Board of Directors of the Company places the deep integration of its development strategy with the ESG management philosophy high on the agenda and assumes full responsibility for the Company's ESG strategies and reporting regarding to the requirements of the *ESG Reporting Guide*. The Board actively explores and continuously improves the Company's ESG management structure and system and continuously strengthens its own supervision and participation in ESG management, creating long-term value for society as well as guarding the sustainable and high-quality development of the Company.

This Report was approved by the Board on 26 March 2024 upon confirmation by the management.

## **CORPORATE HONORS**

In 2023, key honours and rewards obtained were as follows:

•	March 2023	The title of "Shanghai 'Specialized, Refinement, Differential and Innovation' SMEs (2023-2025)"
•	May 2023	"Top 10 Innovative Companies of the Year" and "Top 10 Innovative Research Teams of the Year" by the Securities Times in the 3rd Economic Innovation Awards
•	August 2023	"Innovative SME" by Shanghai Municipal Commission of Economy and Informatization
•	October 2023	"2023 Synthetic Biology Industry Value Gold Ranking" Top 36
•	November 2023	"Top 100 Innovative Pharmaceutical Enterprises in China" by Healthcare Executive Magazine

"Top 10 Innovative Pharmaceutical Enterprises of 2023" by China Times



The trophy of "Top 10 Innovative Pharmaceutical Companies of the Year"



The certificate of "Top 10 Innovative Pharmaceutical Research Teams of the Year"



The certificate of "Top 100 Innovative Pharmaceutical Enterprises in China"

## **1. ESG MANAGEMENT**

#### **1.1. Governance Structure**

A sound ESG governance system is the internal foundation for enterprises to efficiently fulfil their external environmental social responsibilities. With a vision of "Making Cancer Curable", the Group recognise the importance of the corporate social responsibility fulfilment and fully integrates the concept of sustainable development into our business strategies and daily operations. We continuously improve our corporate ESG governance, develop and operate on a more responsible way to achieve better performance in the economy, environment and society, and collaborate with the upstream and downstream partners in the industrial value chain for sustainable development.

Since officially listed on HKEX in June 2021, the Company has adopted and applied the related regulations on ESG governance in the Listing Rules. We have also defined the ESG governance functions of the Board of Directors. In addition to assessing and developing ESG management policies and strategies, as well as overseeing ESG issues, the Board of Directors is fully responsible for the Company's ESG strategies and reporting, regularly reviewing ESG-related issues, ESG-related goals and progress, and approving annual ESG report. Meanwhile, to further implement top-down governance approach of ESG issues, we have set up ESG working groups, which plan and implement the Company's ESG management policies, put ESG policies into practice and report to the Board of Directors about ESG working progress. In the future, we plan to further improve ESG management mechanism and continuously enhance our ESG performance.

#### **1.2. Stakeholder Communication**

We have developed a well-established stakeholder communication mechanism and actively communicate with all stakeholders including shareholders, investors, regulators, suppliers, partners, employees, customers, patients, industry associations, communities and the public on a regular basis. We collect their opinions and advice regarding our ESG strategies and performance, comprehend and include their critical concerns in our ESG management to effectively respond their demands.

Demands and expectations	Communication methods
Return on investment Information disclosure	Annual reports, financial statements and announcements Company's website
NISK CONTION	Meetings, road shows
Operation compliance	Government research
Tax payment in accordance with laws Making contribution to the society	Thematic meeting of the government administration Written reports Industry forums
5	
Product quality and safety Product R&D and innovation	Customers' feedbacks Communication and discussion
Rights & interests Protection Privacy protection	Survey on customer satisfaction
	Return on investment Information disclosure Risk control Operation compliance Tax payment in accordance with laws Making contribution to the society Product quality and safety Product R&D and innovation Rights & interests Protection

Stakeholders	Demands and expectations	Communication methods
Suppliers/partners	Supplier management	Business communication
	Justice and fairness	Regular meetings
	Win-win cooperation	Field visits
	Anti-corruption	Assessment and evaluation
Employees	Training and development	Email communication
	Well-established remuneration and	Internal Meetings
	benefits mechanism	Internal Training
	Equal opportunities and diversification	Team building
	Occupational health and safety	
Industry associations	Communication and cooperation	Industry alliance
	Fair competition	Seminars and exchange conferences
	Industry empowerment	Project cooperation
Community and the public	Community care	Company's website
	Social public benefit activities	Daily communication
	participation	Public services
	Environmental protection	Social media

#### **1.3. Materiality Assessment**

To identify key areas of ESG practice, we have regularly appointed third-party professional organizations to conduct materiality assessment to determine the materiality of ESG topics to the Company's business development and the stakeholders, so as to identify the focus areas of our ESG efforts. The assessment results also serve as an important reference for ESG management strategies and ESG reporting.

#### Step 1 Identify ESG topics

Based on the requirements of the *ESG Guide* and taking the Company's actual business and industry characteristics into account, we have identified 17 ESG-related topics to which the stakeholders paid attention through a series of analysis, and confirmed that these topics were already covered in our ESG practice during the Reporting Period.

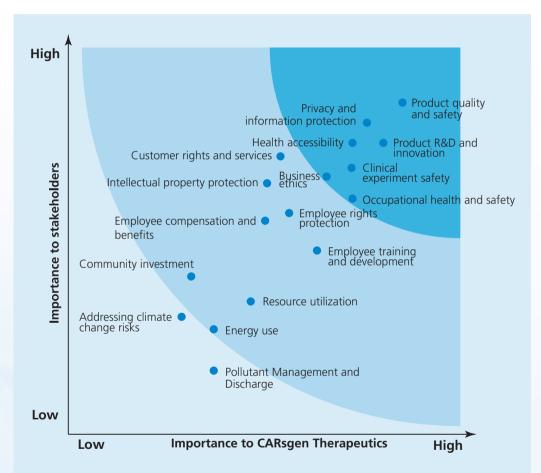
#### Step 2 Determine the materiality

We have assessed and adjusted the topics from the aspects of "importance to CARsgen Therapeutics" and "importance to stakeholders" through internal interviews and discussions as well as seeking external opinions, and generated materiality assessment matrix based on the survey results to set the priority of the ESG topics.

#### Step 3 Verify assessment results

The Board of Directors and senior management of the Company have reviewed and confirmed the assessment results. 7 topics of high importance to the Company have been identified, including product quality and safety, privacy and information protection, product R&D and innovation, health accessibility and clinical experiment safety. We will respond to the topics of high importance in corresponding chapters of the Report in order to address the concerns of all stakeholders.

During the Reporting Period, as there were no significant changes in the Company's business operation model, after reviewing the ESG issues and materiality assessment results, it is considered that the results were still applicable to the Company, and the Company's materiality matrix is as follows:



Materiality assessment results of CARsgen Therapeutics

#### 2. PROMOTING HEALTH AND WELL-BEING THROUGH INNOVATION

Remain true to our original aspiration and keep our mission firmly in mind. We focus on innovative <sup>1</sup>CAR T-cell therapies for the treatment of hematological malignancies and solid tumors since operated in 2014, hoping to continue to lead the development of the biopharmaceutical industry through independent research and development of new technologies. We strive to become a global biopharmaceutical leader by bringing innovative and effective cellular therapies to cancer patients around the world, improving the quality control of our products, and making cancer curable.

#### 2.1. Building Innovative Ecology

#### 2.1.1. Promoting R&D and Innovation

With the vision of "Making Cancer Curable" and regards independent innovation as the core driving force, the Group has established an integrated platform with internal capabilities in target discovery, antibody development, clinical development and commercial-scale production to improve the acceleration of the cell therapy development lifecycle. Meanwhile, through a globally owned product pipeline, we address the major challenges of CAR-T cell therapy including safety enhancement, efficacy in the treatment of solid tumors improving, and the cost of treatment lowering, etc.

We devote ourselves to the promotion of CAR-T technology innovation constantly, with efficacy, safety, patient accessibility and target availability as our four strategic pillars, exploring and developing innovative technology platforms to produce better cellular therapy products for worldwide cancer patients. By the end of the Reporting Period, we had established an integrated R&D platform covering the entire CAR-T development cycle, consisting of target discovery, antibody development, vector design, manufacturing, quality assurance and quality control. Our comprehensive cell therapy platform consists of a target discovery, hybridoma antibody humanisation platform, fully human phage-display antibody library platform, antibody identification platform, immune cell function assessment platform, plasmid and lentiviral vector preparation platform, cell therapy process development platform, analysis platform with molecular, flow cytometry, biochemical, physicochemical and cellular analysis capabilities, biological sample testing platform, clinical scale and commercial scale CAR T manufacturing platform and clinical research platform. With the support of these comprehensive platforms, we are able to scientifically and efficiently develop our product candidates from early stage discovery to clinical trials and continue to explore the possibility of product commercialization. By the end of the Reporting Period, we had a total of 12 product candidates. Various differentiated product pipelines all made steady progress in clinical development, technological innovation and manufacturing capabilities during the Reporting Period. In addition, our Claudin 18.2 companion diagnostic reagent has completed the medical device clinical trial filing and commenced clinical trials.

Case: CT041 received IND approval from the National Medical Products Administration (NMPA) of China for post-operative adjuvant treatment of pancreatic cancer

In April 2023, CT041, the Group's autologous CAR-T cell candidate targeting the Claudin 18.2 (CLDN18.2) protein, was formally granted IND approval by the National Medical Products Administration (NMPA) of China for post-surgical adjuvant treatment of pancreatic cancer with positive CLDN18.2 expression. Pancreatic cancer, as one of the fatal diseases, often has a poor prognosis and is in urgent need of effective treatment. Early clinical trials have shown that CT041 has promising efficacy in the treatment of pancreatic cancer. The approval of the IND allows us to further explore the use of CT041 in adjuvant therapy and the more therapeutic potential it can bring to pancreatic cancer patients.

# Case: CT071 received IND approval from the U.S. Food and Drug Administration (FDA) for the treatment of relapsed/refractory multiple myeloma or relapsed/refractory primary plasma cell leukemia

In December 2023, the IND application for CT071, the Group's autologous CAR-T cell product candidate targeting G protein-coupled receptor group C, member 5, D (GPRC5D), for the treatment of relapsed/refractory multiple myeloma (MM) or relapsed/refractory primary plasma cell leukemia (PCL), was approved by the U.S. Food and Drug Administration (FDA). CT071 is produced through the Group's proprietary CARcelerate<sup>™</sup> technology platform, which can shorten the production time within 2 days, resulting in the creation of newer, healthier and potentially more potent CAR-T cells than conventional production methods, and further increase supply capacity, reduce production costs and improve patient accessibility.

In addition, an investigator-initiated clinical trial (IIT) being conducted concurrently in China to evaluate the safety and efficacy of CT071 for the treatment of relapsed/refractory multiple myeloma or plasma cell leukemia. The preliminary clinical data have demonstrated an acceptable safety profile and preliminary efficacy with CT071.

#### 2.1.2. Intellectual Property Management

The Group continuously improves the management of intellectual property rights and adopts a zero-tolerance attitude to eliminate any infringement of intellectual property rights. We have formulated a series of management documents, including the *Intellectual Property Rights Management Manual*, the *Intellectual Property Rights Management Policy*, the *Intellectual Property Rights Obtaining Control Procedure*, the *Intellectual Property Rights Emergency Plan*, the *Intellectual Property Rights Archives Management Policy*. During the Reporting Period, we also established the *Patent Examination Rules* and revised the *Patent Examination Account* and the *Process Account of the Intellectual Property Department*, to rationalize and standardize the intellectual property-related management rules and operational procedures at each stages, and to enhance our independent innovation capability and core competitiveness.

We carry out risk screening for infringement of patents and intellectual property rights throughout the entire process by conducting Freedom to Operate (FTO) analysis for the established projects and monitoring the use of trademarks within the Group regularly to ensure that the rights and interests of trademarks are enforced. In addition, we emphasize the protection of trade secrets by providing education on trade secrets to new recruits and launching regular publicity campaigns for research and development personnel and other confidential personnel to raise their awareness of the confidentiality of trade and technology secrets. During the Reporting Period, we conducted various trainings related to intellectual property and trade secret protection, which covers the process of patent proposal, the intellectual property incentive system, and patent search analysis methods, etc., with a total of 95 participants.

We have also developed the *Intellectual Property Rights Incentive Measures*, in order to specify application of related intellectual property rights and incentive rules, and established incentive awards such as the "Technology Invention Award", "Achievement Transformation Award", "Golden Idea Award", "Mastermind Award" and "Major Innovation Award", thus motivating employees' enthusiasm and creativity and encouraging the output of intellectual property rights. During the Reporting Period, a total of 23 employees were awarded the "Technology Invention Award" with incentive of RMB118,050 in total. By the end of the Reporting Period, we had been granted 104 patents worldwide.

#### 2.1.3. Improving Communication and Cooperation

While adhering to independent research and development, the Group actively collaborates with various partners to co-innovation in diversified ways. With the integration of resources and complementarity of strengths, we are trying to build an industry innovation ecosystem and realize mutual benefits and win-win situations.

We actively carry out industry-university-research cooperation with government departments, well-known scientific research institutions and universities. We have established academician expert workstations, undergraduate industry-university-research practice bases and internship bases, and settled in Xuhui District postdoctoral innovation practice base, thus fully exploiting the joint advantages of scientific research workstations, the enterprise, innovative practice base and universities to assist in talent attraction and cultivation as well as promote industry, university and research integration and the commercialization of scientific and technological achievements. During the Reporting Period, a number of research results those collaborates with the research institutes and hospitals were published in professional journals. For example, the research result of CXCR4 CAR-T cell therapy targeting Claudin 18.2-positive pancreatic ductal adenocarcinoma (PDAC) has been published in Molecular Therapy with collaboration of the Shanghai Institute of Oncology. The fruitful result of academic exchanges and collaborations have effectively promoted the development of the Group's oncology and CAR-T cell therapy technologies.

# Case: Establishment of strategic cooperation with Jinshan Hospital affiliated to Fudan University

In February 2023, the Group signed a strategic cooperation framework agreement with Jinshan Hospital affiliated to Fudan University. Oriented by clinical value, the Group focuses on developing related products such as CAR-T cell products, and cooperating in the establishment of a CAR-T clinical research and treatment center to create a new paradigm of industry-medicine cooperation. Through this cooperation, CARsgen Therapeutics and Jinshan Hospital will leverage own advantages of innovation and medical resources to overcome the difficulties in the development and industrialization of tumor immunotherapy technology, to promote efficient transfer of research outcomes, enhance clinical research and diagnostic capabilities, and further meet clinical needs.

With an open attitude, we actively communicate with our peers, suppliers, industry organizations and other partners and put forward relevant opinions and suggestions to improve the development of the industry by receiving on-site investigations from government departments, attending special meetings organized by government departments, submitting written reports to government departments, and participating in industry forums. During the Reporting Period, we participated in a number of academic conferences, including the Chinese Innovative Pharmaceutical Medicine Conference and the 10<sup>th</sup> CMAC Annual Meeting, the 65th ASH Annual Meeting and Exposition, the European Society for Medical Oncology Congress 2023, the American Society of Clinical Oncology Congress, the American Association for Cancer Research Congress, etc., to conduct profound academic communications with scientists and other enterprises in the professional field, providing sufficient resources for the cultivation of next-generation researchers and enhance the public awareness of oncology, cancer and other diseases.

In addition, we have repeatedly participated in the feedback activity of documents issued by the National Medical Products Administration and other regulatory authorities to promote the formulation, improve industry standards and contribute to the high-quality development of the industry. During the Reporting Period, we participated in the formulation of the organization standard *Guidance for the Manufacturing Quality Management of Plasmids Used in the Production of Immune Cell Therapy Products* (T/SHPPA 019-2023) and became the first batch of implementing units of this standard, fully utilizing our role as an industry leader.

By the end of the Reporting Period, the main industry associations we participated in were as follows:

Name of association	Position held	Entity
China Society for Drug Regulation (Specialized Committee on Cell Therapy)	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Biopharmaceutics Industry Association	Director unit	CARsgen Therapeutics (Shanghai)
Shanghai Medicine Industry Association	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Biopharmaceuticals Industry Innovation Alliance	Initiating unit	CARsgen Therapeutics (Shanghai)
Cell Immunotherapy Quality Management and Research Committee of Shanghai Medicine Quality Association	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Zhangjiang High-tech Park Development Affairs Consultation and Promotion Association – Biomedical branch	Executive director unit	CARsgen Therapeutics (Shanghai)
Shanghai Pudong International Chamber of Commerce – Biochemical Committee	Director unit	CARsgen Therapeutics (Shanghai)
Shanghai Synthetic Biology Industry Association	Founding Members	CARsgen Therapeutics
Shanghai Jinshan Technology Enterprise Federation	Member unit	CARsgen Therapeutics
Maplewood Life & Health Industry Intellectual Property Alliance	Alliance unit	CARsgen Therapeutics (Shanghai)

#### Case: Co-operation agreement with Moderna Launched

In August 2023, the Group formally initiated a collaboration agreement with Moderna, Inc. (Nasdaq: MRNA) to conduct the combination effect study of the Company's Claudin18.2 CAR-T product candidate (CT041) and Moderna's experimental Claudin18.2 mRNA cancer vaccine. Through the collaboration with Moderna, we hope to explore the potential synergies of combining CAR-T cell therapy with cancer vaccines for the treatment of tumors, and to explore the potential of combining innovative therapies for greater clinical benefits to patients.

#### 2.1.4. Enhancing Access to Health

With the mission to "become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable", the Group is committed to developing universal CAR-T cellular therapies and lowering the cost of CAR-T cellular therapies through technological and product innovations, benefiting more patients from CAR-T cellular therapies. We also hope to leverage the strengths of external partners to improve access to medicines for patients around the world to enhance human health and well-being. During the Reporting Period, we made a commercialization agreement with Huadong Medicine for CT053, hoping to leverage Huadong Medicine's strong commercialization capabilities in the hematology field to enable CT053 to benefit more Chinese patients with multiple myeloma, prolonging their lifetime and improving their quality of life.

## Case: Collaboration with the China Pharmaceutical Innovation and Research Development Association (PhIRDA) to explore the possibility of paying for high-value drugs

In 2023, CARsgen Therapeutics, together with relevant enterprises, supported a research project led by PhIRDA on "Exploring an innovative payment model that combines the price paid by health insurance and the price paid by the patient", to explore the possibility of paying for high-priced products to reduce the burden of patients on the use of high-value medicines, to strike a balance between the availability of innovation and the safety of the health insurance fund, to motivate enterprises to innovate and be sustainable, and to increase the international competitiveness of product prices. The project examines the international payer experience of CAR-T therapy, explores comprehensive payment schemes through interview surveys and desk research, and analyses existing payment schemes with a view to breaking through their limitations and making high-priced drugs more accessible through innovative payment schemes.

#### 2.2. Becoming a Quality Benchmark

The Group takes the responsibility of protecting patients' health and focuses on the whole life cycle of product management. Through stringent quality assurance and quality control, the Group consistently improves the quality of products and provide patients and customers with high-quality and accessible products and services.

#### 2.2.1. Quality Assurance

We strictly comply with the Pharmaceutical Administration Law of the People's Republic of China, the Regulations on the Implementation of the Pharmaceutical Administration Law of the People's Republic of China and GMP (Good Manufacturing Practice) and other relevant laws, regulations and industry standards to ensure that the quality of our products is safe and controllable throughout the entire product life cycle as well as complying with the requirements of the industry's quality management system and the relevant laws and regulations. In order to prepare for the marketing authorisation and commercialization of new products, during the Reporting Period, we continued to refine our quality management system, and launched a comprehensive optimization of system documents and management processes in accordance with the marketing authorisation requirements in order to meet the requirements for the marketing authorisation of our products. Moreover, we have passed the GMP compliance on-site inspection.

Our quality management system, including various Standard Management Procedure (SMPs) and Standard Operation Procedure (SOPs) such as the Quality Manual, the *Quality Risk Management Procedure, the Management Procedure for Quality Management Review*, covers product full life cycle process to ensure the effective operation of product manufacturing, testing and quality management measures. During the Reporting Period, we formulated a number of quality management system documents related to the marketing authorisation of new products, including for medical institutions, DTP pharmacies, distributors, third-party cold chain, orders and logistics, etc. CARsgen Therapeutics Corporation (CARsgen USA) also formulated and published the *Quality Complaints Procedure GSOP-QA-008*, the *Internal Audit Program* and other relevant quality control procedures to ensure that the quality control work is carried out in an orderly manner.

We utilize digital systems such as BMS, PMS and EMS to accurately and efficiently carry out quality control work. The PMS system is used for online monitoring of the cleanliness of the production and operation environment in the clean production area; the EMS is used for the monitoring of temperature, humidity and pressure differences in the areas of production, testing and warehousing; the EMS is also used to monitor the temperature of various types of refrigerators, ultra-low-temperature refrigerators, liquid nitrogen tanks and cold storage equipment to ensure the production environment is in a controlled state and ensure that products and materials are in suitable storage conditions. In accordance with the Management Procedures of Annual Product Review, we have set up a working group to carry out the annual quality review of our products. Moreover, we organize quarterly quality management reviews and clarify the responsibilities of relevant personnel and SOPs for raw material procurement, acceptance, storage, and equipment, facility, production, testing and product transportation management to prevent contamination and potential risks during the review period. During the Reporting Period, we optimized the on-site working methods of operations and processes, and reduced the number of on-site supervisors entering the clean production area when not necessary, so as to minimize the possibility of contamination and cross-contamination.

In addition to signing the *Quality Agreement* with material suppliers and outsourcing service providers to ensure that they meet GMP and our relevant quality requirements, we also sign Quality Agreements with our co-selling hospitals and cooperate with medical institutions to launch operational training and simulation drills for the entire product process, and safeguard the health and safety of our patients by launching external quality audits on a regular basis. In addition, CARsgen USA has conducted regular training to doctors, collectors, and other related personnel to ensure operational compliance and product safety.

