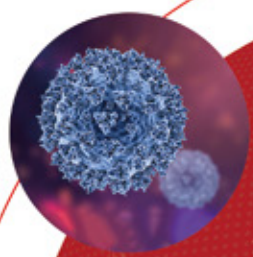
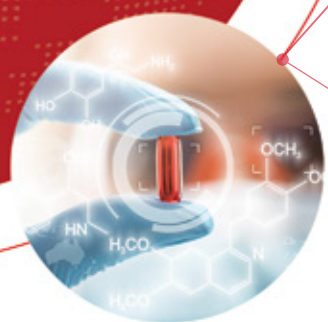
Zai Lab Limited
再鼎醫藥有限公司

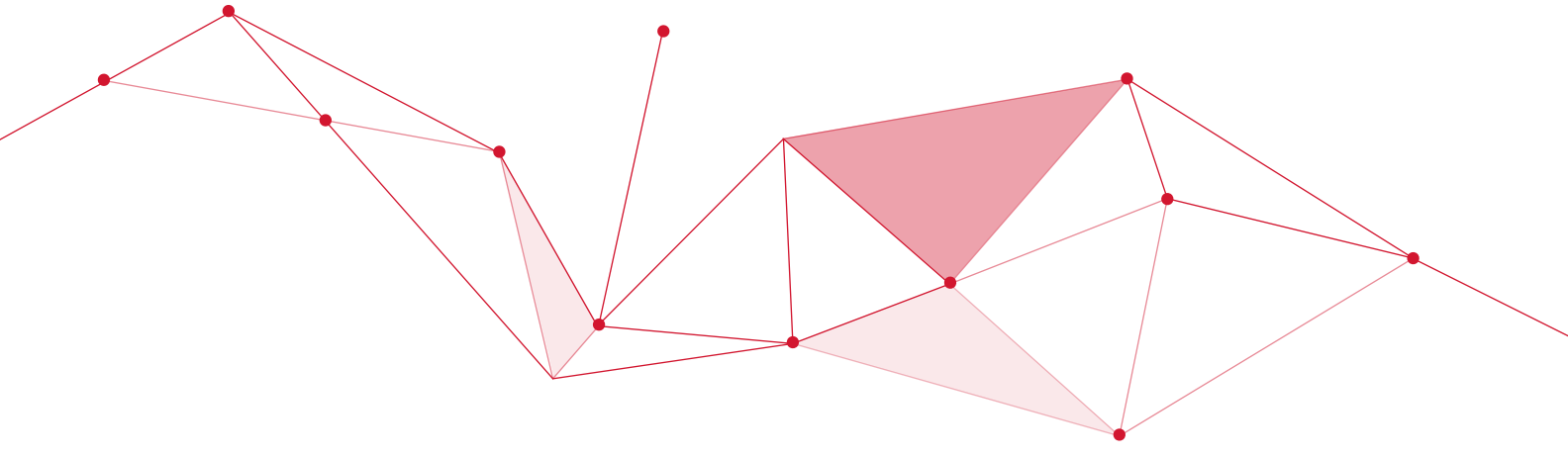
(incorporated in the Cayman Islands with limited liability)
HKEX: 9688
NASDAQ: ZLAB

(於開曼群島註冊成立的有限公司)
香港聯交所：9688
納斯達克：ZLAB



2021
INTERIM REPORT
中期報告





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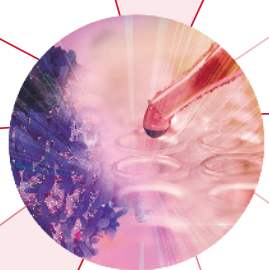

DEFINITIONS

In this report, unless the context otherwise requires, the following terms have the following meanings. These terms and their definitions may not correspond to any industry standard definition, and may not be directly comparable to similarly titled terms adopted by other companies operating in the same industries as the Company.