In order to incorporate quality awareness into the deployment of quality standards and daily operations, we attach great importance to building a quality-centered culture and make full use of our internal Veeva system and other diversified platforms to carry out various forms of online and offline quality training. We have formulated an annual quality training program, which is implemented at both company and departmental levels. Company-level training covers the laws and regulations related to pharmaceutical production, product knowledge and production quality management requirements, while departmental-level training focuses on departmental management, case sharing and operational skills. During the Reporting Period, a total of 12 company-level quality training sessions were conducted, with a total of more than 1,100 participants.





**On-site training** 

#### 2.2.2. Quality Control

We have strong in-house quality testing capabilities and systematic quality control processes. Our in-house professional quality control team consists of physics and chemistry laboratory, microbiology laboratory, biochemistry laboratory, bioactivity laboratory and operating teams, which engage in establishing and maintaining quality standards and test methods, conducting detection on raw materials and adjuvants, packaging materials, pharmaceutical water, in-process products and finished products, effectively implementing product quality control.

We have established related quality standards, verification regulations and developed sampling plans for various products and key raw materials involved, including quality specifications for final products and control requirements on in process products and solutions during the manufacturing process. Meanwhile, to ensure the accuracy and reliability of inspection results, we have formulated documents including the *QC Laboratory Management Procedures*, the *QC Samples Management Procedures* and the *Management Procedure for QC Records* and *Inspection Reports*, which specify inspection operations and report specifications corresponding to inspection methods. During the Reporting Period, we optimized the *QC Laboratory Management Procedures* by adding refrigerator access control, clarifying the liquid level of liquid nitrogen tanks, and further refining the management requirements for various sample storage containers.

We have strictly managed the use and maintenance of inspection instruments, requiring that all the inspection instruments should be necessarily confirmed, verified, measured or checked before being put into use. We have also confirmed the cycle of the instruments and whether the instruments need to be confirmed or verified, measured or checked again based on risk assessment. Our release inspection methods are validated and suitability verified. After the process, the quality control team is responsible for completing records and audits, and issues CoA to ensure that all data are accurate, compliant and complete. We require our staff to finish training and assessment and obtain the appropriate gualifications before they start work. Meanwhile, we require them to sign the Data Reliability Commitment, to make sure that the related personnel record the situation and facts in an unbiased manner during manufacturing, inspection and GMP activities and retain the original data of the activities to ensure the traceability of the data. Moreover, we refine the management norms of classification and partitioning to improve the laboratory management, and optimize the sample information registration process to effectively enhance the level of quality test. Since cell therapy products are still in the early stage of development, we are constantly improving and optimizing our product processes and testing methods by regularly reviewing the problems that have occurred during the actual product testing process, in order to be fully prepared for commercial production with high-quality assurance.

#### **Case: Quality Control Training**

In August 2023, the Group launched a training course on the *Microbiological Knowledge and Personnel Hygiene* for all employees. The trainer introduced microorganisms in a vivid manner by means of on-site examples and pictures, and explained the potential contamination factors in the production of CAR-T products and the control measures to be taken in combination with the operation video. Through the explanation of professional knowledge and the sharing of cases, employees gain a deep impression. During the Reporting Period, our quality control team conducted 3 company-level trainings and 9 department-level trainings, with a completion rate of 100%.



**On-site training** 

#### 2.3. Protecting Patient Health

We strictly comply with the laws, regulations and industry requirements of the countries in which we operate. Through establishing and continuously improving the protection mechanism of patients' rights and interests, we safeguard the patient safety and bring the benefit to patients all over the world.

#### 2.3.1. R&D Ethics

Respected to related moral principles of the *Declaration of Helsinki* and the laws and regulations including the *Consolidation Guidance of Good Clinical Practice (drug and medical device)*, and the *Review Methods for Biomedical Research Ethics Involving Human*, we have conducted ethical inspections on all the clinical projects to ensure related biomedical researches comply with ethical principles such as "informed consent", "control risks" and "privacy protection". CARsgen USA also strictly complies with the relevant laws and regulations including the *US Code of Federal Regulations (CFR)*, the moral principles of the *Declaration of Helsinki*, ICH (the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use)-related guidelines and *Good Clinical Practice (GCP)*, committed to conduct ethical inspection on all the clinical projects to ensure related biomedical researches comply with ethical principles such as "informed consent", "control risks" and "privacy protection".

#### **Informed consent**

Respect and guarantee the rights of the subjects to decide whether to participate in the research, strictly implement informed consent procedures, avoid lying, inducing and threatening the subjects to get their consent to participation, and allow the subjects to quit unconditionally at any stages

#### **Privacy protection**

Practically protect the subjects' privacy truthfully tell the subjects about the storage, utilization and confidential measures about their personal information, and do not expose the information to any third parties without authorization

#### Control risks

Put the personal safety and healthy rights first, followed by science and social interests. Research risks and benefits should be balanced, and avoid hurting the subjects as possible as we can

#### Compensation in accordance with the laws

Where the subjects suffer any damage while participating in the study, they shall receive timely and free treatment and be compensated according to the laws, regulations and the agreement of both parties

#### Free and compensation

Select the subjects in a fair and reasonable manner, charge no fees to the subjects for research participation, and give certain compensation on the subjects' fees spent during the process

#### **Special protection**

Give special protection to children, pregnant women, the mentally disabled and patients with mental disorders

We emphasize the care of our subjects. In some of clinical studies on continuous administration of drugs, after the subjects have completed the follow-up visits stipulated in the protocols of the clinical trials, we will still provide free drugs to those subjects who may continue to benefit from the use of the drugs to fully protect the rights of the subjects.

In addition, we also require that all the design of animal experiments shall comply with "3R" principle<sup>2</sup>, be good to animals, avoid or reduce animals' stress, pain and injury and respect their lives. We strictly abide by relevant requirements of standards and regulations like *Animal Experiment Management Regulations*, formulate the *Standard Operating Procedures for Animal Experiment Barrier Environments* to specify the administrative rules concerning the selection and disposal of related experimental animals, laboratory conditions, professional competence of staff and operation methods.

3R principle for experimental animals refers to Reduction, Replacement and Refinement.

2

#### 2.3.2. Drug Safety

We have strictly abided by the *Pharmaceutical Administration Law of the People's Republic* of *China and the Measures for the Administration of Drug Registration*, formulated the *Marketing Authorization Procedure for Pharmaceuticals* to standardize the documentation preparation, submission, review and approval for drug marketing authorization applications and ensure the safety, efficacy and quality of the registered medicines.

During the Reporting Period, in accordance with ICH related guidelines, Good Pharmacovigilance Practices, Administrative Measures for the Reporting and Monitoring of Adverse Drug Reactions, Standards and Procedures for Expedited Reporting of Safety Data During Drug Clinical Trials and other regulations as well as the requirements for new product marketing applications, we have developed several new system documents such as the Quality Management of Pharmacovigilance Work, the Internal Audit Management Procedures of Pharmacovigilance and the Safety Reporting Management Procedures of Post-market Non-Interventional Studies and have also amended a number of SOPs, continuing to improve our pharmacovigilance system. Moreover, we gradually establish a global pharmacovigilance workflow and quality management system including that of CARsgen USA to ensure that pharmacovigilance is consistent throughout the entire lifecycle of the pharmaceutical products (including both pre-marketing and post-marketing), which safeguard the safety, reasonableness and efficacy of the public's use of the pharmaceutical products.

We have established a standardized and efficient channel for collecting information on adverse drug events to monitor and control drug safety. During the Reporting Period, we formulated and introduced the *Post-marketing Spontaneous Adverse Event Reporting Management Procedure*. By clarifying the procedural standards for the receipt, handling, reporting and follow-up of adverse events, we aim to ensure that the relevant adverse events can be handled promptly, and help us understand the safety characteristics of our products in a time-efficient manner to protect patients' health. In addition, we also consistently organize internal training on pharmacovigilance and organize relevant staff to participate in several external training in the industry, to better enhance the staff's drug safety knowledge reserve and fulfill our corporate responsibilities.

#### 2.3.3. Products and Services

As of the end of the Reporting Period, most of our products stayed in the pre-market R&D stage and were not produced in large quantities, so we mainly obtained product feedback from CRO (contract research organization) and investigators involved in clinical trials. Upon receipt of a Serious Adverse Event (SAE) from a clinical trial, the Pharmacovigilance (PV) staff will evaluate the case firstly, and if the case is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and a quality investigation is required after the evaluation, the PV personnel will raise the quality investigation to the Quality Assurance Department by using the relevant form.

According to the requirements of product listing, in 2023, we revised and optimized our *Quality Complaint Management Procedures* to include clinical trial complaints in the scope of management and added a new product hotline as a channel for quality complaints and adverse reaction reports to further clarify the process and specifications for handling product complaints and recalls; we also launched quality complaint and pharmacovigilance training for hotline operators to ensure efficient communication channels and orderly handling of feedback, so that we can understand the deficiencies of our products in a timely manner and make improvements in a timely manner.

During the Reporting Period, we received one complaint about the breakage of a freezer bag during the recovery process of a donor cell product. In response to the complaint, we initiated a deviation investigation and re-shipped the cellular product for patient retrieval. Follow-up confirmed that the complaint did not affect the quality of the final product or its use by the patients, who eventually received the drug treatment and achieved good results. By the end of the Reporting Period, we had recalled a total of 6 products, except for the rupture of the storage bag, the other 5 cases were caused by the physical condition of the donors who were not suitable for transfusion, and there were no recalls due to safety and health reasons.

#### 3. UPHOLDING ETHICS TO PROPELL LONG-TERM DEVELOPMENT

As a responsible enterprise, we are determined to implement high standards of business ethics in the course of operation, continue to improve the level of corporate governance, pay attention to the protection of information security, launch compliant communication and at the same time practice responsible sourcing, which effectively safeguards the interests of all stakeholders, establishes a good corporate image, as well as lays a solid foundation for long-term development.

#### 3.1. Compliance Operation

We strictly abide by the Anti-Unfair Competition Law of the People's Republic of China, the Code of Conduct for Personnel of Medical Institutions, the Interim Provisions on Banning Commercial Bribery, the Foreign Corrupt Practices Act, and relevant laws and regulations. In accordance with the internal policies and procedures comprising the Code of Conduct, Anti- Bribery and Anti-Corruption Management Policy, Anti-Fraud Management Policy and Anti-Money Laundering Management Policy, requires employees to conduct themselves with strict adherence to anti-corruption measures and in accordance with the Company's code of ethics. During the Reporting Period, we aligned our internal management processes in accordance with the latest RDPAC and Pharmaceutical Industry Compliance Management Policy to ensure that our anti-corruption and anti-bribery management mechanism complies with the latest industry standards.

In 2023, CARsgen USA formulated and published internal policies such as *Expense Reimbursement Policy, Credit Card Policy* and *Transaction Settlement Policy*. Additionally, we hired an external compliance consultant to carry out a comprehensive assessment of the compliance system and to continuously rectify the issues identified. These actions were taken to enhance the Company's overall compliance management.

We build up a complete reporting channel and handling process to facilitate employees at all levels and all parties in the community to report unprofessional conduct or related incidents via the reporting mailbox and physical mailbox. If any violation of policies and procedures has been confirmed upon investigation, we will take immediate action according to the relevant policies, and the final disciplinary results will be published and archived for future reference. The *Anti-Fraud Management Policy* outlines measures to safeguard whistleblowers and prohibits the disclosure of any information and reporting contents related to whistleblowers.

To ensure that our employees fully understand and comply with our business ethics requirements, we have signed the *Annual Compliance Training Confirmation* with the employees to fully enhance their compliance awareness. Moreover, we urged them to abide by the compliance policy and practice the Company's moral standards in their work. During the reporting period, we organized annual compliance training for all Board of Directors, management and employees, and strengthened our compliance policy and business ethics requirements in the training for new employees, with a view to creating a clean and honest corporate atmosphere and implementing a culture of integrity and compliance. We also encourage some of our employees to join in the Association of China Compliance Professionals (ACCP) and regularly participate in its activities to gain a better understanding of compliance standards and operational practices in the pharmaceutical industry. During the Reporting Period, the Group had no cases related to corruption, money laundering or fraud.

We not only adopt a "Zero Tolerance" attitude towards any form of corruption and bribery, unjust enrichment and disclosure of business information in the course of our own operational activities, but also expect our external partners to adhere to the same standards. In the course of business cooperation, we require all qualified suppliers to sign the *Integrity Building Agreement* and the *Confidentiality Agreement* in accordance with the *Supplier Compliance Guidelines*. These agreements explicitly include provisions related to anti-corruption, confidentiality, personal privacy and the retention of the right to audit in the contract. To reduce compliance risks, we issue conflict of interest questionnaires to service and engineering suppliers. During the reporting period, we provided online compliance training for suppliers for the year 2023, and sent meeting invitations to important suppliers accounting for the top 80% of the procurement amount. The training covered topics such as the tendering and procurement process, anti-corruption and anti-bribery requirements, and an introduction to the Company's internal compliance management measures, etc., with a total of 76 attendees participating in the training.

#### **3.2. Information Security Protection**

The Group attaches great importance to the information security and the protection of personal privacy. Stringently following the *Cybersecurity Law*, the Data *Security Law*, the *Personal Information Protection Law*, and other relevant regulations of the People's Republic of China, we continuously improve the information security management system to prevent data leakage and guarantee the information and data security at the maximum extent.

We have standardized the workflow of computerized system management, reinforced system permission management and ensured data security and integrity through the *Computer System Management Procedures*, the *Computer System Change Management Procedures*, the *Management Procedures for Computer Virus Prevention and Control*, the *Computer Room Management Procedures* and other policies. During the Reporting Period, we revised the *Data Backup and Recovery System Operating Procedures* and formulated and published a series of operating procedures to further clarify internal responsibilities and authority as well as management standards.

We have set up an information security engineer position, with a dedicated staff responsible for network monitoring, data protection, responding to security incidents and other related work. At the same time, we also back up the data in accordance with the *Disaster Recovery Management Procedures* and the *Data Backup and System Operation Recovery Procedures*, as well as normalize the management and utilization of the Company's data backup and system recovery to prevent data loss and other information security events, thereby ensuring the business continuity effectively. During the Reporting Period, the information technology department of the Group, in conjunction with the quality-related departments, regularly conducted quality reviews on account and security management, data integrity and data backup and other related management situations, and planned to further strengthen information security management.

We respect and protect the information and privacy data of patients, employees and business partners. We standardize data retention and utilization process to minimize the collection of unnecessary data. We desensitize and encrypt patient data as required by the *Good Clinical Practice* (GCP), and provide patients with instructions for privacy protection. We require all related employees to sign confidentiality agreements with partners to avoid leakage of patients' privacy and information and to eliminate the possibility of releasing relevant information to unauthorized and unrelated business personnel.

During the Reporting Period, we launched 2 information security training sessions for all staff, the contents of which included but were not limited to information security awareness popularization, phishing emails and virus protection popularization, etc., which effectively strengthened the Group's internal information security awareness and capacity building.

#### 3.3. Practicing Responsible Marketing

To protect consumers' rights and interests, we avoid exaggeration and deceitful and misleading information in strict compliance with the Advertising Law of the People's Republic of China and relevant laws and regulations. Through internal management systems and procedures such as the *External Communication Management Policy*, the *Issuance Standard and Management Policy of WeChat Official Account and the CARsgen Therapeutics Style Guidelines*, we have clarified the management of internal promotional materials, review of external publicity content and relevant work processes, established the responsibilities of relevant departments and the principles of information disclosure, and elucidates the principle of external publicity for all employees, thus ensuring the accuracy of external publicity and product information.

During the Reporting Period, we standardized the management of news output, media interviews, advertisements and image logos, and the contents of our product promotions were fully reviewed by the relevant departments in advance to ensure that they were in compliance with the requirements of the relevant policies and regulations. In addition, our external communications team maintained close communication and cooperation with various departments of the Group to ensure the accuracy of the contents of all types of external promotions.

We continue to improve the establishment of our communication channels. Relying on the Company's platforms including official website, WeChat official account and overseas operations, we conduct the media communication in a compliant and efficient way to create a favourable public opinion environment and brand image. We also pay attention to related potential risks in real-time, and handle crisis by the public opinion classification mechanism. In addition, we provide internal and external compliance publicity training on a regular basis to reduce and avoid potential risks.

#### 3.4. Building a Responsible Supply Chain

#### 3.4.1. Supplier Management

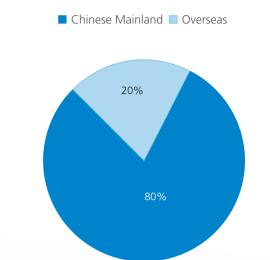
We strictly abide by the *Good Manufacturing Practices for Pharmaceutical Products* and relevant laws and regulations, and formulate and continuously improve the *Supplier Management Policy*, the *Procurement and Bidding Procedures*, the *Indirect Procurement Management Policy*, the *Material Inventory Coding Management Process* and other internal policies. We have established a full life cycle management process for suppliers that covers various stages such as supplier screening, assessment and management, and termination of cooperation. We also utilize multiple digital management systems to ensure the stability of product, service quality as well as business continuity. During the Reporting Period, CARsgen USA developed the *CARsgen Therapeutics Corporation Purchase Application and Approval Process* and *Purchase Order Approval and Management Process* to standardize the process of purchase orders creating, requesting, and approving, ensuring the process effectiveness and operability, which further standardizes procurement management.



Supplier admission process

We focus on the development and maintenance of qualified suppliers, while confirming that the product quality, service ability, business status, production capacity, quality management system, price, reputation, geographical location of suppliers are in line with the relevant admission requirements, while providing suppliers with an open, fair and impartial competition platform. In the supplier admission stage, by integrating quality management, risk control and other considerations, we continue to optimize the admission evaluation criteria for clinical development service providers, and further strengthen the selection of high-quality clinical development service providers.

We conduct on-site reviews and performance evaluation for suppliers at regular intervals in accordance with the *Supplier Management Policy*, the *On-site Review Procedures of Suppliers*, the *Performance Assessment Standards for Service Suppliers*, the *Performance Assessment Standards for Material Suppliers*, etc. Suppliers are classified by assessment results into four levels, i.e., strategic suppliers, key suppliers, mature suppliers and suppliers to be eliminated. For key suppliers, we assign reviewers (PSO) of relevant key suppliers to conduct annual appraisal and classification. For the suppliers to be eliminated, we require them to take corrective and preventive actions, and timely follow up rectifications; otherwise, we will stop sourcing materials and services from them. We also establish the *Supplier Audit Practice Procedures*. We review the suppliers governed by GCP, GMP and *Good Laboratory Practice* (GLP) on a quarterly basis, to ensure the quality of the raw materials purchased. During the Reporting Period, we reviewed 18 related suppliers.



As of the end of the Reporting Period, the Group had 556 suppliers. The geographical distribution is shown as below:

#### 3.4.2. Management of Supply Chain Risks

We regard the stability of the supply chain as an important guarantee for the steady development of our business, and regularly carry out reasonable monitoring and control of potential risks in the supply chain to enhance the resilience of the supply chain.

In view of the environmental and social risks in all aspects of the supply chain, we specify the relevant requirements for suppliers to fulfill the social responsibilities in the *Supplier Management Policy*. For example, the occupational health and safety, labor rights protection and other relevant provisions are clearly listed in the procurement contract, and suppliers are required to shoulder the responsibility for social and environmental impacts arising from their decisions and activities. Besides, we draw up the *Supplier Compliance Notice* to clarify and standardize supplier procurement work flow and code of business ethics, and require qualified suppliers to sign the *Confidentiality Agreement* and the *Integrity Co-construction Agreement* to further guarantee the fairness, impartiality and openness of procurement projects and prevent the violations of disciplines and laws. As of the end of the Reporting Period, there were approximately 70% of suppliers holding ISO 45001, ISO 9001, GXP and other system certifications.

In addition, we actively carry out green procurement practices, not only requiring suppliers to fill in the questionnaire related to environmental protection, but also encourage suppliers to actively fulfill environmental responsibilities. We are committed to cooperating with the upstream value chain suppliers to jointly build a green and sustainable industrial chain. As of the end of the Reporting period, many of our suppliers have received various types of environment-related certifications or certificates such as ISO 14001, ISO 50001, Green Lab Gold certification. As one of our key suppliers, Sartorius is already using 100% hydropower in its German production sites and has set a goal of 100% renewable energy consumption by 2030. Shanghai Haizhi Construction Engineering Co., Ltd. uses fast growing materials as far as possible to reduce the use of fossil raw materials in wood factory. STEMCELL Technologies also has extensive recycling and composting facilities to effectively reduce the amount of waste such as plastic, aluminum foil, cardboard, metal, batteries and electronics to landfills and reduce the environmental impact.

In order to continuously optimize and maintain a stable supply chain, we develop a Business Continuity Plan (BCP), hold regular production meetings with user departments, organize internal inventory, and purchase required raw materials in advance. We actively communicate with suppliers and assist them in formulating BCP to ensure a stable material supply and achieve the goal of ensuring continuous and stable business operation. In addition, we are also actively seeking opportunities for domestic raw materials to replace imported raw materials, hoping to drive the development of the local industrial chain while ensuring business continuity.

#### 3.4.3. Communication with Suppliers

We actively facilitate supplier communication: we hold the Quarterly Business Review (QBR) meetings at regular intervals and organize in-depth exchanges between key employees and suppliers to brief and review the performance assessment results and the problems arising from past cooperation, helping solve their bottlenecks. Meanwhile, we share the future development plans with suppliers to promote the coordinated development with them. During the Reporting Period, we conducted a total of 17 QBR meetings, effectively solving a number of cooperation or technical bottleneck problems, and laying a good foundation for the establishment of long-term mutually beneficial and in-depth cooperation.

## 4. ADHERING TO THE VALUE OF PEOPLE-ORIENTATION, SHARING SOCIAL RESPONSIBILITY TOGETHER

We regard talents as the core power to promote the long-term stable operation and sustainable development of the enterprise, and earnestly practice the value of "people-orientation". We fully respect the legitimate rights and interests of each employee, attach importance to the diverse composition and fair development of employees, and are committed to providing each employee with a safe and healthy working environment and a high-quality platform to promote growth and development. At the same time, we actively cooperate with partners and make use of our own resources and technological advantages to contribute to the construction of a harmonious and beautiful society.

#### 4.1. Empowering Employees' Growth

#### 4.1.1. Safeguard Employees' Rights and Interests

We strictly adhere to the Labor Law of the People's Republic of China, the Labor Contract Law of the People's Republic of China and the Provisions on the Prohibition of Child Labor. We establish a series of rules and regulations regarding employment including the Planning of Human Resources Demands and Recruitment Process, Overtime and Leave Management Policy and Employee Internal Recruitment Management System to effectively safeguard the basic legal rights and interests of each employee or applicant. During the Reporting Period, we formulated the New Employee Entry Management Process, Disciplinary Management System and other systems to strengthen employment and human resources management; CARsgen USA has formulated and issued a series of policies and systems such as Employee Classification Policy, Guide for Promotion Salary Planning Performance Management, Attendance Management Policy, etc., to gradually establish and improve the employee management system.

We firmly prohibit the recruitment of child labor, strictly follow the relevant regulations of the labor protection authorities, and implement a strict entry process. All candidates must provide authentic and valid supporting documents and pass a series of recruitment procedures such as basic qualification examinations and interviews. During the Reporting Period, the Group had no violations involving child labor or forced labor.

#### \* Recruitment and Diversity

Outstanding talent is the core pillar of the sustainable development of enterprises. In order to attract and select outstanding talents, we set up diversified recruitment channels such as online recruitment, campus recruitment and internal recommendation, combined with scientific interview methods, to ensure that all candidates are provided with fair and equal opportunities. We follow the *Planning of Human Resources Demands and Recruitment Process*. Through standardized and procedural recruitment procedures, we clearly define the responsibilities of the human resources department and related departments, orderly plan the human resource demands, so as to better support the strategic development of the company. We attach importance to the cooperation between schools and enterprises and strengthen the construction of internal talent echelons through school recruitment projects and management training project, as well as increase the international talent reserve and create inexhaustible impetus for steadily promoting the strategic expansion of the company.

## Case: CARsgen cooperated with a collection of universities to carry out a special campus job fair

During the Reporting Period, the Group initiated recruitment projects for CMC (Chemistry, Manufacturing, Control) and production business talents; actively cooperated with China Pharmaceutical University, East China University of Science and Technology, Zhejiang University, Nanjing University and other well-known universities in China. We actively planned and participated in a number of campus job fairs and biopharmaceutical job fairs, and further expanded the recruitment scope, attracting more talents with relevant professional backgrounds and practical experience. We also make full use of the company's official website, recruitment website, social media and other online channels to widely publish recruitment information and receive resumes. During the Reporting Period, we recruited a total of 26 employees through the school recruitment program, including 7 graduates and 9 undergraduates.



We actively create a more inclusive and humane work environment, provide equal opportunities for all employees in employment, training, compensation, benefits and career development, prohibit all forms of discrimination. All employees and job applicants are not restricted by their gender, age, race and ethnicity, color, religious belief, national origin, sexual orientation, physical condition and other factors. We prohibit any act that may be harmful to the dignity of the individual. We actively responded to the national policies and guidelines on the protection of persons with disabilities and participated in the Employment Poverty Alleviation Project for Persons with Disabilities in Inner Mongolia. During the Reporting Period, we hired four severely disabled persons, and placed them in the employment base for persons with disabilities in Inner Mongolia according to the actual situation of these special employees. By taking initiatives to adjust corresponding job positions, we hope that each employee can give full play to their potential in the most suitable position, achieving the idea of "provide right positions for people". In addition, we actively provide equal opportunities and platforms for female employees. We support and promote gender equality in the workplace and help female job seekers and employees realize their selfworth.

## Case: CARsgen USA participated in the "Women in Biotechnology" event in Durham, North Carolina

In October 2023, the Group participated as one of the sponsoring companies in the annual "Women In Bio" (WIB) - RTP Branch networking event held in Durham, North Carolina. With more than 75 participants, the event attracted a number of female job seekers looking for full-time positions in manufacturing, quality control, R&D, engineering and project management, as well as internship opportunities. Through this event, we hope to bring together professionals to promote women's career development in the life sciences industry, cultivate women's leadership and entrepreneurship, and inject vitality into the development of the industry.

As of the end of the Reporting Period, the Group had a total of 516 employees, with 61.0% of them female.

Employee structure	Number of employees in 2023
Total	516
By gender	
Male	201
Female	315
By employment type	
Full-time	516
Part-time	0
By age	
Under 30 years old	165
30-50 years old	315
Over 50 years old	36
By region	
Chinese mainland	398
Overseas	118

During the Reporting Period, our turnover rate of employees was 23.0%.

Employees turnover rate structure indicator	Turnover rate in 2023 (%)
Total	23.0%
By gender	
Male	22.7%
Female	23.2%
By age	
Under 30 years old	17.1%
30-50 years old	24.5%
Over 50 years old	33.3%
By region	
Chinese mainland	21.3%
Overseas	28.0%

*Note:* Employees turnover rate = Turnover number during the Reporting Period/(Turnover number during the Reporting Period + Number of employees at the end of the Reporting Period) \*100%.

#### 4.1.2 Supporting Career Development

We attach importance to talent training and employee empowerment. We encourage employees to continuously improve their professional skills and provide employees with a broad platform for continuous learning and career growth. We also promote employees to achieve self-improvement, and at the same time, work together with the company towards a sustainable future.

#### Employee Training

We design and develop a series of courses and development projects to meet the business development needs of the company. We follow the *Training Management Policy* and other policies and system documents to meet the training requirements of different job roles. We are gradually exploring a set of efficient and applicable training systems to provide employees with offline customized development training and online corresponding supporting course resources, improving the professional skills, management abilities and organizational development ability of employees. During the Reporting Period, according to the development needs of employees, we continued to tap internal resources, invite internal lecturers to conduct courses for employees, and enrich the types of training courses. We added internal lecturers training and new manager training on the basis of the comprehensive upgrade of the new staff training plan. In addition, we provided special oral training for employees to help them adapt to an English working environment more quickly.

#### Case: Internal lecturers training

During the Reporting Period, we conducted professional teaching skills training for our internal lecturers, aiming to further optimize the building of our internal lecturer team, improve the quality of teaching, and enhance the learning experience of students. During the training process, the internal lecturer team has learned core knowledge and skills such as how to effectively guide students to achieve learning goals and how to meet the personalized learning needs of different students. This training has provided a strong foundation for the instructor team to enhance the course, innovate the teaching methods and create an interactive classroom. As of the end of the Reporting Period, the size of the Group's internal lecturer team has expanded to more than 20 members.

#### **Case: New manager training**

In order to continuously improve the management ability of the company's management layer and build an efficient team, the Group launched a special training on "Leadership Improvement" in 2023. The training analysed the challenges faced by management during the role transformation process. It identified the key responsibilities of managers, optimized management concepts, and improved their methods and skills in work management, personnel management and leadership. And finally shape a management team that can create outstanding performance for the company. The training was held in two sessions, with approximately 45 managers participating in total. We also held salon activities after the training to promote the application discussion in practical work.



New manager training Program

#### Case: Dispatched employees oral English training

During the Reporting Period, we implemented a special language training program to assist our dispatched employees in overcoming the language barriers, adapting to the US working environment, and effectively supporting the business operations of CARsgen USA. The training adopts the form of online human-computer dialogue combined with offline communication with real speakers. The training content is universal and practical, covering various daily life and work scenarios such as shopping, medical treatment, dining, transportation, and business. Through practical operations and simulation exercises, employees can effectively deepen their understanding and cognition of American culture and social customs. By the end of the Reporting Period, we have successfully held 5 training activities, and nearly 40 employees who will be working in the United States actively participated. This not only improves their English language skills but also gradually enhances their confidence in working in the United States.

During the Reporting Period, the Group's trainings involved 76.6% of the Group's employees participated in training, with an average annual training time of 35.2 hours per employees.

Indicator	Proportion of employees receiving training (%)	Training hours per employee (hours)
By gender		
Male	66.7	28.5
Female	82.9	39.5
By employment type		
Senior management	40.0	2.8
Middle management	63.4	43.3
Junior employees	85.7	31.3

#### Note:

- Proportion of employees receiving training = Employees receiving training/Total number of employees \*100
  Proportion of employees by category = Employees receiving training under this category/Total number of
  employees under this category \*100
- Average training hours per employee = Total number of training hours/Total number of employees Average training hours per employee by category = Total number of training hours of employees under a particular category/Total number of employees under a particular category

#### Promotion and Performance Management

We fully acknowledged the significant contribution of each employee in their respective roles, and lay a clear and unimpeded career development path for employees through comprehensive performance management and promotion and transfer mechanism.

We adhere to the *Performance Management Policy* and other internal management systems, implementing scientific and efficient performance management strategies, and setting reasonable organizational goals, departmental goals and personal goals. We also advocate performance evaluation and communication from time to time throughout the year to provide employees with fair evaluation, and clear and effective performance feedback. We have formulated the *Employee Hierarchy Development System and Plan* to clarify the promotion process, evaluation criteria and key behavior indicators. This will help us create a fair, open and just promotion system for employees, provide them with opportunities for job transfer, and offer a dual-channel development platform for technology management, as well as fully respect and support employees in choosing their own career development path.

In order to motivate employees to give full play to their potential and promote the flow of internal talents, we have formulated the *Employee Internal Recruitment Management Policy* to encourage employees to apply for positions internally. We combine the development intention and business needs of backbone employees, arrange employees for job-transition, job-rotation and multiple-job holding to achieve horizontal career development in different positions. During the Reporting Period, we helped more than 30 employees transfer internally, providing them with broader opportunities and helping the company accelerate new business development. In addition, combined with the company's business development, we continue to dispatch employees from China to CARsgen USA to work, study and exchange through our global talent allocation program. We also provide various kinds of training to employees to help employees become industry-leading all-round talents.

#### Employee Incentives

We attach great importance to attracting and retaining outstanding talents. During the Reporting Period, we revised the *Employee Honor and Reward Policy* to clarify the definition, criteria, nomination and review procedures of various honor awards. We reward and commend outstanding employees and teams who demonstrate a high degree of professionalism and core values of the group, as well as contributing to the Company's strategic development goals through various honorary awards such as the CEO Award, Outstanding Contribution Award, Innovation Award, Dedication Award, Long-term Service Award, etc. In 2023, following the principle of "more work, more win", we set up the Clinical Project Enrollment Award to encourage the team to achieve and exceed the enrollment goal, ensuring that the clinical research project is completed on time and on quality. At the same time, we added dispatch incentives to encourage overseas dispatched employees to undertake dispatch tasks, fully mobilizing their work enthusiasm and promoting the common development of employees and the company.

In addition, we implement an employee equity incentive plan, which grants equity to eligible employees every year, recognizing and rewarding employees for their hard work and outstanding achievements.

#### 4.1.3 Protecting Safety and Health

Our basic commitment is to protect the health and safety of our employees and to take responsibility for environmental protection. We strive to provide a safe working environment for all employees and those who come to our factory. We strictly abide by the Labor Law of the People's Republic of China, the Work Safety Law of the People's Republic of China, the Law of the People's Republic of China on the Prevention and Control of Occupational Diseases and other relevant laws and regulations. Based on the scientific and complete EHS (Environment, health and safety) management system, we comprehensively implement the company's environmental and health and safety management. Our EHS management system covers leadership and commitment, policies, management structure and responsibilities, hazard identification, risk evaluation and control, operational control, inspection, corrective and preventive actions, incident investigation, emergency response, review and other elements.

Safety first, focusing on prevention, comprehensive control; Scientific approach, sufficient risk control, prevent incident; People oriented, caring for health and safety; Protect the environment, Conserve natural resources, sustainable development.

#### **EHS policy of CARsgen Therapeutics**

The EHS committee is the highest management organization for our EHS work with the company president and COO being the chairmen of the committee, department heads of relevant departments being the committee members, and the EHS specialist as the coordinator. The responsibilities of relevant personnel at all levels and the requirements of supervision and inspection are clearly defined, and compliance with EHS-related regulations is ensured. At the same time, we require all departments to assign safety officers to assist and participate in the Company's safety management work, further implement management practices, and ensure the health and safety of employees. In addition, we continue to pay attention to the collection, update, management and implementation of EHS related laws and regulations, and continue to optimize the EHS management Manual, Occupational Health and Safety Management Requirements and other internal EHS management system documents to promote the efficient operation of the EHS management system. During the Reporting Period, CARsgen USA developed a number of internal procedure documents related to EHS management, and steadily promoted the construction of EHS management system for U.S. factories and business operations.

We follow the principle of "preventing danger", carry out comprehensive risk identification and evaluation at each process of R&D and production, implement a dual prevention mechanism for risk control, and thus to ensure the health and safety of personnel in business activities and protection towards them. In the past three years, there were no work-related fatalities in the Group. During the Reporting Period, the number of lost days due to work injury was zero.

#### Safety Management

We actively implement the main responsibility of enterprise safety production, constantly promote the standardization of safety production, identify, classify and evaluate potential safety risks in the daily operation process. We implement safety management measures into the front-line work, and further improve our safety management level. By the end of the Reporting Period, we have obtained the Work Safety Standardization Level 3 Certificate.

We follow the EHS Management Requirements for Contractors and Suppliers, the Biosecurity Laboratory Work Conduct Guidelines, the Laboratory Personnel Management Policy, the Production Safety Responsibility Policy and other internal rules and regulations in order to gradually improve the biosafety, laboratory safety, workshop production safety, chemical management, construction safety management. During the Reporting Period, according to the new regulations of the State Administration for Market Supervision and Administration, Provisions on the Implementation of the Supervision and Administration of Enterprise Main Responsibility by Special Equipment Users, we formulated new internal regulations such as Special Equipment Hidden Danger Investigation and Management Manual, Daily control, weekly investigation, and monthly scheduling management System of security risks of Special Equipment, Daily Inspection List of Special Equipment, and Responsibilities of Special Equipment-Related Personnel; CARsgen USA has formulated the Cryogenic Safety, Compressed Gas Safety, Electrical/Arc Flash Safety Bloodborne Pathogens and other regulations to guide employees to operate dangerous production equipment safely so as to reduce the risk of accidents and injuries.

During the production process, we carry out EHS inspections and supervision, make hazard source and risk analysis regarding every process of the Company's production and operation activities, and timely rectify the potential safety hazards. During the Reporting Period, we actively responded to the National Major Accident Hidden Dangers Special Investigation and Rectification 2023 Special Action of the Safety Committee of The State Council, investigated dangerous operations such as hot fire and electric welding, and strengthened the management and supervision of high-risk operations. We conduct monthly safety inspections and EHS performance evaluations for high-risk departments, optimize personnel qualification management and strengthen personnel training and assessment. We optimize the Company's safety production process and clarify inspection requirements through practical daily inspection lists and item lists to improve efficiency and ensure strict implementation of safety inspections. In addition, we have fully updated the signage system and posted emergency response signs on the site and fire facilities, enhancing the convenience and accuracy of emergency operations.

In response to sudden incidents and emergencies, we have formulated relevant documents such as the Emergency Response Plan and the Comprehensive Emergency Plan for Production Safety Incidents, set up different special emergency plans and on-site treatment plans, as well as established an emergency organization and defined relevant responsibilities, standardized emergency response work process, to prevent and deal with situations efficiently and timely. In regard to fire safety management, we strictly follow the Fire Protection Law of the People's Republic of China. We have entrusted the professional third parties to carry out routine maintenance of fire safety systems in the production plants, and regular inspections and testing on fire safety facilities. During the Reporting Period, we equipped the emergency smoke outlet valves on each floor with manual execution device panels, installed new fire doors in the office area and upgraded the existing fire doors to comprehensively improve the fire performance of the Company's buildings. The site buildings of CARsgen USA are also equipped with a sound fire and firefighting system, which can issue an alarm and start the fire extinguishing program in the first time of the fire starts. CARsgen USA also set up an emergency notification system to ensure that important information can be quickly communicated in an emergency. At the same time, we hire a professional third-party agency responsible for regular inspections and maintenance work to ensure the normal operation of the system.

We implement a work access system and a work ticket system for high-risk operations, requiring foreign workers to sign relevant safety management agreements to ensure the safety of external workers in an orderly manner.

#### Health Management

We attach great importance to occupational health management. The *Occupational Health Management Procedures* formulated by us in accordance with relevant laws and regulations clarifies the specific responsibilities of relevant departments, and standardizes the occupational health management process to control and eliminate occupational disease risks arising from the workplace and production, eradicate and reduce the occurrence of occupational diseases, and protect the health of employees. During the Reporting Period, CARsgen USA formulated occupational health security systems such as *Access to Medical Records* and Ergonomics to standardize and record and manage employees' occupational history, occupational exposure and health examination results, so as to prevent employees from chronic occupational diseases such as cervical spondylosis and lumbar spondylosis caused by long working hours.

We strictly implement the health care policy, and have formulated the *Occupational Health Examination and Management Regulations*, providing prejob, on-the-job and off-the-job health examinations for all personnel exposed to occupational health hazards. During the Reporting Period, there were no abnormalities found in the results of the physical examinations.

We conduct regularly monitoring of the occupational health hazard factors in the workplace, and timely rectify ungualified issues if identified. During the Reporting Period, the testing results were all qualified. We continue to strengthen the establishment and management of occupational disease hazard warning signs, safety risk instructions and necessary protective measures in various workplaces, and provide and distribute various safety, hygiene and other personal protective equipment (PPE) for employees or their respective positions according to the position and work exposure to risk factors, including head protective supplies, eye and face protective supplies, hearing protective supplies, respiratory protective supplies, torso protective supplies, hand protective supplies, foot protective supplies, anti-fall supplies, cleaning and skin care supplies to comprehensively protect employees' work safety and occupational health. We also, on the basis of the Personal Protective Supplies Provision, clarify the responsibilities of relevant departments to effectively ensure the provision and management of personal protective supplies within the Company in terms of PPE provision, procurement, storage, distribution, wearing requirements and usage methods, so as to reduce the Company's production safety and occupational health risks.

In addition, CARsgen USA also adopt a series of strict occupational safety and security measures. We conduct a comprehensive risk analysis of laboratories, manufacturing plants and contractor operations. We develop a prevention plan based on the risk assessment results, taking targeted actions according to the risk priority, covering all possible physical, electrical, chemical and biological hazards. We provide employees with PPE according to the work hazard analysis to ensure occupational health and safety of employees.

#### EHS Training and Exercise

Raising employee safety awareness is essential to reduce the risk of health and safety incidents. We have formulated the *EHS Training Management Procedure* and an annual EHS internal training plan, defining the Company's internal and external EHS training content, and standardizing work processes about training records and assessments to make sure all employees understand relevant laws, regulations and requirements, working related risks, risk control measures to be implemented, and emergency measures related to EHS. We have placed safety alert and notification signs at the production sites, laboratory and office areas, and annually carry out several emergency drills, and fire training and drills.

In order to further strengthen employees' awareness of production safety, we organized knowledge competitions on chemical safety, fire protection, special equipment operation, etc., and carried out knowledge promotion on fire protection and gas safety. CARsgen USA RTP Manufacturing Facility also provides a variety of training for employees, including EHS induction training for new employees, laboratory safety training, DOT hazardous transportation training, annual fire evacuation drills and tornado evacuation drills. During the Reporting Period, we conducted various forms of online and offline EHS training for employees, suppliers and visitors, covering a total of 2,100 people\*.



CARsgen USA RTP Manufacturing Facility fire training

#### 4.1.4 Comprehensive Communication and Care

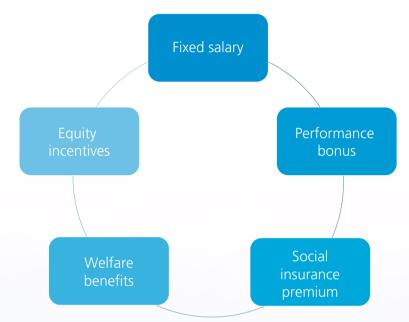
We respect and cherish every employee, pay attention to the needs of employees, continue to improve the welfare of employees and improve the working and living conditions of employees, with aim to enhance the cohesion of employees, enhance the sense of belonging of employees, and create a happy and warm workplace environment.

#### \* Working Hours and Holidays

We have formulated the *Overtime and Leave Management Policy*, which standardizes the management of working hours and ensures employees reasonably adequate rest time to achieve a better balance between work and life. We prohibit forced labor and encourage employees to complete their work within normal working hours. Overtime work in special cases is required to obtain prior approval from the department manager and to be reviewed by the Human Resources Department. Our employees are entitled to all kinds of leaves, including national statutory holidays, annual leave, sick leave, maternity leave, personal leave, marriage leave, paternity leave, parental leave, bereavement leave, etc. On this basis, we give full consideration to the needs of overseas employees and set up additional welfare leave and family leave for them.

#### Remuneration and Benefits

We have developed a fair, reasonable and market-competitive compensation and benefits system and established the *Remuneration Control Process* to illustrate emolument structure and consideration criteria, and to standardize the payroll management workflow.



We pay social insurance and housing provident fund in full and timely in accordance with the relevant regulations of the national and local governments. Meanwhile, we provide employees with diversified welfare allowances.

Mandated benefits	Medical insurance, maternity insurance, pension insurance, unemployment insurance, employment injury insurance and housing funds
Other benefits	Overtime meal subsidy, mission allowance, employee dormitory benefits, marriage and maternity allowance, employee recommendation bonus, blood donation subsidy, transportation subsidy, overtime pay, home leave, additional welfare leave, etc.

Composition of welfare benefits

Amongst all the benefits, CARsgen USA complying with local laws and regulations and offers 13 medical plan options for our employees to select from, as well as disability insurance (short and long term), life and accidental death and dismemberment insurance and disability, unemployment insurance, worker's compensation insurance and social security retirement plan. We also subsidize our employee contribution premiums based on position level. In addition, CARsgen USA has set up generous 401-K contributory retirement plan, overtime pay, shift differential premiums, incentive compensation for exempt employees and additional welfare leave to satisfy the daily and extra demands of all employees. During the Reporting Period, according to the needs of employees, we continued to optimize the compensation and benefits of dispatched employees, and expanded the range of post allowances from director to president, providing multi-directional protection for employees' rights and interests.

#### \* Employee Communication and Activities

We provide a wide variety of communication platforms for our employees, advocating open and sincere two-way communication. Through regular employee surveys, we actively collect valuable opinions from employees, gaining an indepth understanding of the operating status of the organization and the level of employee engagement, so as to respond quickly and address the needs and concerns of employees to create a happy working environment. During the Reporting Period, we conducted research, collected opinions from Chinese and American employees, listened to their voices, and provided an effective basis for optimizing management and improving employee satisfaction.



We advocate the balance between work and life and through the trade union regularly organize tourism groups, birthday parties, women's care activities, fun development games, public welfare lectures and other activities, to enrich the leisure life of employees while promoting the physical and mental health of employees. In addition, CARsgen USA also organized various activities for overseas employees and dispatched employees to promote mutual integration between Chinese and American employees and enhance team cohesion.



Employees and their families participate in union building activities



Chinese New Year celebration for overseas Chinese and American employees

#### 4.2 Building a Better Society Together

As a biopharmaceutical company committed to bringing innovative and effective cell therapies to cancer patients around the world and making cancer curable, while making cell therapies more accessible and affordable, we also pay extensive attention to social needs, continue to care for people's well-being, and call on employees to jointly use their strengths to contribute more to social development and build harmony with society.

During the Reporting Period, we actively responded to the initiative of Shanghai Municipal People's Government on unpaid blood donation activities. We organized 14 employees to participate in unpaid blood donation activities, and they received a total of RMB14,000 in sympathy money from the the Company's labor union. We also obtained a certificate of honor for unpaid blood donation issued by the Shanghai Blood Management Office. We also continue to support medical scientific research. Under the Company's initiative and call, a total of 15 employees participated in apheresis activities and donated their immune cells to make contributions to cancer research and treatment. After the event, the company's trade union issued a total of RMB29,000 to employees who actively participated in public welfare activities to show recognition and encouragement.

In addition, in order to support rural revitalization, in April 2023, we donated a total of more than RMB30,000 worth of winter supplies such as sleeping bags, blankets, and water mats to the Xiadawu Township School in Maqin County, Guoluo Prefecture, Qinghai Province, to protect the healthy growth of rural children and convey social warmth.



Winter supplies donation activity

#### 5. PRACTICING LOW-CARBON OPERATION TO PROTECT THE ENVIRONMENT

The Group adheres to green development, practices low-carbon operations and actively takes environmental responsibility. We continue to strengthen our environmental management system, improve the efficiency of energy and resource utilization, minimize the environmental impact of our operations, and continue to respond to climate change, with a view to jointly protecting the planet on which we live through responsible and greener R&D and production operations.

#### 5.1 Consolidating Environmental Management

We strictly abide by the Environmental Protection Law of the People's Republic of China and other environmental laws and regulations, and set up an EHS management team to coordinate the group's environmental governance work. According to the EHS Policy, the EHS Management Manual, the Requirements for EHS Management and other system documents, we have defined the responsibilities of departments and personnel and the environmental management process, and carried out environmental management work in a systematic and standardized manner. We also carry out environmental risk identification and assessment for the company's various operating sites, prepare environmental impact assessment reports and environmental emergency plans, establish targeted management procedures, formulate and implement countermeasures, and configure relevant environmental governance facilities to effectively control environmental risks. During the Reporting Period, there were no environmental protection violations.

In accordance with the requirements of the Law of the People's Republic of China on the Prevention and Control of Water Pollution, the Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution, the Law of the People's Republic of China on the Prevention and Control of Environmental Pollution by Solid Waste, the Law of the People's Republic of China on Soil Pollution Prevention and Control, and the Regulations on the Management of Medical Waste and other relevant laws and regulations, we continue to carry out discharge testing of waste water, waste gas and other environmental pollution factors. And through improving management technology, upgrading facilities and equipment and other measures, on the basis of ensuring compliance with emission standards, we minimize the negative impact of production and business activities on the environment. During the Reporting Period, we have obtained renewed pollution permits. In addition, we strictly comply with government regulatory requirements, timely report relevant emission index data on government platforms, continue to improve online monitoring, standardize and strengthen environmental data statistics.

For waste gas emissions, we use activated carbon adsorption devices to treat the waste gas containing volatile organic solvents generated in the production and research and development process. We also use high efficiency filters to filter the exhaust gas that may contain microorganisms.

We use secondary biochemical wastewater treatment facilities to treat production wastewater and ensure that it meets the standards for discharge. During the Reporting Period, we conducted regular maintenance of the wastewater treatment station for every three years, and upgraded the online monitoring equipment for wastewater drainage, effectively improving the efficiency of wastewater treatment and the sensitivity of monitoring. For solid waste, the Company regulates the classification, collection, temporary storage, transportation and disposal processes of various types of waste in accordance with the internal system documents such as the *Medical Waste Management Procedures, Hazardous Waste Management Regulations*, and the Hazardous Waste Removal of CARsgen USA. In order to ensure timely and scientific treatment of hazardous waste, we strictly classify and manage hazardous waste and medical waste, carry out harmless treatment such as high-temperature and high-pressure steam sterilization for waste with biohazard risk, and timely entrust a qualified third party to carry out final disposal to avoid potential environmental pollution incidents.

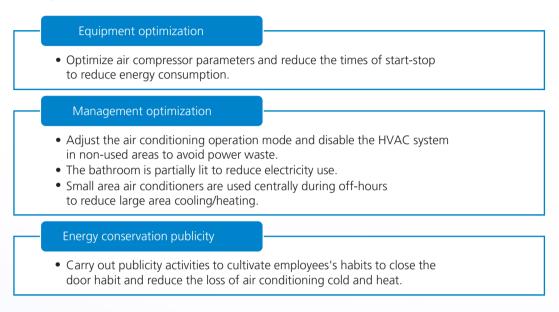
#### 5.2 Optimizing Resource Utilization

#### 5.2.1 Energy Conservation and Carbon Reduction

We follow the *Energy Conservation Law of the People's Republic of China* and other relevant laws and regulations to standardize the use of outsourced electricity, industrial steam, gasoline and diesel (mainly for transportation vehicles) and promote their efficient use. The Company has set up an Energy Conservation team, led by the Chief Operating Officer (COO), which includes relevant professionals from departments include EHS, Engineering Equipment, and Administration Management. The main responsibilities are as follows:

Rules and regulations construction	• Responsible for developing and improving the company's energy conservation and emission reduction rules and regulations, to ensure that all activities are in compliance with national and local environmental regulations and policies
Data monitoring and analysis	<ul> <li>Monitoring, collection and statistical analysis of daily energy consumption data</li> <li>Explore potential energy-saving opportunities through data analysis, and formulate corresponding plans and measures</li> </ul>
Program implementation and tracking	• Implement the approved energy conservation and emission reduction programs and plans one by one, and track and evaluate the effect of the implemented programs
Publicity and training	• Organize and carry out energy-saving and emission- reduction publicity activities and employee trainings to enhance the environmental awareness and energy-saving skills of all employees

During the Reporting Period, under the leadership of the Energy Conservation team, we continued to practice green office practices, carried out several energy conservation and environmental protection publicity activities, and effectively reduced energy consumption through equipment and management model optimization, contributing to the green development.



In addition, the design and construction of the CARsgen USA RTP Manufacturing Facility have fully considered the principles of energy conservation and consumption, and the process equipment is equipped with modern components to achieve high efficiency, low resource consumption and low emissions. The manufacturing process at the RTP Manufacturing Facility, which follows the strict requirements of the U.S. Food and Drug Administration and other international regulatory agencies, uses hot and cold water to regulate the internal environment of industrial air handling systems rather than relying on traditional HVAC refrigerants. In addition, the RTP Manufacturing Facility is equipped with three small rooftop HVAC units using R-410A environmentally friendly refrigerant to meet the air conditioning needs of unclean areas.

During the Reporting Period, we saved approximately 150,000 KWH of electricity throughout the year by adopting various energy-saving measures.

#### 5.2.2 Water Resource Management

We strictly abide by the *Water Law of the People's Republic of China* to standardize the water use management process. All water used by the Group comes from municipal water, and no water violations occurred during the Reporting Period. We actively explore water-saving technologies to help improve water efficiency in production and operations, and promote water-saving awareness and avoid water waste through initiatives such as posting water-saving slogans. In 2023, we retrofitted the hot water closed circulation system with a sealed seal and increased preventive maintenance of the chilled water circulation system, effectively reducing water consumption and saving about 1,100 tons of water a year.

#### 5.3 Response to Climate Change

Climate change has become a prominent global challenge that continues to affect both human health and sustainable business operations. We actively respond to China "3060" dual carbon goals, continue to strengthen the degree of attention to climate-related issues, strictly follow the framework of the Working Group on Climate-related Financial Disclosure (TCFD) recommendations, and proactively identify and comb through climate change-related risks and opportunities and potential impacts on us, in order to provide a basis for strengthening energy and emissions management and laying out management issues related to climate change. The specific identification results are as follows:

Climate-relat for the Grou	ed risks and oppor p	tunities identified	Potential impact
Risks	Transition risks	Policy and Legal	<ul> <li>Increase environmental compliance costs to meet regulatory requirements</li> </ul>
		Technology	<ul> <li>Increase investment in the exploration and research of new technologies and retrofit existing development and production facilities to improve operating costs in order to transition to low-carbon operations</li> </ul>
		Market	<ul> <li>Increased input costs to keep up with customer demand trends for environmentally friendly products and services</li> </ul>
		Reputation	<ul> <li>Responding to stakeholders' expectations for proactive action and greater transparency in information disclosure on climate action to avoid the potential reputational impact of adverse climate action resulting in increased operating costs</li> </ul>
	Entity risk	Acute	<ul> <li>Increased severity and frequency of extreme weather events that disrupt production and operating plans, resulting in reduced capacity and reduced operating income</li> </ul>
		Chronic	<ul> <li>Disruption of supply chain transport routes due to extreme weather events such as typhoons or heavy rains, resulting in reduced capacity and reduced operating income</li> <li>Increased operating costs due to increased temperatures</li> </ul>
			<ul> <li>due to long-term shifts in climate patterns, resulting in additional energy consumption to ensure optimal temperature at production sites</li> <li>To ensure the health of employees in a high-temperature environment, additional subsidies and insurance costs are</li> </ul>
Opportunities	Products and Servi	ices	<ul> <li>added</li> <li>Increased demand for energy efficiency and low-carbon products and services can lead to revenue growth</li> <li>As climate change may lead to an increase in the incidence of certain diseases, providing solutions through research and innovation can lead to increased revenue</li> </ul>
	Resource Efficiency	у	<ul> <li>Improve the efficiency of resource use, including energy and water, and reduce operating costs</li> </ul>
	Resilience		<ul> <li>Reduce operating costs</li> <li>Reduce operating costs by enhancing the stability and reliability of business operations and supply chains through continued resilience to climate change risks</li> </ul>

We set up a series of internal systems, including the *Emergency Response Plan, Management Requirements for Response to Climate Change, the Requirements for Business Continuity Management, and Business Continuity Plan to clarify the Company's emergency organizational structure, as well as the responsibilities of related departments and personnel, and provide standardized procedures for accident reporting, response and disposal, so as to ensure the health and safety of employees and the security of the Company's properties.* 

During the Reporting Period, our production plant located in Shanghai Jinshan Park signed the *Environmental Emergency Rescue and Mutual Assistance Agreement* with other companies in the park to jointly respond to emergencies. In addition, we organize and carry out extreme weather emergency drills, improve the company and employees' response capacity in emergency situations, and increase the reserve of flood and flood prevention materials to ensure timely and effective disaster relief at critical moments.

#### 5.4 Environmental KPIs

During the Reporting Period, the Group's products were still in the stage of clinical research and have not been put into production on a large scale. Therefore, the environmental KPIs are expected to fluctuate in the coming years. The Group's environmental KPIs for 2023 are as follows:

Pollutant emissions	Unit	2023	2022	2021
Waste water emissions				
Total waste water emissions	Tons	17,642.0	12,897.8	54,233.3
Including: COD	Tons	3.80	2.57	1.02
Ammonia nitrogen	Tons	0.315	0.20	0.06
Waste gas emissions				
Total waste gas emissions	Tons	0.0472	2.24	/
Including: Hydrogen chloride	Tons	0.0258	1.84	0.25
Sulfuric acid mist	Tons	0.0035	0.09	0.02
Ammonia	Tons	0.0179	0.32	/
Waste emissions	Unit	2023	2022	2021
Total hazardous waste	Tons	35.2	24.9	24.2
Hazardous waste intensity	Tons/product batch	0.16	0.10	0.08
Total non-hazardous waste	Tons	117.13	12.70	10.14
Non-hazardous waste intensity	Tons/product batch	0.52	0.05	0.04

Energy consumption	Unit	2023	2022	2021
Direct energy consumption				
Including: Diesel	MWh	36.34	55.60	392.67
Gasoline	MWh	187.77	169.05	68.75
Natural gas	MWh	2,489.50	34,597.65	/
Indirect energy consumption				
Including: Purchased electricity	MWh	14,219.67	13,444.03	8,325.18
Purchased steam	MWh	10,709.25	9,278.48	8,615.28
Total energy consumption	MWh	27,642.52	26,406.92	17,009.21
Energy consumption intensity	MWh/product batch	122.31	110.49	59.68
Greenhouse gas emissions	Unit	2023	2022	2021
Total greenhouse gas emissions	tCO <sub>2</sub> e	15,327.77	17,179.52	9,385.52
Including: Direct greenhouse gas	tCO <sub>2</sub> e	3,639.12	5,031.79	117.10
emissions (Scope 1)				
Indirect greenhouse gas emissions (Scope 2)	tCO <sub>2</sub> e	11,688.65	12,147.73	9,268.41
Greenhouse gas emission intensity	tCO <sub>2</sub> e/product batch	67.82	71.88	32.92
	2			
Resource consumption	Unit	2023	2022	2021
Water consumption	_		76 400	62 227
Total water consumption	Tons	90,040	76,102	63,327
Water consumption intensity	Tons/product batch	398.41	318.41	222.20
Packaging material consumption				
Total packaging material	ka	12.66	13.38	15.84
consumption	kg	12.00	15.58	15.84
Packaging material consumption intensity	kg/product batch	0.056	0.056	0.056
intensity	ky/product batch	0.050	0.030	0.050

#### Note:

1. Environmental KPIs for the current year cover office, laboratories and factories in Shanghai, and overseas factories, since 2023, Non-hazardous waste from CARsgen USA RTP Manufacturing Facility has been included in the statistics.

2. In 2023, the power grid emission factor we used refers to the *Notice on the Management of Corporate GHG Emissions Reporting in Power Generation Industry from 2023 to 2025* issued by the Ministry of Ecology and Environment.

#### **APPENDIX I: HKEX ESG GUIDE INDEX**

Subject Areas, Aspects, General Disclosures and KPIs

Aspect		Disclosure Requirement	Sections in ESG Report
A. Environmental			
Aspect A1: Emissions	(b) comp on the water Note: Air en laws and re oxide, hydro		
	KPI A1.1	The types of emissions and respective emissions data.	
	KPI A1.2	Direct (Scope 1) and energy indirect (Scope 2) greenhouse gas emissions (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	PRACTICING LOW-CARBON OPERATION TO PROTECT THE
	KPI A1.3	Total hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	ENVIRONMENT
	KPI A1.4	Total non-hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	
	KPI A1.5	Description of emissions target(s) set and steps taken to achieve them.	
	KPI A1.6	Description of how hazardous and non-hazardous wastes are handled, and a description of reduction target(s) set and steps taken to achieve them.	

Aspect		Disclosure Requirement	Sections in ESG Report
A. Environmental			
Aspect A2: Use of Resources	materials.	e efficient use of resources, including energy, water and other raw ces may be used in production, in storage, transportation, in buildings,	
	KPI A2.1	Direct and/or indirect energy consumption by type (e.g. electricity, gas or oil) in total (kWh in '000s) and intensity (e.g. per unit of production volume, per facility).	
	KPI A2.2	Water consumption in total and intensity (e.g. per unit of production volume, per facility).	PRACTICING LOW-CARBON OPERATION TO PROTECT THE
	KPI A2.3	Description of energy use efficiency target(s) set and steps taken to achieve them.	ENVIRONMENT
	KPI A2.4	Description of whether there is any issue in sourcing water that is fit for purpose, water efficiency target(s) set and steps taken to achieve them.	
	KPI A2.5	Total packaging material used for finished products (in tonnes) and, if applicable, with reference to per unit produced.	
Aspect A3 : The Environment and Natural Resources	General Discl Policies on m natural resou	inimising the issuer's significant impacts on the environment and	
	KPI A3.1	Description of the significant impacts of activities on the environment and natural resources and the actions taken to manage them.	LOW-CARBON
Aspect A4 : Climate Change		osure entification and mitigation of significant climate-related issues which d, and those which may impact, the issuer.	OPERATION TO PROTECT THE ENVIRONMENT
	KPI A4.1	Description of the significant climate-related issues which have impacted, and those which may impact, the issuer, and the actions taken to manage them.	

Aspect		Disclosure Requirement	Sections in ESG Report
B. Social			
Aspect B1: Employment	(b) complia on the promot		ADHERING TO THE VALUE OF PEOPLE- ORIENTATION, SHARING SOCIAL
	KPI B1.2	parttime), age group and geographical region. Employee turnover rate by gender, age group and geographical region.	RESPONSIBILITY TOGETHER
Aspect B2: Health and Safety		bsure	
	(b) complia on the	ince with relevant laws and regulations that have a significant impact issuer relating to providing a safe working environment and protecting ees from occupational hazards.	ADHERING TO THE VALUE OF PEOPLE-
	KPI B2.1	Number and rate of work-related fatalities occurred in each of the past three years including the reporting year.	ORIENTATION, SHARING SOCIAL
	KPI B2.2	Lost days due to work injury.	RESPONSIBILITY TOGETHER
	KPI B2.3	Description of occupational health and safety measures adopted, and how they are implemented and monitored.	
Aspect B3:	General Disclo	osure	
Development and Training	work. Descrip	proving employees' knowledge and skills for discharging duties at tion of training activities. g refers to vocational training. It may include internal and external	ADHERING TO THE VALUE
	-	by the employer The percentage of employees trained by gender and employee category (e.g. senior management, middle management).	OF PEOPLE- ORIENTATION, SHARING
	KPI B3.2	The average training hours completed per employee by gender and employee category.	SOCIAL RESPONSIBILITY TOGETHER

Aspect		Disclosure Requirement	Sections in ESG Report
B. Social			
Aspect B4: Labour Standards	(b) compli		ADHERING TO THE VALUE OF PEOPLE- ORIENTATION, SHARING SOCIAL RESPONSIBILITY
	KPI B4.2	Description of steps taken to eliminate such practices when discovered.	TOGETHER
Aspect B5: Supply Chain Management	General Discl Policies on m	osure anaging environmental and social risks of the supply chain.	
5	KPI B5.1	Number of suppliers by geographical region.	
	KPI B5.2	Description of practices relating to engaging suppliers, number of suppliers where the practices are being implemented, and how they are implemented and monitored.	UPHOLDING ETHICS TO PROPELL
	KPI B5.3	Description of practices used to identify environmental and social risks along the supply chain, and how they are implemented and monitored.	LONG-TERM DEVELOPMENT
	KPI B5.4	Description of practices used to promote environmentally preferable products and services when selecting suppliers, and how they are implemented and monitored.	
Aspect B6: Product Responsibility	(b) compli on the		UPHOLDING ETHICS TO
	KPI B6.1	Percentage of total products sold or shipped subject to recalls for safety and health reasons.	PROPELL LONG-TERM DEVELOPMENT
	KPI B6.2	Number of products and service related complaints received and how they are dealt with.	PROMOTING HEALTH AND
	KPI B6.3	Description of practices relating to observing and protecting intellectual property rights.	WELL-BEING THROUGH INNOVATION
	KPI B6.4	Description of quality assurance process and recall procedures.	
	KPI B6.5	Description of consumer data protection and privacy policies, and how they are implemented and monitored.	

Aspect		Disclosure Requirement	Sections in ESG Report	
B. Social				
Aspect B7: Anti-corruption	(b) compl			
	KPI B7.1	Number of concluded legal cases regarding corrupt practices brought against the issuer or its employees during the reporting period and the outcomes of the cases.	PROPELL LONG-TERM	
	KPI B7.2	Description of preventive measures and whistle-blowing procedures, and how they are implemented and monitored.	DEVELOPMENT	
	KPI B7.3	Description of anti-corruption training provided to directors and staff.		
Aspect B8:	<b>B8:</b> General Disclosure			
Community Investment	Policies on community engagement to understand the needs of the communities where the issuer operates and to ensure its activities take into consideration the communities' interests.		ADHERING TO THE VALUE OF PEOPLE- ORIENTATION,	
	KPI B8.1	Focus areas of contribution (e.g. education, environmental concerns, labour needs, health, culture, sport).	-	
	KPI B8.2	Resources contributed (e.g. money or time) to the focus area.	TOGETHER	

## **Independent Auditor's Report**



Ernst & Young 27/F, One Taikoo Place 979 King's Road Quarry Bay, Hong Kong 安永會計師事務所 香港鰂魚涌英皇道 979號 太古坊一座27樓 Tel 電話: +852 2846 9888 Fax 傳真: +852 2868 4432 ev.com

To the Shareholders of CARsgen Therapeutics Holdings Limited

(Incorporated in the Cayman Islands with limited liability)

#### **OPINION**

We have audited the consolidated financial statements of CARsgen Therapeutics Holdings Limited (the "Company") and its subsidiaries (the "Group") set out on pages 142 to 211, which comprise the consolidated statement of financial position as at December 31, 2023, and the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including material accounting policy information.

In our opinion, the consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at December 31, 2023, and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB") and have been properly prepared in compliance with the disclosure requirements of the Hong Kong Companies Ordinance.

#### **BASIS FOR OPINION**

We conducted our audit in accordance with International Standards on Auditing ("ISAs") issued by the International Auditing and Assurance Standards Board ("IAASB"). Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report. We are independent of the Group in accordance with the *Code of Ethics for Professional Accountants* (the "Code") issued by the Hong Kong Institute of Certified Public Accountants, and we have fulfilled our other ethical responsibilities in accordance with the Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Independent Auditor's Report

#### **KEY AUDIT MATTERS**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the consolidated financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the consolidated financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying consolidated financial statements.

#### Key audit matter

How our audit addressed the key audit matter

#### Risk of misstatement of research and development expenses

development ("R&D") expenses of RMB662 million walkthroughs over the key controls of the R&D expense as disclosed in the consolidated statement of profit process; or loss and other comprehensive income for the year ended December 31, 2023, in which a material portion We inquired management about the reasons for is service fees paid to contract research organisations periodical fluctuations in R&D expenses and assessed ("CROs") and clinical site management operators the reasonableness of those fluctuations; ("SMOs") (collectively referred to as "Outsourced Service Providers").

Providers are documented in agreements and are basis for R&D expenses with reference to the progress typically performed over an extended period. These of the R&D projects based on the inspection of expenses are charged to profit or loss based on the supporting documents; progress of the R&D projects. We identified the measurement of R&D expenses as a key audit matter We, on a sampling basis, reviewed the payments on due to its significant amount and the completeness and R&D expenses and other supporting documents in allocation of these costs to the appropriate reporting both the current and subsequent periods, in order to period based on the progress of the research and determine the completeness and cut-off of the R&D development projects involved judgement.

The accounting policy and the disclosure for significant accounting judgement related to R&D expenses have been disclosed in note 2.4 and note 3 to the consolidated financial statements.

The Group incurred significant research and We obtained an understanding of and performed

We, on a sampling basis, reviewed the key terms set out in R&D related agreements with Outsourced Service The R&D activities with these Outsourced Service Providers and evaluated the method for the calculation

expenses.

#### OTHER INFORMATION INCLUDED IN THE ANNUAL REPORT

The directors of the Company are responsible for the other information. The other information comprises the information included in the Annual Report, other than the consolidated financial statements and our auditor's report thereon.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### **RESPONSIBILITIES OF THE DIRECTORS FOR THE CONSOLIDATED FINANCIAL STATEMENTS**

The directors of the Company are responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRSs issued by the IASB and the disclosure requirements of the Hong Kong Companies Ordinance, and for such internal control as the directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the directors of the Company are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors of the Company either intend to liquidate the Group or to cease operations or have no realistic alternative but to do so.

The directors of the Company are assisted by the Audit Committee in discharging their responsibilities for overseeing the Group's financial reporting process.

## AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE CONSOLIDATED FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Our report is made solely to you, as a body, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

## Independent Auditor's Report

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

## Independent Auditor's Report

From the matters communicated with the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

The engagement partner on the audit resulting in this independent auditor's report is Wang Jun Ying.

Ernst & Young Certified Public Accountants

Hong Kong March 26, 2024

# **Consolidated Statement of Profit or Loss and Other Comprehensive Income** For the year ended December 31, 2023

	Notes	2023 <i>RMB'000</i>	2022 RMB'000
Administrative expenses		(131,689)	(135,795)
Research and development expenses		(661,659)	(680,301)
Other income	5	56,536	35,595
Other losses – net	6	(30,837)	(100,796)
Operating loss		(767,649)	(881,297)
Finance income		24,926	5,866
Finance costs		(4,664)	(15,521)
Finance income/(costs) – net	7	20,262	(9,655)
		()	
Loss before income tax		(747,387)	(890,952)
Income tax expense	11	(407)	(1,295)
Loss for the year and attributable to ordinary			
equity holders of the parent		(747,794)	(892,247)
Other comprehensive (loss)/income for the year:			
Items that may be reclassified to profit or loss			
Exchange differences on translation of subsidiaries		(33,065)	(63,456)
Items that will not be reclassified to profit or loss			
Exchange differences on translation of the Company		88,317	377,717
Other comprehensive income for the year, net of tax		55,252	314,261
		-	<u>.</u>
Total comprehensive loss for the year and attributable			
to ordinary equity holders of the parent	(692,542)	(577,986)	
Loss per share attributable to ordinary equity holders			
of the parent			
Basic and diluted loss per share (in RMB)	13	(1.34)	(1.62)

## **Consolidated Statement of Financial Position**

As at December 31, 2023

	Notes	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment	14	311,952	363,850
Right-of-use assets	15	49,438	77,533
Intangible assets	17	8,660	14,476
Other non-current assets and prepayments	18	14,076	6,321
Total non-current assets		384,126	462,180
CURRENT ASSETS			
Inventories	19	683	_
Other receivables	20	9,792	11,834
Other current assets and prepayments	20	12,861	20,769
Cash and bank balances	22	1,849,752	2,268,036
Total current assets		1,873,088	2,300,639
CURRENT LIABILITIES			
Accruals and other payables	23	158,008	141,114
Borrowings	24	2,522	4,850
Lease liabilities	16	12,230	17,134
Income tax payable		-	1,341
Deferred income	25	13,220	6,565
Contract liabilities	26	10,237	_
Total current liabilities		196,217	171,004
NET CURRENT ASSETS		1,676,871	2,129,635
TOTAL ASSETS LESS CURRENT LIABILITIES		2,060,997	2,591,815

## Consolidated Statement of Financial Position

As at December 31, 2023

	Notes	2023 <i>RMB'000</i>	2022 RMB'000
NON-CURRENT LIABILITIES			
Borrowings	24	-	2,523
Lease liabilities	16	70,468	94,938
Deferred income	25	10,387	21,180
Contract liabilities	26	178,442	-
Total non-current liabilities		259,297	118,641
Net assets		1,801,700	2,473,174
EQUITY			
Equity attributable to owners of the parent			
Share capital	27	1	1
Reserves	28	1,801,699	2,473,173
Total equity		1,801,700	2,473,174

**Zonghai Ll** Director Hua JIANG Director

# Consolidated Statement of Changes in Equity For the year ended December 31, 2023

		Attributable to owners of the parent				
	Notes	Share capital <i>RMB'000</i>	Other reserves** <i>RMB'000</i> (note 28)	Accumulated losses** <i>RMB'000</i>	Total <i>RMB'000</i>	
At January 1, 2022		1	0 546 447	(6 540 799)	2 006 660	
At January 1, 2022 Loss for the year		I	9,546,447	(6,549,788) (892,247)	2,996,660 (892,247)	
Other comprehensive income	28	_	314,261	(092,247)	(892,247) 314,261	
Total comprehensive income/(loss)		_	314,261	(892,247)	(577,986)	
Share-based payments	29	_	43,995	_	43,995	
Issue of shares held in trust	27	_*	_*	_	_*	
Issue of shares to employees under Employee						
Incentive Schemes	27	_*	8,034	_	8,034	
Transfer of treasury shares to employees						
under Employee Incentive Schemes	27	_*	2,471	-	2,471	
At December 31, 2022		1	9,915,208	(7,442,035)	2,473,174	
At January 1, 2023		1	9,915,208	(7,442,035)	2,473,174	
Loss for the year		1	5,515,200	(747,794)	(747,794)	
Other comprehensive income	28	-	55,252	-	55,252	
Total comprehensive income/(loss)		_	55,252	(747,794)	(692,542)	
				(,	(//	
Share-based payments	29	_	14,458	-	14,458	
Issue of shares held in trust	27	_*	_*	-	_*	
Issue of shares to employees under Employee						
Incentive Schemes	27	-*	6,406	-	6,406	
Transfer of treasury shares to employees						
under Employee Incentive Schemes	27	-*	204	-	204	
At December 31, 2023		1	9,991,528	(8,189,829)	1,801,700	

The amounts are less than RMB1,000. \*

\*\* The reserve accounts comprised RMB1,801,699,000 in the consolidated statements of financial position as at December 31, 2023 (2022: RMB2,473,173,000).

# **Consolidated Statement of Cash Flows**

For the year ended December 31, 2023

	Notes	2023 <i>RMB'000</i>	2022 RMB′000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before income tax		(747,387)	(890,952)
Adjustments for:			
Finance (income)/costs – net	7	(20,262)	9,655
Interest income on term deposits with original maturity between			
three and twelve months	5	(47,865)	(21,700)
Depreciation of property, plant and equipment	14	62,228	51,619
Depreciation of right-of-use assets	15	17,765	22,997
Amortisation of intangible assets	17	7,402	6,917
Foreign exchange losses – net	6	30,467	97,351
Losses/(Gains) on disposals of property, plant and equipment		2,420	(23)
Write-off of intangible assets	17	-	2,910
Losses/(Gains) from termination of lease agreements		561	(68)
Government grants relating to investing activities		(4,639)	(7,450)
Share-based payment expenses	29	14,458	43,995
		(684,852)	(684,749)
		(602)	
Increase in inventories		(683)	(2, 600)
Decrease/(Increase) in other receivables		3,110	(2,609)
Decrease in other current assets and prepayments		7,908	1,261
(Increase)/Decrease in other non-current assets and prepayments		(4,751)	5,137
Increase in accruals and other payables		16,451	39,873
Decrease/(Increase) in deferred income on government grants Increase in contract liabilities		661 188,679	(180)
		100,079	
Cash used in operations		(473,477)	(641,267)
Interest received		20,290	5,866
Income tax paid		(1,748)	(7,647)
Net cash used in operating activities		(454,935)	(643,048)

# Consolidated Statement of Cash Flows

For the year ended December 31, 2023

Notes	2023 <i>RMB'000</i>	2022 RMB'000
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of items of property, plant and equipment	(8,835)	(135,406)
Proceeds from disposals of items of property, plant and		26
equipment Purchases of intangible assets	(714)	(3,208)
Purchase of term deposits with original maturity between three	(714)	(3,200)
and twelve months	(2,037,989)	(3,482,681)
Proceeds from collection of term deposits with original maturity	(_/~~/~~~/	(0) 102/001/
between three and twelve months	2,037,989	5,925,683
Interest received from term deposits with original maturity		
between three and twelve months	47,865	21,700
Lease incentive received	-	33,657
Refund of input VAT related to the acquisition of		
non-current assets	135	17,104
Government grant received in relation to the acquisition of		
non-current assets	800	10,115
Net cash generated from investing activities	39,251	2,386,990
CASH FLOWS FROM FINANCING ACTIVITIES Proceeds from issue of shares to employees under Employee Incentive Schemes Proceeds from transfer of treasury shares to employees under	6,406	8,034
Employee Incentive Schemes	204	2,471
Principal portion of lease payments	(18,918)	(11,821)
Interest paid for lease liabilities	(4,388)	(4,980)
Changes in rental deposits	(303)	-
Proceeds from bank borrowings	-	108,415
Repayments of bank borrowings Interest paid for bank borrowings	(4,851)	(327,748)
	(292)	(10,885)
Net cash used in financing activities	(22,142)	(236,514)
NET (DECREASE)/INCREASE IN CASH AND CASH		
EQUIVALENTS	(437,826)	1,507,428
Cash and cash equivalents at beginning of the year	2,268,036	691,284
Effect of foreign exchange rate changes, net	19,542	69,324
CASH AND CASH EQUIVALENTS AT END OF THE YEAR 22	1,849,752	2,268,036
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS Cash and bank balances as stated in the consolidated statement of financial position	1,849,752	2,268,036
	1,045,752	2,200,050

For the year ended December 31, 2023

#### 1. CORPORATE AND GROUP INFORMATION

CARsgen Therapeutics Holdings Limited (hereinafter the "Company") was incorporated under the law of the Cayman Islands as a limited liability company on February 9, 2018. The address of the Company's registered office is P.O. Box 31119 Grand Pavilion, Hibiscus Way, 802 West Bay Road, Grand Cayman, KY1-1205 Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (hereinafter collectively referred to as the "Group") are a global clinical-stage biopharmaceutical company discovering, researching and developing cell therapies in the People's Republic of China (the "PRC") and the United States of America (the "US").

The consolidated financial statements are presented in thousands of Renminbi ("RMB"), unless otherwise stated, and were approved and authorized for issue by the Board of Directors of the Company on March 26, 2024.

#### Information about subsidiaries

Particulars of the Company's principal subsidiaries are as follows:

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued share and paid-up capital	Ownershi held by the	p interest e Company
				2023 %	2022 %
Directly hold					
CARsgen Pharma Holdings Limited	Hong Kong, February 21, 2018, Limited liability company	Holding company, Hong Kong	HK\$10	100	100
Indirectly hold					
Cleanings Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100
Excelsiory Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100
Panzenith Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100
CARsgen USA	United States of America, May 4, 2016, Limited liability company	Drug research and development, manufacturing and import and export handling, the United States	USD1,000	100	100

For the year ended December 31, 2023

#### 1. CORPORATE AND GROUP INFORMATION (continued)

#### Information about subsidiaries (continued)

Particulars of the Company's principal subsidiaries are as follows: (continued)

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued share and paid-up capital	Ownership held by the	
				2023 %	2022 %
CARsgen Life Sciences Co., Ltd. 愷興生命科技 (上海) 有限公司**	PRC/Chinese Mainland, March 22, 2018, Limited liability company (Registered as wholly foreign owned enterprises under PRC law)	Drug research and development, manufacturing and import and export handling, PRC/Chinese Mainland	USD40,000,000	100	100
Indirectly hold					
CARsgen Diagnostics Co., Ltd. 上海愷興診斷 技術有限公司**	PRC/Chinese Mainland, November 23, 2020, Limited liability company	Drug research and development, manufacturing and import and export handling, PRC/Chinese Mainland	RMB10,000,000	100	100
CARsgen Therapeutics (Beijing) Co., Ltd. 科濟 生物醫藥(北京)有限公 司 **	PRC/Chinese Mainland, February 11, 2022, Limited liability company	Drug research and development, manufacturing and import and export handling, PRC/Chinese Mainland	RMB15,000,000/ RMB7,000,000	100	100
CAFA Therapeutics Limited 佧珐藥業有限 公司	Ireland, January 8, 2021, Limited liability company	Drug research and development, manufacturing and import and export handling, Ireland	Euro1,000	100	100
CRAGE Medical Co., Limited 克萊格醫學有 限公司	Hong Kong, December 9, 2021, Limited liability company	Drug research and development, manufacturing and import and export handling, Hong Kong	HK\$1,000	100	100

For the year ended December 31, 2023

#### 1. CORPORATE AND GROUP INFORMATION (continued)

#### Information about subsidiaries (continued)

Particulars of the Company's principal subsidiaries are as follows: (continued)

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued share and paid-up capital	Ownershi held by the	•
				2023 %	2022 %
Controlled by the Com	pany pursuant to the Contrac	tual Agreements (Note 2.1)			
CARsgen Therapeutics Co., Ltd 科濟生物醫藥 (上海)有限公司**	PRC/Chinese Mainland, October 30, 2014, Limited liability company	Drug research and development, manufacturing and import and export handling, PRC/Chinese Mainland	RMB40,000,000	100	100
CARsgen Pharmaceuticals Co., Ltd 上海科濟製藥有	PRC/Chinese Mainland, November 15, 2017,	Drug research and development,	RMB50,000,000/ RMB35,082,900	100	100
LUU 上一件件 <b>消</b> 裂宗有 限公司** ("CARsgen Pharmaceuticals")	Limited liability company	manufacturing and import and export handling, PRC/Chinese Mainland			

\* Save for disclosed in this annual report, none of the subsidiaries had issued any debt securities at the end of the year.

\*\* The English names of these companies represent the best effort made by the directors of the Company (the "Directors") to translate the Chinese names as these companies have not been registered with any official English names.

#### 2. ACCOUNTING POLICIES

#### 2.1 Basis of preparation

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs") as issued by the International Accounting Standards Board (the "IASB") and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

#### Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the "Group") for the year ended December 31, 2023. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

#### 2. ACCOUNTING POLICIES (continued)

#### **2.1 Basis of preparation** (continued)

#### Basis of consolidation (continued)

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the currency translation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.1 Basis of preparation (continued)

#### Contractual arrangements

Due to the restrictions imposed by the relevant laws and regulatory regime of Chinese Mainland on foreign ownership of companies engaged in the gene therapy business carried out by subsidiaries of the Group, namely CARsgen Therapeutics Co., Ltd (科濟生物醫藥(上海)有限公司) ("CARsgen Therapeutics") and its wholly owned subsidiary, CARsgen Pharmaceuticals Co., Ltd. (上海科濟製藥有限公司), hereinafter collectively "CARsgen Therapeutics Group", CARsgen Life Sciences Co., Ltd. (愷興生命科技(上海)有限公司) ("CARsgen Life Sciences") entered into the contractual arrangements (the "Contractual Arrangements") with CARsgen Therapeutics and its registered shareholders who collectively hold 100% equity interests of CARsgen Therapeutics on April 18, 2018, which enable CARsgen Life Science and the Group to:

- expose, or have rights, to variable returns from their involvement with the investee and have the ability to affect those returns through its power over CARsgen Therapeutics Group;
- exercise equity holders' controlling voting rights of CARsgen Therapeutics Group;
- receive substantially all of the economic interest returns generated by CARsgen Therapeutics Group in consideration for the business support, technical and consulting services provided by CARsgen Therapeutics Group;
- obtain an irrevocable and exclusive right to purchase all or part of equity interests in CARsgen Therapeutics Group from its equity holders at the same amount of its registered capital. CARsgen Life Science may exercise such options at any time until it has acquired all equity interests and/or all assets of CARsgen Therapeutics Group. In addition, CARsgen Therapeutics Group is not allowed to sell, transfer, or dispose of any assets, or make any distributions to its equity holders without prior consent of CARsgen Life Science; and
- obtain a pledge over the entire equity interest of CARsgen Therapeutics Group from its equity holders as collateral security to guarantee the performance of their contractual obligations under the Contractual Arrangements.

The Group does not have any legal equity interest in CARsgen Therapeutics Group. However, as a result of the Contractual Arrangements, the Group has power over CARsgen Therapeutics Group, has rights to variable returns from its involvement with CARsgen Therapeutics Group and has the ability to affect those returns through its power over CARsgen Therapeutics Group and is considered to have control over CARsgen Therapeutics Group. Consequently, the Company regards CARsgen Therapeutics Group as controlled structured entities and consolidated the financial position and results of operations of CARsgen Therapeutics Group.

#### 2. ACCOUNTING POLICIES (continued)

#### 2.2 Changes in accounting policies and disclosures

The Group has adopted the following new and revised IFRSs for the first time for the current year's financial statements.

IFRS 17	Insurance Contracts
Amendments to IAS 1 and	Disclosure of Accounting Policies
IFRS Practice Statement 2	
Amendments to IAS 8	Definition of Accounting Estimates
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising
	from a Single Transaction
Amendments to IAS 12	International Tax Reform – Pillar Two Model Rules

The nature and the impact of the new and revised IFRSs that are applicable to the Group are described below:

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has disclosed the material accounting policy information in note 2 to the financial statements. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's financial statements.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.2 Changes in accounting policies and disclosures (continued)

The nature and the impact of the new and revised IFRSs that are applicable to the Group are described below: (continued)

(c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. The Group has applied the amendments on temporary differences related to leases as at January 1, 2022. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset amounting to RMB18,754,000 for all deductible temporary differences associated with lease liabilities (provided that sufficient taxable profit is available), and (ii) a deferred tax liability amounting to RMB18,754,000 for all taxable temporary differences associated with right-of-use assets at January 1, 2022. The adoption of amendments to IAS 12 had no cumulative effect on the Group's financial statements.

(d) Amendments to IAS 12 International Tax Reform – Pillar Two Model Rules introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

#### 2. ACCOUNTING POLICIES (continued)

#### 2.3 Issued but not yet effective IFRSs

The Group has not applied the following revised IFRSs, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10	Sale or Contribution of Assets between an Investor
and IAS 28	and its Associate or Joint Venture <sup>3</sup>
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback <sup>1</sup>
Amendments to IAS 1	Classification of Liabilities as Current or Non-current <sup>1</sup>
Amendments to IAS 1	Non-current Liabilities with Covenants <sup>1</sup>
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements <sup>1</sup>
Amendments to IAS 21	Lack of Exchangeability <sup>2</sup>
	11

<sup>1</sup> Effective for annual periods beginning on or after January 1, 2024

<sup>2</sup> Effective for annual periods beginning on or after January 1, 2025

<sup>3</sup> No mandatory effective date yet determined but available for adoption

The Group has already commenced an assessment of the impact of these revised standards and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, these standards and amendments are not expected to have a significant impact on the Group's financial performance and position.

#### 2.4 Material accounting policies

#### Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Fair value measurement (continued)

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

#### Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

#### 2. ACCOUNTING POLICIES (continued)

#### **2.4 Material accounting policies** (continued)

#### **Related parties**

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person:
  - (i) has control or joint control over the Group;
  - (ii) has significant influence over the Group; or
  - (iii) is a member of the key management personnel of the Group or of a parent of the Group;
- or
- (b) the party is an entity where any of the following conditions applies:
  - (i) the entity and the Group are members of the same group;
  - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
  - (iii) the entity and the Group are joint ventures of the same third party;
  - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
  - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group; and the sponsoring employers of the postemployment benefit plan;
  - (vi) the entity is controlled or jointly controlled by a person identified in (a);
  - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
  - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Building and fixtures	5% to 20%		
Plant and lab equipment	10% to 20%		
Office and transportation equipment	14% to 33%		
Leasehold improvements	Over the shorter of the lease terms and or the		
	estimated useful life		

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress is stated at cost less any impairment losses, and is not depreciated. It is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

#### 2. ACCOUNTING POLICIES (continued)

#### **2.4 Material accounting policies** (continued)

#### Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

#### Patents and software

Purchased patents and software are stated at cost less any impairment losses and are amortised on the straight-line basis over their estimated useful lives of 3 to 10 years.

#### Research and development costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

#### Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for shortterm leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

#### (a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Land use right Offices and dormitory 45 years 1.5 to 10 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### *Leases* (continued)

Group as a lessee (continued)

#### (b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of office and dormitories (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment and laptop computers that are considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Investments and other financial assets

#### Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Receivables that do not contain a significant financing component or for which the Group has applied the practical expedient or for which the Group has applied the practical expedient are measured at the transaction price.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest ("SPPI") on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset.

#### Subsequent measurement

#### Financial assets at amortised cost

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a "pass-through" arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

#### Impairment of financial assets

The Group recognises an allowance for expected credit losses ("ECLs") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Impairment of financial assets (continued)

#### General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information. The Group considers that there has been a significant increase in credit risk when contractual payments are past due.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group.

A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Debt investments at fair value through other comprehensive income and financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

- Stage 1 Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

#### 2. ACCOUNTING POLICIES (continued)

#### **2.4 Material accounting policies** (continued)

#### Simplified approach

For receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

#### Financial liabilities

#### Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as borrowings, and accruals and other payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of borrowings, and accruals and other payables, net of directly attributable transaction costs.

The Group's financial liabilities include borrowings and accruals and other payables.

#### Subsequent measurement

Financial liabilities at amortised cost (borrowings and accruals and other payables)

After initial recognition, borrowings, and accruals, and other payables, are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in profit or loss.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss.

#### Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

#### Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the first-in, first-out basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

#### Cash and cash equivalents

Cash and cash equivalents in the statement of financial position comprise cash and bank balances, subject to an insignificant risk of changes in value.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash and bank balances.

#### 2. ACCOUNTING POLICIES (continued)

#### **2.4 Material accounting policies** (continued)

#### Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Income tax (continued)

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred taxable profit will be available to allow all or part of the deferred taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

#### Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

#### Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

#### Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

#### 2. ACCOUNTING POLICIES (continued)

#### **2.4 Material accounting policies** (continued)

#### Share-based payments

The Company operates share incentive schemes. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments ("equity-settled transactions"). The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 29 to the financial statements.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be nonvesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification. Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of loss per share.

For the year ended December 31, 2023

#### 2. ACCOUNTING POLICIES (continued)

#### 2.4 Material accounting policies (continued)

#### Other employee benefits

#### Pension schemes

The employees of the Group's subsidiaries which operate in Chinese Mainland are required to participate in a central pension scheme operated by the local municipal government. Subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

The subsidiary in the US maintains multiple qualified contributory savings plans as allowed under Section 401(k) of the Internal Revenue Code in the US. These plans are defined contribution plans covering substantially all its qualifying employees and provide for voluntary contributions by employees, subject to certain limits. The contributions are made by both the employees and the employer. The employees' contributions are primarily based on specified dollar amounts or percentages of employee compensation. The only obligation of the subsidiary in the US with respect to the retirement benefit plans is to make the specified contributions under the plans.

#### Foreign currencies

These financial statements are presented in RMB. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

The functional currencies of certain overseas subsidiaries are currencies other than the RMB. As at the end of the reporting period, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve, except to the extent that the differences are attributable to non-controlling interests. On disposal of a foreign operation, the cumulative amount in the reserve relating to that particular foreign operation is recognised in profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the average exchange rates for the year.

For the year ended December 31, 2023

#### 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

#### Judgements

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

#### Research and development expenses

Development costs incurred on the Group's drug product pipelines are capitalised only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development costs which do not meet these criteria are expensed when incurred. Determining the amounts to be capitalised requires management to make judgement regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits. During the years ended December 31, 2023 and 2022, all expenses incurred for research and development activities were regarded as research expenses and therefore were expensed when incurred.

#### Contractual arrangements

The Group conducts its business through CARsgen Therapeutics Group in Chinese Mainland. Due to the regulatory restrictions on the foreign ownership in the operation of CAR-T cell therapies business in Chinese Mainland, the Group does not have any legal equity interest in CARsgen Therapeutics Group. The Directors assessed whether or not the Group has control over CARsgen Therapeutics Group by assessing whether it has the rights to variable returns from its involvement with CARsgen Therapeutics Group and has the ability to affect those returns through its power over CARsgen Therapeutics Group. After assessment, the Directors concluded that the Group has control over CARsgen Therapeutics Group as a result of the Contractual Arrangements and accordingly the financial position and the operating results of CARsgen Therapeutics Group are included in the Group's consolidated financial statements throughout the years ended December 31, 2023 and 2022. Nevertheless, the Contractual Arrangements may not be as effective as direct legal ownership in providing the Group with direct control over CARsgen Therapeutics Group and uncertainties presented by the PRC legal system could impede the Group's beneficiary rights of the results, assets and liabilities of CARsgen Therapeutics Group. The Directors, based on the advice of their legal counsel, consider that the Contractual Arrangements with CARsgen Therapeutics Group and its equity holders are in compliance with the relevant PRC laws and regulations and are legally enforceable.

For the year ended December 31, 2023

#### 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (continued)

#### **Estimation uncertainty**

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

#### Research and development expenses

The Group relies on Outsourced Service Providers to conduct, supervise, and monitor the Group's ongoing clinical trials. Determining the amounts of research and development expenses incurred up to the end of each reporting period requires the management of the Group to estimate and measure the progress of receiving research and development services under the contracts with Outsourced Service Providers using inputs such as the number of patient enrolments, time elapsed and milestone achieved.

#### Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgement on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation.

Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies.

#### Fair value of share-based payment transactions

Estimating the fair value of share-based payment transactions requires the determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility, and dividend yield and making assumptions about them.

For the measurement of the fair value of share-based payment transactions with employees at the grant date, the Group uses a binomial model. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in note 29 to the financial statements.

For the year ended December 31, 2023

#### 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (continued)

#### Estimation uncertainty (continued)

#### Leases – Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate ("IBR") to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates.

#### Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including right-of-use assets) at the end of the reporting period. The non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

For the year ended December 31, 2023

#### 4. SEGMENT INFORMATION

The Group's business activities are regularly reviewed and evaluated by the chief operating decisionmakers. The chief operating decision-makers, who are responsible for allocating resources and assessing performance of the operating segment, have been identified as the executive directors of the Group.

As a result of this evaluation, the executive directors of the Group consider that the Group's operations are operated and managed as a single operating segment. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

#### **Geographical information**

#### Non-current assets

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
The PRC	149,133	202,779
The US	234,993	259,401
Total non-current assets	384,126	462,180

The non-current asset information above is based on the locations and legal owners of the assets.

#### 5. OTHER INCOME

	2023 <i>RMB'000</i>	2022 RMB′000
Government grants (i)	8,671	13,815
Interest income on term deposits with original maturity between three and twelve months	47,865	21,700
Others	-	80
Total	56,536	35,595

(i) The government grants mainly represent subsidies received from the government to support on certain research and development projects that are related to both expenses and assets. Government grants were released to profit or loss either over the periods that the expenses for which it is intended to compensate, or over the expected useful life of the relevant asset, when all attaching conditions and requirements are compliant with.

#### 6. OTHER LOSSES – NET

	2023 <i>RMB'000</i>	2022 RMB′000
Foreign exchange losses – net Others	(30,467) (370)	(97,351) (3,445)
Total	(30,837)	(100,796)

#### 7. FINANCE INCOME/(COSTS) – NET

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Finance income		
Interest income	24,926	5,866
Finance costs		
Interest expense on lease liabilities	(4,388)	(4,980)
Interest expense on bank borrowings	(276)	(10,541)
Total finance costs	(4,664)	(15,521)
Total finance income/(costs) – net	20,262	(9,655)

For the year ended December 31, 2023

#### 8. LOSS BEFORE TAX

The Group's loss before tax from continuing operations is arrived at after charging:

	Notes	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Employee benefit expenses		325,337	353,228
Testing and clinical expenses		249,638	252,470
Depreciation of property, plant and equipment	14	62,228	51,619
Research and development consumables		54,632	51,494
Professional service expenses		20,626	24,407
Depreciation of right-of-use assets	15	17,765	22,997
Utilities		20,577	20,061
Office expenses		9,702	15,433
Travelling and transportation expenses		8,905	6,988
Amortisation of intangible assets	17	7,402	6,917
Short-term lease and low-value lease expenses	15	5,470	1,537
Auditors' remuneration		4,191	3,445
– Audit service		4,191	3,260
– Non-audit service		-	185
Other expenses		6,875	5,500
Total		793,348	816,096
Administrative expenses		131,689	135,795
Research and development expenses		661,659	680,301
Total		793,348	816,096

#### 9. DIRECTORS' AND CHIEF EXECUTIVE'S REMUNERATION

Directors' and chief executive's remuneration for the year, disclosed pursuant to the Listing Rules, section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Fees <i>RMB'000</i>	Salary <i>RMB'000</i>	Discretionary bonus <i>RMB'000</i>	Share-based payments <i>RMB'000</i>	Pension costs <i>RMB'000</i>	Other benefits <i>RMB'000</i>	Total <i>RMB'000</i>
Year ended December 31, 2022							
Chairman, executive director and chief executive							
Zonghai Ll	_	1,070	776	_	63	84	1,993
Executive directors	-	1,070	770	_	05	04	1,335
Huamao Wang		1,088	844		63	141	2,136
-	-	840	56	87	63	79	
Hua Jiang <i>(i)</i>	-	840	00	87	03	79	1,125
Non-executive directors							
Bingsen Guo	-	-	-	-	-	-	-
Yachao Zhao <i>(ii)</i>	-	-	-	-	-	-	-
Ronggang Xie	-	-	-	-	-	-	-
Huaqing Guo	-	-	-	-	-	-	-
Independent non-executive directors							
Chunhai Fan <i>(iii)</i>	402	-	-	-	-	-	402
Guangmei Yan	402	-	-	-	-	-	402
Tak Young So <i>(iv)</i>	402	-	-	-	-	-	402
	1,206	2,998	1,676	87	189	304	6,460

For the year ended December 31, 2023

#### 9. DIRECTORS' AND CHIEF EXECUTIVE'S REMUNERATION (continued)

	Fees <i>RMB'000</i>	Salary <i>RMB'000</i>	Discretionary bonus <i>RMB'000</i>	Share-based payments <i>RMB'000</i>	Pension costs <i>RMB'000</i>	Other benefits <i>RMB'000</i>	Total <i>RMB'000</i>
Year ended December 31, 2023							
Chairman and executive director							
Zonghai Ll	_	1,047	789		68	180	2,084
Executive directors		.,					_,
Huamao Wang	_	1,110	857	_	68	75	2,110
Hua Jiang <i>(i)</i>	-	845	66	337	68	75	1,391
Non-executive directors							
Bingsen Guo	-	-	-	-	-	_	-
Ronggang Xie	-	-	-	-	-	-	-
Huaqing Guo	-	-	-	-	-	-	-
Independent non-executive directors							
Chunhai Fan <i>(iii)</i>	-	-	-	-	-	-	-
Guangmei Yan	222	-	-	-	-	-	222
Tak Young So <i>(iv)</i>	202	-	-	-	-	-	202
Huabing Li (v)	83	-	-	-	-	-	83
Xiangke Zhao <i>(vi)</i>	80	-	-	-	-	-	80
	587	3,002	1,712	337	204	330	6,172

(i) Ms. Hua Jiang was appointed as an executive Director on August 1, 2022.

(*ii*) Ms. Yachao Zhao was appointed as a director on September 13, 2018, re-designated as a non-executive Director on February 23, 2021 and resigned on May 27, 2022.

(iii) Dr. Chunhai Fan was appointed as an independent non-executive director on June 18, 2021, and resigned on January 11, 2023.

(iv) Mr. Tak Young So was appointed as an independent non-executive director on June 18, 2021, and resigned on June 30, 2023.

(v) Mr. Huabing Li was appointed as an independent non-executive director on March 9, 2023.

(vi) Ms. Xiangke Zhao was appointed as an independent non-executive director on July 4, 2023.

There were no other remunerations payable to the independent non-executive directors during the year (2022: Nil).

There was no arrangement under which a director or the chief executive waived or agreed to waive any remuneration during the year.

#### **10. FIVE HIGHEST PAID INDIVIDUALS**

The five highest paid employees during the year include no directors for the year ended December 31, 2023 (2022: nil). Details of the remuneration for the year of the five (2022: five) highest paid employees who are neither a director nor chief executive of the Company are as follows:

	2023 <i>RMB'000</i>	2022 RMB'000
Basic salaries, housing allowances, share-based payments,		
other allowances and benefits in kind	19,320	29,924
Discretionary bonuses	2,264	3,087
Contribution to pension scheme	600	451
Total	22,184	33,462

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	2023	2022
HK\$3,500,001 to HK\$4,000,000	1	-
HK\$4,000,001 to HK\$4,500,000	2	_
HK\$4,500,001 to HK\$5,000,000	1	-
HK\$5,500,001 to HK\$6,000,000	-	1
HK\$6,000,001 to HK\$6,500,000	-	1
HK\$7,000,001 to HK\$7,500,000	-	1
HK\$7,500,001 to HK\$8,000,000	1	-
HK\$8,000,001 to HK\$8,500,000	-	1
HK\$9,500,001 to HK\$10,000,000	-	1
Total	5	5

During the year and in prior years, equity-settled transactions were granted to non-director and nonchief executive highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 29 to the consolidated financial statements. The fair value of such equity-settled transactions, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amount included in the consolidated financial statements for the current year is included in the above non-director and non-chief executive highest paid employees' remuneration disclosures.

For the year ended December 31, 2023

#### **11. INCOME TAX EXPENSE**

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Current income tax		
<ul> <li>Chinese Mainland corporate income Tax</li> </ul>	-	-
– Ireland Capital Gains Tax	407	1,295
Deferred income tax	-	-
	407	1,295

A reconciliation of the tax expense applicable to loss before tax at the statutory tax rates for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates is as follows:

	2023 <i>RMB'000</i>	2022 RMB′000
Loss before income tax	(747,387)	(890,952)
Tax calculated at Chinese Mainland tax rate of 25% Effect of different tax rates Expenses not deductible for taxation purposes	(186,847) 17,209 2,756	(222,738) 25,794 1,973
Temporary differences and tax loss not recognised Additional deductible allowance for qualified research and	236,850	269,955
development expenses	(69,561) 407	(73,689)

#### **Current income tax**

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operated.

#### (a) Cayman Islands income tax

The Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands and accordingly, is exempted from Cayman Islands income tax.

#### 11. INCOME TAX EXPENSE (continued)

#### Current income tax (continued)

#### (b) Hong Kong profits tax

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% (2022: 16.5%) as the Company has no estimated assessable profits in Hong Kong.

#### (c) Chinese Mainland corporate income tax

Subsidiaries in Chinese Mainland are subject to income tax at a rate of 25% (2022: 25%) pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), exception for CARsgen Therapeutics which obtained its High and New Technology Enterprise qualification in year 2023 and hence is entitled to a preferential tax rate of 15% (2022: 15%) for a three-year period commencing from 2023.

No provision for Chinese Mainland corporate income tax was made for, as were no assessable profits arising in Chinese Mainland.

#### (d) US corporate income tax

CARsgen USA, which was incorporated in Delaware, the United States on May 4, 2016, was subject to statutory U.S. Federal corporate income tax at a rate of 21% (2022: 21%) for the year ended December 31, 2023. CARsgen USA was also subject to the state income tax during for the years ended December 31, 2023 and 2022.

No provision for US corporate income tax was provided for as there were no assessable profits arising in the US.

#### (e) British Virgin Islands income tax

Under the current laws of BVI, the subsidiary incorporated in BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Group's BVI subsidiaries, no BVI withholding tax is imposed.

#### (f) Ireland corporation income tax and Ireland capital gains tax

The subsidiary in Ireland is subject to income tax at rates of 12.5% (2022: 12.5%) on the estimated assessable profit and 33% (2022: 33%) on the capital gains. Provision for Ireland capital gains tax has been provided as the subsidiary has realised capital gains for the years ended December 31, 2023 and 2022.

For the year ended December 31, 2023

#### 11. INCOME TAX EXPENSE (continued)

#### **Current income tax** (continued)

#### (g) Deferred tax assets not recognised:

The Group has not recognised any deferred tax assets in respect of the following items:

	2023 <i>RMB'000</i>	2022 RMB′000
Deductible temporary differences Tax losses	459,221 4,002,570	296,239 3,085,988
Total	4,461,791	3,382,227

# (h) Tax losses that are not recognised as deferred tax assets will expire are analyzed as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
2024	75,757	75,757
2025	134,188	134,188
2026	793,032	793,032
2027	859,763	859,763
2028 and later	2,139,830	1,223,248
	4,002,570	3,085,988

The tax losses of the Company's PRC subsidiaries with the exception of those of CARsgen Therapeutics will expire within five years. CARsgen Therapeutics, as a High and New Technology Enterprise, can carry forward losses for 10 years. The tax losses of the Company's other subsidiaries can be carried forward indefinitely. No deferred tax asset has been recognised in respect of the tax losses due to the unpredictability of future profit streams.

#### **12. DIVIDEND**

No dividend was declared or paid by the Company during the years ended December 31, 2023 (2022: nil).

#### 13. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares in issue (excluding shares reserved for share incentive scheme) during the reporting period.

No adjustment has been made to the basic loss per share amount presented for the reporting period in respect of a dilution as the impact of outstanding potential ordinary shares in relation to share-based payments had an anti-dilutive effect on the basic loss per share amount presented.

The calculation of the basic and diluted loss are based on:

	2023	2022
Loss attributable to ordinary equity holders of the parent <i>(RMB'000)</i> Weighted average number of ordinary shares in issue during the year, used in the basic and diluted loss per share	(747,794)	(892,247)
calculation ('000)	556,125	551,626
Basic and diluted loss per share (RMB)	(1.34)	(1.62)

For the year ended December 31, 2023

#### 14. PROPERTY, PLANT AND EQUIPMENT

Net book amount	51,339	104,781	16,393	179,189	12,148	363,850
Accumulated depreciation	(29,576)	(70,565)	(10,080)	(18,282)	-	(128,503)
Cost	80,915	175,346	26,473	197,471	12,148	492,353
As at December 31, 2022						
Closing net book amount	51,339	104,781	16,393	179,189	12,148	363,850
Depreciation charges	(10,553)	(22,568)	(4,459)	(14,039)	_	(51,619)
Disposals	(4.0.552)	(22.5.00)	(3)	-	-	(3)
Completion of construction in progress	2,028	32,596	11,959	183,517	(230,100)	-
Additions	406	15,075	3,439	2,166	78,147	99,233
Exchange differences	-	3,831	(90)	(366)	11,966	15,341
Opening net book amount	59,458	75,847	5,547	7,911	152,135	300,898
As at December 31, 2022						
Net book amount	59,458	75,847	5,547	7,911	152,135	300,898
Accumulated depreciation	(19,023)	(47,898)	(5,743)	(3,876)	_	(76,540)
<b>At January 1, 2022</b> Cost	78,481	123,745	11,290	11,787	152,135	377,438
	RMB'000	<i>RMB'000</i>	RMB'000	RMB'000	RMB'000	RMB'000
	and fixtures	equipment	equipment	improvements	in progress	Total
	Building	Plant and lab	transportation	Leasehold	Construction	
			Office and			

#### 14. PROPERTY, PLANT AND EQUIPMENT (continued)

	Building and fixtures <i>RMB'000</i>	Plant and lab equipment <i>RMB'000</i>	Office and transportation equipment <i>RMB'000</i>	Leasehold improvements <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
At January 1, 2023						
Cost	80,915	175,346	26,473	197,471	12,148	492,353
Accumulated depreciation	(29,576)	(70,565)	(10,080)	(18,282)	-	(128,503)
Net book amount	51,339	104,781	16,393	179,189	12,148	363,850
As at December 31, 2023						
Opening net book amount	51,339	104,781	16,393	179,189	12,148	363,850
Exchange differences	-	533	180	2,828	82	3,623
Additions	400	4,278	1,178	-	3,271	9,127
Completion of construction in progress	-	9,610	1,257	471	(11,338)	-
Disposals	-	(387)	-	-	(2,033)	(2,420)
Depreciation charges	(10,704)	(24,592)	(5,961)	(20,971)	-	(62,228)
Closing net book amount	41,035	94,223	13,047	161,517	2,130	311,952
As at December 31, 2023						
Cost	81,315	189,204	28,687	200,932	2,130	502,268
Accumulated depreciation	(40,280)	(94,981)	(15,640)	(39,415)	-	(190,316)
Net book amount	41,035	94,223	13,047	161,517	2,130	311,952

As at December 31, 2023, the Group's building with a net book amount of RMB29,388,000 (2022: RMB31,247,000) was pledged for the Group's borrowings (note 24).

During the year ended December 31, 2023, the disposal of construction in progress was related to the cost of design for the terminated leasehold improvements before ready to use.

For the year ended December 31, 2023

#### **15. RIGHT-OF-USE ASSETS**

The carrying amounts of the Group's right-of-use assets and the movements during the year are as follows:

	Land use right <i>RMB'000</i>	Offices and dormitory RMB'000	<b>Total</b> <i>RMB'000</i>
As at January 1, 2022 Cost	7,098	109,223	116,321
Accumulated depreciation	(312)	(30,718)	(31,030)
·		,	
Net book amount	6,786	78,505	85,291
As at December 31, 2022			
Opening net book amount	6,786	78,505	85,291
Additions	-	19,135	19,135
Termination of lease agreements	_	(6,513)	(6,513)
Depreciation charge	(156)	(22,841)	(22,997)
Exchange differences		2,617	2,617
Closing net book amount	6,630	70,903	77,533
As at December 31, 2022			
Cost	7,098	121,845	128,943
Accumulated depreciation	(468)	(50,942)	(51,410)
Net book amount	6,630	70,903	77,533
As at December 31, 2023			
Opening net book amount	6,630	70,903	77,533
Additions	-	1,457	1,457
Termination of lease agreements	-	(12,474)	(12,474)
Depreciation charge	(156)	(17,609)	(17,765)
Exchange differences	-	687	687
Closing net book amount	6,474	42,964	49,438
As at December 31, 2023			
Cost	7,098	110,828	117,926
Accumulated depreciation	(624)	(67,864)	(68,488)

As at December 31, 2023, the Group's land use right with a net book amount of RMB6,474,000 (2022: RMB6,630,000) was pledged as collateral for the Group's borrowings (note 24).

#### 15. RIGHT-OF-USE ASSETS (continued)

# (i) Amounts recognised in the consolidated statement of profit or loss and other comprehensive income

The consolidated statements of profit or loss and other comprehensive income contain the following amounts relating to leases:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Depreciation charge of right-of-use assets ( <i>note 15</i> ) Interest expenses ( <i>note 7</i> ) Expenses relating to short-term lease and low-value lease	17,765 4,388	22,997 4,980
expenses	5,470	1,537

For the year ended December 31, 2023

#### **16. LEASE LIABILITIES**

The carrying amount of lease liabilities and the movements during the year are as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
		NIVID 000
Carrying amount at January 1	112,072	111,339
New leases	1,457	19,135
Termination of lease agreements	(11,913)	(6,581)
Accretion of interest recognised during the year	4,388	4,980
Payments	(23,306)	(16,801)
Carrying amount at December 31	82,698	112,072
Analysed into:		
Current portion	12,230	17,134
Non-current portion	70,468	94,938

The maturity analysis of lease liabilities is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Present value of lease liabilities	82,698	112,072
Less: Current portion lease liabilities	12,230	17,134
Non-current portion of lease liabilities	70,468	94,938
– Within 1 year	12,230	17,134
– Between 1 and 2 years	12,644	15,323
– Between 2 and 5 years	37,047	43,514
– Over 5 years	20,777	36,101
Present value of lease liabilities	82,698	112,072

The Group leases land use right and offices and dormitory. Lease on land use right has been fully paid and leases on offices and dormitory were measured at the net present value of the lease payments to be paid during the lease terms.

Lease liabilities were discounted at incremental borrowing rates of the Group entities.

#### **17. INTANGIBLE ASSETS**

	<b>Software</b> <i>RMB'000</i>	<b>Patents</b> <i>RMB'000</i>	<b>Total</b> <i>RMB'000</i>
	RIVIB UUU	RIVIB UUU	RIVIB UUU
As at January 1, 2022			
Cost	4,757	54,800	59,557
Accumulated depreciation	(1,281)	(38,143)	(39,424)
Net book amount	3,476	16,657	20,133
As at December 31, 2022			
Opening net book amount	3,476	16,657	20,133
Additions	2,839	_	2,839
Write-off	_	(2,910)	(2,910
Amortisation charges	(1,618)	(5,299)	(6,917
Exchange differences	_	1,331	1,331
Closing net book amount	4,697	9,779	14,476
As at December 31, 2022			
Cost	7,596	50,689	58,285
Accumulated depreciation	(2,899)	(40,910)	(43,809
Net book amount	4,697	9,779	14,476
As at December 31, 2023			
Opening net book amount	4,697	9,779	14,476
Additions	714	-	714
Amortisation charges	(2,219)	(5,183)	(7,402
Exchange differences	-	872	872
Closing net book amount	3,192	5,468	8,660
As at December 31, 2023 Cost	0.340	E1 EC1	E0 074
Accumulated depreciation	8,310 (5,118)	51,561 (46,093)	59,871 (51,211
	(3,110)	(+0,033)	(31,211
Net book amount	3,192	5,468	8,660

For the year ended December 31, 2023

#### **18. OTHER NON-CURRENT ASSETS AND PREPAYMENTS**

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Value-added tax recoverable	6,180	2,427
Prepayments for purchase of property, plant and equipment	1,318	2,110
Rental deposits	6,578	1,784
Total	14,076	6,321

#### **19. INVENTORIES**

	2023 <i>RMB'000</i>	2022 RMB'000
Raw materials	683	-

#### **20. OTHER RECEIVABLES**

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Deposits	1,128	6,309
Interest receivables	5,375	739
Others	3,289	4,786
Total	9,792	11,834

None of the above assets is past due. The financial assets included in the above balances related to deposits and others for which there was no history of default and the expected credit losses are considered minimal.

The maximum exposure to credit risk at the reporting date is the carrying value of the receivables mentioned above.

The carrying amounts of the Group's other receivables approximate to their fair values.

#### **21. OTHER CURRENT ASSETS AND PREPAYMENTS**

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Value-added tax recoverable	3,151	11,053
Prepayments to suppliers	9,710	9,716
Total	12,861	20,769

#### 22. CASH AND BANK BALANCES

	2023 <i>RMB'000</i>	2022 RMB′000
Cash at banks		
– RMB	779,122	906,855
– HK\$	12,236	3,821
– USD	1,058,394	1,357,360
Total	1,849,752	2,268,036

The carrying amount of cash and cash equivalents approximates to their fair value. The RMB is not freely convertible into other currencies, however, under Chinese Mainland's Foreign Exchange Control Regulations and Administration of Settlement, and Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

#### 23. ACCRUALS AND OTHER PAYABLES

	2023 <i>RMB'000</i>	2022 RMB′000
Accrued expenses (i)	111,103	81,536
Staff salaries and welfare payables	36,800	51,017
Other taxes payable	2,621	4,094
Payables for acquisition of property, plant and equipment	1,029	1,529
Payables for research and development consumables	512	503
Interest payables	33	49
Others	5,910	2,386
Total	158,008	141,114

(i) Accrued expenses were mainly expenses incurred for the research and development activities.

For the year ended December 31, 2023

#### 24. BORROWINGS

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Non-current		
Secured bank borrowings	-	2,523
Current		
Secured bank borrowings	2,522	4,850
Total	2,522	7,373

As at December 31, 2023, the Group's bank borrowings of RMB2,522,000 (2022: RMB7,373,000) were secured by property, plant and equipment and right-of-use assets of the Group (Notes 14 and 15).

As at December 31, 2023 and 2022, the Group's borrowings were repayable as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Within 1 year	2,522	4,850
Between 1 and 2 years	-	2,523
Total	2,522	7,373

The weighted average effective interest rates at the end of each reporting period were as follows:

	2023 <i>RMB'000</i>	2022 RMB'000
Bank borrowings	5.23%	5.23%

The fair values of the borrowings approximate to their carrying amounts as the discounting impact is not significant.

As at December 31, 2023, the Group's secured borrowings will mature within one year.

#### **25. DEFERRED INCOME**

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Non-current	10,387	21,180
Current	13,220	6,565
Total	23,607	27,745

Deferred income represented government grants received relating to property, plant and equipment to be recognised upon the compliance of the Group with the conditions attached to the grants over the remaining useful lives of the related assets and government grants received relating to profit or loss to be recognised when all conditions are fulfilled.

#### **26. CONTRACT LIABILITIES**

The Group has recognised the following liabilities related to contracts with customers:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Advances received from a customer		
Grant of an exclusive distribution agreement	188,679	-
Non-current	178,442	-
Current	10,237	_
Total	188,679	_

Contract liabilities include upfront payments received for the grant of an exclusive distribution right. On January 16, 2023, CARsgen Life Sciences Co., Ltd. ("CARsgen Life Science"), a wholly-owned subsidiary of the Company and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. entered into an exclusive distribution agreement for the commercialisation of zevorcabtagene autoleucel (the "Agreement") with total upfront and milestone payments up to RMB1,225 million. In March 2023, CARsgen Life Sciences received an upfront payment of RMB200,000,000 (RMB188,679,000 excluding VAT) under the Agreement. The upfront fee is restricted by the term in the Agreement, and the current portion is expected to be realised within one year.

For the year ended December 31, 2023

#### 27. SHARE CAPITAL

#### Authorized:

	Number of shares In thousands	Nominal value of shares USD	RMB equivalent value <i>RMB'000</i>
As at January 1, 2022 and December 31, 2022 and 2023	200,000,000	50,000	349

#### Issued and fully paid:

	Number of ordinary shares at USD0.00000025 par value In thousands	RMB equivalent value RMB'000
As at January 1, 2022	567 527	1
As at January 1, 2022 Issue of shares held in trust (i)	567,537 2,187	-*
Issue of shares to employees under Employee Incentive	2,107	
Schemes (ii)	2,901	_*
As at December 31, 2022	572,625	1
Issue of shares held in trust (iii)	2,013	_*
Issue of shares to employees under Employee Incentive Schemes (iv)	1,002	_*
As at December 31, 2023	575,640	1

\* The amounts are less than RMB1,000.

#### 27. SHARE CAPITAL (continued)

- (i) On April 28, 2022, the Company allotted and issued 2,187,299 shares to Carfe Unity Limited, which was wholly owned by the 2019 Equity Incentive Plan Trustee. Such shares are to be held in trust by the 2019 Equity Incentive Plan Trustee to facilitate the transfer of shares to the grantees upon vesting of the relevant share options and share awards. The shares of the Company held in Carfe Unity Limited were accounted from as "Reserve Treasury shares held in trust".
- (*iii*) During the year ended December 31, 2022, the Company issued 2,900,889 ordinary shares at the cost of HK\$8,994,000 (equivalent to RMB8,034,000 approximately) in total at prices ranging from nil to HK\$10.92 per share to employees under Employee Incentive Schemes.
- (iii) On June 21, 2023, the Company allotted and issued 2,012,554 shares to Carfe Unity Limited, which was wholly owned by the 2019 Equity Incentive Plan Trustee. Such shares are to be held in trust by the 2019 Equity Incentive Plan Trustee to facilitate the transfer of shares to the grantees upon vesting of the relevant Share Options and Share Awards. The shares of the Company held in Carfe Unity Limited were accounted as "Reserve – Treasury shares held in trust".
- (*iv*) During the year ended December 31, 2023, the Company issued 1,002,193 ordinary shares at the cost of HK\$7,069,000 (equivalent to RMB6,406,000 approximately) in total at prices ranging from nil to HK\$10.81 per share to employees under Employee Incentive Schemes.

#### Movements in treasury shares during the year:

	Number of treasury shares In thousands	RMB equivalent value RMB'000
As at January 1,2022	19,568	_*
Issue of shares held in trust	2,187	_*
Transfer of treasury shares to employees related to employee		
share-based payment (i)	(4,119)	_*
As at December 31, 2022	17,636	_*
Issue of shares held in trust	2,013	-*
Transfer of treasury shares to employees related to employee		
share-based payment (ii)	(1,242)	_*
As at December 31, 2023	18,407	_*

\* The amounts are less than RMB1,000.

- (i) During the year ended December 31, 2022, the Company transferred 4,119,678 treasury shares to employees under Employee Incentive Schemes at a cost of HK\$2,767,000 (equivalent to RMB2,471,000 approximately) in total at prices ranging from nil to HK\$10.81 per share.
- (*ii*) During the year ended December 31, 2023, the Company transferred 1,242,000 treasury shares to employees under Employee Incentive Schemes at a cost of HK\$225,000 (equivalent to RMB204,000 approximately) in total at prices ranging from HK\$0.30 to HK\$4.01 per share.

For the year ended December 31, 2023

#### 28. RESERVES

	Capital reserve RMB'000 (i)	Share premium RMB'000	Treasury shares RMB'000	Currency translation reserve RMB'000	Other reserve RMB'000	Share-based compensation <i>RMB'000</i> (ii)	Accumulated losses RMB'000	<b>Total</b> <i>RMB'000</i>
Balance at January 1, 2022	54,800	9,419,815	_	44,476	_	27,356	(6,549,788)	2,996,659
Loss for the year	-	-	-	-	_		(892,247)	(892,247)
Exchange differences	_	_	_	314,261	_	_	(052,247)	314,261
Share-based payments	_	_	_	-	_	43.995	_	43,995
Issue of shares held in trust	_	_	_*	_	_		_	-*
Issue of shares to employees								
under Employee Incentive Schemes	-	8.034	_	_	_	_	_	8,034
Transfer of treasury shares to employees		0,001						0,001
under Employee Incentive Schemes	-	2,471	_*	_	_	_	-	2,471
Balance at December 31, 2022	54,800	9,430,320	_*	358,737	-	71,351	(7,442,035)	2,473,173
Balance at January 1, 2023	54,800	9,430,320	-	358,737	_	71,351	(7,442,035)	2,473,173
Loss for the year		-	-	-	-	-	(747,794)	(747,794
Exchange differences	-	-	-	55,252	-	-	-	55,252
Share-based payments		-	-	-	-	14,458	-	14,458
Issue of shares held in trust		-	_*	-	-	-	-	-
Issue of shares to employees								
under Employee Incentive Schemes		6,406	-	-	-	-	-	6,406
Transfer of treasury shares to employees								
under Employee Incentive Schemes	-	204	_*	-	-	-	-	204
Balance at December 31, 2023	54,800	9,436,930	_*	413,989	-	85,809	(8,189,829)	1,801,699

\* The amounts are less than RMB1,000.

(i): Capital reserve arose from the capital contribution of patents, which were recognised as intangible assets, from CARsgen Therapeutics' equity shareholder, Shanghai Yijie Bio-tech Co., Ltd., on the date of CARsgen Therapeutics' incorporation.

(ii): Share-based payments arose from share-based payments granted to employees of the Group (Note 29).

#### **29. SHARE-BASED PAYMENTS**

#### (a) Employee share option schemes

The Group adopted a number of share incentive plans to provide long-term incentives for its employees and directors of the Group to deliver long-term shareholder returns. Under the plans, participants are granted options which only vest if certain conditions are met. 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.

During the years ended December 31, 2023 and 2022, the Group adopted the following share option plans to provide certain employees and directors of the Group, with rewards for their services, full time devotion and professional expertise to certain of the Group's subsidiaries.

Share option scheme	Number of options granted	Exercise price per share option (HK\$)
2022 Share option Scheme ("2022 Plan") 2022 Additional Share option Scheme	5,013,002	16.32
("2022 Additional Plan")	1,004,000	13.58
2023 Share option Scheme ("2023 Plan")	3,394,000	14.46
2023 Additional Share option Scheme ("2023 Additional Plan")	622,000	11.39

Under the 2022 Plan, 800,000 options can be vested in several tranches with the following vesting schedule: 25% of the share options can be vested on the first anniversary of the vesting commencement date and the remaining 75% are to be vested monthly thereafter in 36 equal monthly installments. 4,213,002 options can be vested in several tranches with the following vesting schedule: 25% of the share options can be vested on the fourth anniversary of the vesting commencement date separately.

Under the 2022 Additional Plan, 800,000 options can be vested in several tranches with the following vesting schedule: 25% of the share option can be vested on the fourth anniversary of the vesting commencement date separately. 204,000 options can be vested in several tranches with the following vesting schedule: 25% of the share options can be vested the first anniversary of the vesting commencement date and the remaining 75% are to be vested monthly thereafter in 36 equal monthly instalments.

For the year ended December 31, 2023

#### 29. SHARE-BASED PAYMENTS (continued)

#### (a) Employee share option schemes (continued)

Under the 2023 Plan and 2023 Additional Plan, those granted options can be vested in several tranches with the following vesting schedule: 25% of the share options can be vested on the fourth anniversary of the vesting commencement date respectively.

The following table summarises the Group's share option movements during the years ended December 31, 2023 and 2022.

	2023		20	22
	Average		Average	
	exercise		exercise	
	price per	Number	price per	Number
	share	of share	share	of share
	option	options	option	options
	HK\$		HK\$	
Outstanding as at beginning				
of the year	7.41	18,692,186	3.62	20,651,338
Execution of employee share option	4.94	(1,474,856)	1.85	(6,583,624)
Granted during the year	13.98	4,016,000	15.86	6,017,002
Forfeited during the year	18.40	(2,504,300)	13.91	(1,392,530)
Outstanding as at the end of the year	7.61	18,729,030	7.41	18,692,186



#### 29. SHARE-BASED PAYMENTS (continued)

#### (a) Employee share option schemes (continued)

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

#### 2023

options Exercise price* Exercise pe <i>'000 HK\$ per share</i>	eriod
11,186 0.00-10.81 December 28, 2020 to December 27,	2028
157 31.00 July 22, 2022 to July 21,	2031
2,761 16.32 March 24, 2023 to March 23,	2032
972 13.58 April 7, 2023 to October 20,	2032
3,031 14.46 April 13, 2024 to April 12,	2033
622 11.39 November 28, 2024 to November 27,	2033
18,729	

2022

Number of options ′000	Exercise price* <i>HK\$ per share</i>	Exercise period
12,896	0.00-10.81	December 28, 2020 to December 27, 2028
679	31.00	July 22, 2022 to July 21, 2031
4,145	16.32	March 24, 2023 to March 23, 2032
972	13.58	April 7, 2023 to October 20, 2032
18,692		

For the year ended December 31, 2023

#### 29. SHARE-BASED PAYMENTS (continued)

#### (b) Employee restricted share schemes

The Group adopted a number of employee restricted share plans to provide long-term incentives for its employees and directors of the Group to deliver long-term shareholder returns. Under the plans, participants are granted restricted shares which only vest if certain conditions are met. 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.

During the years ended December 31, 2023 and 2022, the Group adopted the following restricted share plans to provide certain employees and directors of the Group, with rewards for their services, full time devotion and professional expertise to certain of the Group's subsidiaries.

	Number of restricted
Restricted share scheme	shares granted
2022 Stock RSU Scheme ("2022 RSU Plan")	701,276
2022 Additional Stock RSU Scheme ("2022 RSU Additional Plan")	1,719,000
2023 Stock RSU Scheme ("2023 RSU Plan")	2,012,554
2023 Additional Stock RSU Scheme ("2023 RSU Additional Plan")	45,500

The following table summarises the Group's restricted share incentive scheme activities during the year ended December 31, 2023 and 2022.

	2023 Number of restricted shares	2022 Number of restricted shares
<b>Executed by the Company:</b> Outstanding as at beginning of the year	2,937,098	1,568,957
Granted during the year	2,058,054	2,420,276
Vested during the year Forfeited during the year	(769,107) (1,035,005)	(436,943) (615,192)
Outstanding as at the end of the year	3,191,040	2,937,098

#### 29. SHARE-BASED PAYMENTS (continued)

#### (b) Employee restricted share schemes (continued)

The exercise periods of the restricted shares outstanding as at the end of the reporting period are as follows:

#### 2023

Number of restricted shares ′000	Vesting period
192	July 22, 2022 to July 21, 2025
295	March 24, 2023 to March 23, 2026
1,064	October 22, 2023 to October 21, 2026
1,594	April 13, 2024 to April 12, 2027
46	November 28, 2024 to November 27, 2027
3,191	

2022

Vesting period	Number of restricted shares '000
July 22, 2022 to July 21, 2025	858
March 24, 2023 to March 23, 2026	394
October 22, 2023 to October 21, 2026	1,685
	2,937

For the year ended December 31, 2023

#### 29. SHARE-BASED PAYMENTS (continued)

#### (c) Fair value of share options and restricted shares granted

The assessed fair values at grant date of share options and restricted shares granted during the years ended December 31, 2023 and 2022 were as follows:

Share option and restricted share schemes	Fair value as at grant date RMB'000
2022 Plan	32,682
2022 Additional Plan	5,786
2022 RSU Plan	9,310
2022 RSU Additional Plan	19,186
2023 Plan	16,792
2023 Additional Plan	2,456
2023 RSU Plan	25,461
2023 RSU Additional Plan	432

The fair value of restricted shares at the grant date approximates to the fair value of ordinary shares.

The fair value of share options at grant date is independently determined using the binomial option-pricing model by taking into account the exercise price, fair value of ordinary shares at the grant date, the term of the option, the expected price volatility, the expected dividend yield, and the risk free interest rate.

The model inputs for share options granted during the years ended December 31, 2023 and 2022 are:

	2023 Plan	2023 Additional Plan	2022 Plan	2022 Additional Plan
Exercise price	HK\$14.46	HK\$11.39	HK\$16.32	HK\$13.58
Risk-free interest rate	2.89%	3.64%	2.12%	4.17%
Volatility	49.65%	47.36%	47.22%	45.68%
Expected dividend yield	Nil	Nil	Nil	Nil

The directors estimated the risk-free interest rate based on the yield of curve of US Treasury strips with a maturity life close to the life of share option. Volatility was estimated at the grant date based on the average of historical volatility of the comparable companies with length commensurable to the time to maturity of the share option. Dividend yield is based on the directors' estimation at the grant date.

#### 29. SHARE-BASED PAYMENTS (continued)

#### (d) Expenses arising from Share-based payment transactions

Expenses for the share-based payments have been charged to profit or loss as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Administrative expenses Research and development expenses	548 13,910	7,685 36,310
Total	14,458	43,995

At the end of the reporting period, the Company had 18,729,030 share options and 3,191,040 restricted shares outstanding under the share option schemes and restricted share schemes. The exercise or vesting in full of the outstanding share options and restricted shares would, under the present capital structure of the Company, result in the issue of 21,920,070 additional ordinary shares of the Company and additional share capital of USD5.48 (before issue expenses).

At the date of approval of these financial statements, the Company had 18,467,989 share options and 2,959,492 restricted shares outstanding under the share option schemes and the restricted share schemes, which represented approximately 3.72% of the Company's shares in issue as at that date.

For the year ended December 31, 2023

#### **30. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS**

#### (a) Major non-cash transactions

During the year, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB1,457,000 (2022: RMB19,135,000) in respect of lease arrangements for offices and dormitory.

#### (b) Changes in liabilities arising from financing activities

	Borrowings and interest payables <i>RMB'000</i>	Lease liabilities <i>RMB'000</i>	
At January 1, 2022	227,099	111,339	
Changes from financing cash flows	(230,218)	(16,801)	
New leases	_	19,135	
Termination of leases	_	(6,581)	
Interest expenses	10,541	4,980	

At December 31, 2022	7,422	112,072
----------------------	-------	---------

	Borrowings and interest payables <i>RMB'000</i>	Lease liabilities <i>RMB'000</i>
At 1	7 422	442.072
At January 1, 2023	7,422	112,072
Changes from financing cash flows	(5,143)	(23,306)
New leases	-	1,457
Termination of leases	-	(11,913)
Interest expenses	276	4,388
At December 31, 2023	2,555	82,698

#### (c) Total cash outflow for leases

The total cash outflow for leases included in the consolidated statement of cash flows is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Within operating activities	3,085	1,537
Within financing activities	23,306	16,801
Total	26,391	18,338

#### **31. PLEDGE OF ASSETS**

Details of the Group's assets pledged for the Group's borrowings are included in notes 14 and 15 to the consolidated financial statements.

#### **32. COMMITMENTS**

#### (a) Capital commitments

Capital expenditure contracted for by the Group at the end of each reporting period but not yet incurred is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Property, plant and equipment	1,436	2,923

#### **33. RELATED PARTY TRANSACTIONS**

The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of business during the years ended December 31, 2023 and 2022.

#### (a) Key management compensation

Compensation for key management other than those for directors as disclosed in Note 9 is set out below.

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Basic salaries, share-based payments, other allowances and		
benefits in kind	36,451	32,590
Discretionary bonus	2,369	3,907
Social security costs	807	973
Total	39,627	37,470

For the year ended December 31, 2023

#### 34. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of the reporting period are as follows:

Financial assets	2023	2022
	RMB'000	<i>RMB'000</i>
Other receivables	9,792	11,834
Financial assets included in other non-current assets	6,578	1,784
Cash and bank balances	1,849,752	2,268,036
Total	1,866,122	2,281,654
Financial liabilities	2023	2022
	RMB'000	<i>RMB'000</i>
Borrowings – current	2,522	4,850
Borrowings – non-current	-	2,523
Financial liabilities included in accruals and other payables	118,587	86,003
Total	121,109	93,376



For the year ended December 31, 2023

#### 35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

#### **35.1 Financial risk factors**

The Group's principal financial instruments comprise borrowings and cash and bank balances. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as other receivables, financial assets included in other non-current assets and prepayments, and financial liabilities included in other payables and accruals, which arise directly from its operations.

The main risks arising from the Group's financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

#### Foreign currency risk

Foreign exchange risk arises when future commercial transactions or recognised assets and liabilities are denominated in a currency that is not the functional currency of the relevant group entity.

The Group has operations in the US and the PRC. There are certain cash and bank balances, other receivables, accruals and other payables denominated in a currency that is not the functional currency. The Group constantly reviews the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary.

At December 31, 2023 and 2022, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, the net loss for the years would have been RMB89,794,000 higher/lower and RMB77,949,000 higher/lower, respectively.

#### Credit risk

The carrying amounts of cash and bank balances, other receivables and financial assets included in other non-current assets and prepayments included in the consolidated statement of financial position represent the Group's maximum exposure to credit risk in relation to its financial assets.

As at December 31, 2023 and 2022, cash and bank balances were all deposited with high quality financial institutions without significant credit risk. While cash and bank balances are also subject to the impairment requirements of IFRS 9, the identified impairment loss was immaterial.

Management has assessed that during the years ended December 31, 2023 and 2022, other receivables and financial assets included in other non-current assets and prepayments 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 management. The Group does not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables was recognised.

For the year ended December 31, 2023

#### 35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

#### 35.1 Financial risk factors (continued)

#### Liquidity risk

The Group aims to maintain sufficient cash and bank balances. Due to the dynamic nature of the underlying business, the policy of the Group is to regularly monitor the Group's liquidity risk and to maintain adequate cash and bank balances to meet the Group's liquidity requirements.

The maturity profile of the Group's financial liabilities as at the end of the reporting period, based on the contractual undiscounted payments, is as follows:

	Less than 1 year RMB'000	Between 1 and 2 years RMB'000	Between 2 and 5 years RMB'000	Over 5 years RMB'000	<b>Total</b> <i>RMB'000</i>
A					
As at December 31, 2023					
Accruals and other payables	118,587	-	-	-	118,587
Borrowings	2,577	-	-	-	2,577
Lease liabilities	15,362	15,252	42,095	22,976	95,685
Total	136,526	15,252	42,095	22,976	216,849
As at December 31, 2022					
Accruals and other payables	86,003	_	_	_	86,003
Borrowings	5,097	2,546	_	_	7,643
Lease liabilities	21,451	18,936	50,332	39,580	130,299
Total	112,551	21,482	50,332	39,580	223,945

#### 35.2 Capital management

The Group's objectives of managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for equity holders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may return capital to equity holders, issue new shares, make borrowings or sell assets to reduce debt. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the years ended December 31, 2023 and December 31, 2022.

The Group monitors capital by regularly reviewing the capital structure. As a part of this review, the Company considers the cost of capital and the risks associated with the issued share capital. In the opinion of the directors of the Company, the Group's capital risk is low.

#### 35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

#### 35.3 Fair value estimation

#### (i) Fair value hierarchy

As at December 31, 2023 and 2022, the Group has no assets or liabilities that are measured at fair value.

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements for the year ended December 31, 2023.

#### (ii) Valuation techniques used to determine fair values

Specific valuation techniques used to value financial instruments include the binomial optionpricing model or discounted cash flow analysis.

There were no changes in valuation techniques for the years ended December 31, 2023 and 2022.

#### (iii) Valuation processes

The finance department of the Group has a team that performs the valuation of financial instruments required for financial reporting purposes. This team reports directly to the the board of directors.

#### **36. EVENTS AFTER THE REPORTING PERIOD**

On March 1, 2024, the Company announced that the National Medical Products Administration ("NMPA") of China has approved the New Drug Application ("NDA") of zevorcabtagene autoleucel, for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy. According to the contract with Huadong Medicine Co., Ltd., the Company has received the first commercial milestone payments of RMB75 million as at the date of this report.

For the year ended December 31, 2023

#### **37. FINANCIAL POSITION AND RESERVE MOVEMENT OF THE COMPANY**

#### (a) Statement of Financial Position of the Company

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
NON-CURRENT ASSETS		
Investments in subsidiaries	732,388	705,894
Other receivables	3,510,022	2,864,149
Total non-current assets	4,242,410	3,570,043
CURRENT ASSETS		
Cash and cash equivalents	1,074,376	1,610,852
Total current assets	1,074,376	1,610,852
CURRENT LIABILITIES		
Accruals and other payables	6,642	4,407
NET CURRENT LIABILITIES	1,067,734	1,606,445
	1,007,754	1,000,445
TOTAL ASSETS LESS CURRENT LIABILITIES AND		
NET ASSETS	5,310,144	5,176,488
	5,510,111	3,170,100
EQUITY		
Share capital	1	1
Reserves	5,310,143	5,176,487
Total equity	5,310,144	5,176,488

#### 37. FINANCIAL POSITION AND RESERVE MOVEMENT OF THE COMPANY (continued)

#### (b) Reserve movement of the Company

	Share premium <i>RMB'000</i>	Treasury shares RMB'000	Currency translation reserve RMB'000	Other reserve RMB'000	Share-based compensation RMB'000	Accumulated losses RMB'000	<b>Total</b> <i>RMB'000</i>
Balance at January 1, 2022	9,682,487	_	11,375	_	27,356	(5,032,322)	4,688,896
Loss for the year	5,002,407	_	-	_	27,550	(2,010)	(2,010)
Exchange differences	_	_	435,101	_	-	(2,010)	435,101
Share-based payments	_	-	-	_	43,995	_	43,995
Issue of shares held in trust	_	_*	_	_	-	_	_*
Issue of shares to employees							
under Employee Incentive Schemes	8,034	_	_	_	-	-	8,034
Transfer of treasury shares to employees							-, ·
under Employee Incentive Schemes	2,471	-	-	-	-	-	2,471
Balance at December 31, 2022	9,692,992	_*	446,476	-	71,351	(5,034,332)	5,176,487
						(	
Balance at January 1, 2023	9,692,992		446,476	-	71,351	(5,034,332)	5,176,487
Profit for the year			-	-	-	24,599	24,599
Exchange differences			87,989	-	-	-	87,989
Share-based payments		-	-	-	14,458	-	14,458
Issue of shares held in trust		_*	-	-		-	-*
Issue of shares to employees							
under Employee Incentive Schemes	6,406			-		-	6,406
Transfer of treasury shares to employees							
under Employee Incentive Schemes	204	-	-	-	-	-	204
Balance at December 31, 2023	9,699,602	_*	534,465	_	85,809	(5,009,733)	5,310,143

\* The amounts are less than RMB1,000.

#### **38. APPROVAL OF THE FINANCIAL STATEMENTS**

The financial statements were approved and authorised for issue by the board of directors on March 26, 2024.

# **Financial Summary**

	As at December 31,				
	2023	2022	2021	2020	2019
	RMB'000	<i>RMB'000</i>	<i>RMB'000</i>	RMB'000	<i>RMB'000</i>
Total current assets	1,873,088	2,300,639	3,070,853	1,055,795	115,000
Total non-current assets	384,126	462,180	434,782	198,056	210,811
Total assets	2,257,214	2,762,819	3,505,635	1,253,851	325,811
Total current liabilities	196,217	171,004	389,172	145,231	1,021,370
Total non-current liabilities	259,297	118,641	119,803	2,784,748	37,045
Total liabilities	455,514	289,645	508,975	2,929,979	1,058,415
Equity attributable to equity holders					
of the Company	1,801,700	2,473,174	2,996,660	(1,676,128)	(732,604)
Total equity/(deficit)	1,801,700	2,473,174	2,996,660	(1,676,128)	(732,604)
Total equity and liabilities	2,257,214	2,762,819	3,505,635	1,253,851	325,811

	For the year ended December 31				
	2023	2022	2021	2020	2019
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Revenue		_	25,813	_	_
Gross profit	_	_	25,813	_	_
Operating loss	(767,649)	(881,297)	(573,905)	(327,045)	(227,400)
Loss before income tax	(747,387)	(890,952)	(4,736,778)	(1,064,049)	(265,133)
Loss for the year	(747,794)	(892,247)	(4,744,423)	(1,064,049)	(265,133)
Loss attributable to equity holders					
of the Company	(747,794)	(892,247)	(4,744,423)	(1,064,049)	(265,133)

## **Forward-Looking Statements**

All statements in this report that are not historical fact or that do not relate to present facts or current conditions are forward-looking statements. Such forward-looking statements express the Group's current views, projections, beliefs and expectations with respect to future events as of the date of this report. Such forward-looking statements are based on a number of assumptions and factors beyond the Group's control. As a result, they are subject to significant risks and uncertainties, and actual events or results may differ materially from these forward-looking statements and the forward-looking events discussed in this report might not occur. Such risks and uncertainties include, but are not limited to, those detailed under the heading "Principal Risks and Uncertainties" in our most recent annual report and interim report and other announcements and reports made available on our corporate website, https://www.carsgen.com. No representation or warranty is given as to the achievement or reasonableness of, and no reliance should be placed on, any projections, targets, estimates or forecasts contained in this report.

# Definitions

"2019 Equity Incentive Plan"	the equity incentive plan of our Company as adopted by way of written resolutions of the Board on January 22, 2019, the principal terms of which are set out in the section headed "Statutory and General Information – D. 2019 Equity Incentive Plan" in the Prospectus
"affiliate"	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
"Articles of Association"	the memorandum and articles of association of the Company
"Audit Committee"	the audit committee of the Company
"Board of Directors", "Board" or "our Board"	our board of Directors
"BVI"	the British Virgin Islands
"CARsgen Life Sciences"	CARsgen Life Sciences Co., Ltd (愷興生命科技(上海)有限公司), a wholly foreign-owned enterprise incorporated in the PRC on March 22, 2018 and an indirectly wholly-owned subsidiary of our Company
"CARsgen Pharmaceuticals"	CARsgen Pharmaceuticals Co., Ltd (上海科濟製藥有限公司), a company incorporated in the PRC with limited liability on November 15, 2017 and wholly-owned by CARsgen Therapeutics (Shanghai)
"CARsgen Therapeutics (Shanghai)"	CARsgen Therapeutics Co., Ltd (科濟生物醫藥(上海)有限公司), a company incorporated in the PRC with limited liability on October 30, 2014, and one of our Consolidated Affiliated Entities
"China" or "PRC"	the People's Republic of China, which for the purpose of the Prospectus and for geographical reference only, excludes Hong Kong, Macao and Taiwan
"Company", "our Company", "the Company", "CARsgen Therapeutics" or "CARsgen"	CARsgen Therapeutics Holdings Limited (科濟藥業控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on February 9, 2018
"Companies Ordinance"	the Companies Ordinance (Cap. 622), as amended, supplemented or otherwise modified from time to time
"Consolidated Affiliated Entities"	the entities we control through the Contractual Arrangements, namely CARsgen Therapeutics (Shanghai) and its wholly-owned subsidiary, CARsgen Pharmaceuticals
"Contractual Arrangements"	the series of contractual arrangements entered into among CARsgen Life Sciences, CARsgen Therapeutics, the Corporate Registered Shareholder and the Individual Registered Shareholders details of which are described in the section headed "Contractual Arrangements" in this report

"Core Product Candidate"	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to CT053
"Corporate Governance Code" or "CG Code"	the Corporate Governance Code set out in Appendix C1 to the Listing Rules
"Corporate Registered Shareholder"	YIJIE Biotech (Shanghai) Holding Limited (上海益傑生物技術有限公司), being the registered shareholder of CARsgen Therapeutics
"Director(s)"	the director(s) of the Company
"Group", "our Group", "we", "us" or "our"	our Company, its subsidiaries and consolidated affiliated entities from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries and consolidated affiliated entities, such subsidiaries and consolidated affiliated entities as if they were subsidiaries and consolidated affiliated entities of our Company at the relevant time
"HK\$" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong
"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the People's Republic of China
"Individual Registered Shareholders"	Dr. Zonghai Ll, Mr. Bingsen GUO, Dr. Huamao WANG, Mr. Huaqing GUO and Mr. Haiou CHEN, being the registered shareholders of the Corporate Registered Shareholder
"Latest Practicable Date"	April 8, 2024, being the latest practicable date prior to the printing of this report for the purpose of ascertaining certain information contained in this report
"Listing Date"	June 18, 2021
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"Model Code"	Model Code for Securities Transactions by Directors of Listed Issuers
"MOFCOM"	the Ministry of Commerce of the PRC (中華人民共和國商務部)
"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)
"Nomination and Corporate Governance Committee"	the nomination and corporate governance committee of the Company
"NMPA"	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA

## Definitions

"Post-IPO RSU Scheme"	the post-IPO RSU scheme adopted by our Company on April 30, 2021, the principal terms of which are set out in the section headed "Appendix V – Statutory and General Information" in the Prospectus
"Post-IPO Share Option Scheme"	the post-IPO share option scheme adopted by our Company on April 30, 2021, the principal terms of which are set out in the section headed "Appendix V – Statutory and General Information" in the Prospectus
"Prospectus"	the prospectus issued by the Company on June 7, 2021 in connection with the IPO
"Reporting Period"	the period from January 1, 2023 to December 31, 2023
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"RSU(s)"	restricted share unit(s)
"Remuneration Committee"	the remuneration committee of the Company
"Share(s)"	ordinary share(s) in the share capital of our Company with a par value of US\$0.00000025 each
"SFO"	the Securities and Futures Ordinance (Cap. 571), as amended, supplemented or otherwise modified from time to time
"United States" or "U.S." or "US"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US\$" or "U.S. dollars" or "USD"	United States dollars, the lawful currency of the United States

In this report, the terms "associate", "connected person", "controlling shareholder" and "subsidiary" shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

# Glossary

"ADCC"	antibody-dependent cellular cytotoxicity is an immune mechanism through which Fc receptor-bearing effector cells recognize and kill antibody-coated target cells expressing tumor- or pathogen-derived antigens on their surface
"antigen"	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body's infection-fighting white blood cells
"BCMA"	B-cell maturation antigen, a protein that is highly expressed in multiple myeloma with limited expression on normal tissues other than plasma cells
"BLA"	Biologics License Application
"B2M"	beta 2 microglobulin
"CAR(s)"	chimeric antigen receptor(s)
"CAR-T" or "CAR T"	chimeric antigen receptor T cell
"CD19"	a cell surface protein expressed on the surface of almost all B cell leukemia and lymphoma
"CDC"	complement-dependent cytotoxicity, an effector function of IgG and IgM antibodies $% \left( {{\left[ {{\left[ {{\left[ {\left[ {\left[ {\left[ {\left[ {\left[ {\left[ $
"CDE"	Center for Drug Evaluation, an institution under the NMPA
"CGMP"	Current Good Manufacturing Practices
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"CLDN18.2"	Claudin18.2, a target in the treatment of certain solid tumors such as gastric cancer, esophageal cancer and pancreatic cancer
"CMC"	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
"cohort"	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
"combination therapy"	treatment in which a patient is given two or more therapeutic agents for the treatment of a single disease
"CRS"	Cytokine Release Syndrome, a form of systemic inflammatory response syndrome that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T cell therapies

## Glossary

"CycloCAR®"	a next-generation CAR-T technology under development by the Company, which features co-expression of cytokines IL-7 and chemokine CCL21 in the CAR T-cells to potentially improve clinical efficacy and reduced requirement for lymphodepletion conditioning
"cytokine"	a broad and loose category of small proteins that are important in cell signaling. Their release affects the growth of all blood cells and other cells that help the body's immune and inflammation responses
"EGFR"	epidermal growth factor receptor
"EGFRvIII"	variant III of epidermal growth factor receptor
"EMA"	European Medicines Agency
"FDA" or "U.S. FDA"	U.S. Food and Drug Administration
"GMP"	Good Manufacturing Practice
"GPC3"	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
"Grade"	term used to refer to the severity of adverse events
"GvHD"	graft versus host disease
"HCC"	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
"HLA"	human leukocyte antigen
"HvGR"	host versus graft response
"ІНС"	immunohistochemistry, which is the identification of antigens in tissues using antibodies that are linked to enzymes, fluorescent dyes, or radioactive labels. IHC is used to diagnose and track specific cellular anomalies, such as cancers
"IIT" or "investigator-initiated trial"	clinical trial sponsored and conducted by independent investigators
"IND"	Investigational New Drug or investigational new drug application, also known as clinical trial application in China
"LADAR®"	Local Action Driven by Artificial Receptor technology, with similar mechanism of synNotch system, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor
"mAb" or "monoclonal antibody"	antibodies that are made by identical immune cells which are all clones belonging to a unique parent cell

"mesothelin"	cell-surface protein whose expression is mostly restricted to mesothelial cell layers lining the pleura, pericardium and peritoneum
"MM" or "R/R MM"	multiple myeloma, a type of cancer that forms in the white blood cells; cancer that relapses or does not respond to treatment is called relapsed and/or refractory multiple myeloma
"NDA"	New Drug Application
"NK cell"	natural killer cell, the human body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
"NKG2A"	also named KLRC1, killer cell lectin-like receptor subfamily C, member 1
"NMPA"	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA
"neurotoxicity"	possible adverse side effect of T cell therapies that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"Phase I"	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 Ib"	a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial
"Phase II"	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 disease, and to determine dosage tolerance and optimal dosage
"confirmatory trial" or "pivotal trial"	the trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"PRIME"	PRIority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on medicine's benefits and risks, and accelerate assessment of medicines applications, for medicines that target an unmet medical need with advantages over existing treatments

# Glossary

"Regenerative Medicine Advanced Therapy" or "RMAT"	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition
"solid tumor"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"TCR"	T cell receptor
"THANK-uCAR®"	the Company's proprietary technology to generate CAR T cells with improved expansion and persistence from T cells that are sourced from third-party donors
"United States" or "U.S."	the United States of America, its territories, its dependencies and all areas subject to its jurisdiction