"ADS(s)"	American Depositary Shares (each representing one Share of our Company)
"Chairperson"	chairperson of the Board
"China", "mainland China" or "PRC"	the People's Republic of China, which for the purpose of this report and for geographical reference only, excludes Hong Kong, Macau and Taiwan
"Company", "our Company", "the Company", "Zai Lab", "we" or "us"	Zai Lab Limited (NASDAQ: ZLAB; Hong Kong Stock Exchange Stock code: 9688), a company incorporated in the Cayman Islands with limited liability on March 28, 2013, the shares of which are listed on the NASDAQ and the Main Board of the Hong Kong Stock Exchange
"Core Product(s)"	ZEJULA and Tumor Treating Fields, the designated core products as defined under Chapter 18A of the Listing Rules
"Director(s)"	the director(s) of the Company
"FDA"	U.S. Food and Drug Administration
"Greater China"	China, Hong Kong, Macau and Taiwan
"Group", "our Group", "the Group", "we", "us" or "our"	the Company and its subsidiaries from time to time
"HK$" or "HK dollars" and "HK cents"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"Hong Kong Listing Rules" or "Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited
"Hong Kong Stock Exchange" or "Stock Exchange"	The Stock Exchange of Hong Kong Limited
"Latest Practicable Date"	August 9, 2021, being the latest practicable date prior to the publication of this report for the purpose of ascertaining certain information contained in this report

"Nasdaq"	the Nasdaq Global Market
"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) of the PRC, 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 SDA
"R&D"	research and development
"Reporting Period"	the six months ended June 30, 2021
"RMB"	Renminbi, the lawful currency of the PRC
"SEC"	the U.S. Securities and Exchange Commission
"SFC"	the Securities and Futures Commission of Hong Kong
"SFO"	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (as amended from time to time)
"Shareholder(s)"	holder(s) of Shares and, where the context requires, ADSs
"Shares"	ordinary share(s) of par value US$0.00006 per share, in the capital of the Company
"Takeovers Code"	the Hong Kong Codes on Takeovers and Mergers and Share Buy-backs (as amended from time to time)
"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US$"	United States dollars, the lawful currency of the United States
ZEJULA"	also known as niraparib, a once-daily small-molecule poly (ADP-ribose) polymerase 1/2 inhibitor

CORPORATE INFORMATION

BOARD OF DIRECTORS

Directors

Dr. Samantha Du *(Director, Chairperson and Chief Executive Officer)*

Mr. Tao Fu *(Director, President, Chief Operating Officer and Chief Strategy Officer) (resigned as Director, President and Chief Operating Officer and appointed as Chief Strategy Officer on May 7, 2021)*

Independent Directors

Dr. Kai-Xian Chen

Dr. John Diekman

Ms. Nisa Leung

Mr. William Lis

Mr. Leon O. Moulder, JR.

Mr. Peter Wirth

HEAD OFFICE AND PRINCIPAL PLACE OF BUSINESS IN THE PRC

4560 Jinke Road

Bldg. 1, 4/F

Pudong, Shanghai

China 201210

PRINCIPAL PLACE OF BUSINESS IN HONG KONG

Room 2301, 23/F.

Island Place Tower

510 King's Road

North Point

Hong Kong

AUTHORIZED REPRESENTATIVES

Dr. Samantha Du

4560 Jinke Road

Bldg. 1, 4/F

Pudong, Shanghai

China 201210

Mr. William Ki Chul Cho

4560 Jinke Road

Bldg. 1, 4/F

Pudong, Shanghai

China 201210

AUDIT COMMITTEE

Dr. John Diekman *(Chair)*

Mr. William Lis

Mr. Peter Wirth

COMPENSATION COMMITTEE

Mr. Peter Wirth *(Chair)*

Ms. Nisa Leung

Mr. Leon O. Moulder, Jr.

REGISTERED OFFICE

Harbour Place 2nd Floor

103 South Church Street

P.O. Box 472

Grand Cayman

KY1-1106

Cayman Islands

PRINCIPAL SHARE REGISTRAR AND TRANSFER AGENT

International Corporation Services Ltd.

P.O. Box 472, Harbour Place

2nd Floor, 103 South Church Street

George Town,

Grand Cayman

KY1-1106

Cayman Islands

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

COMPLIANCE ADVISOR

Somerley Capital Limited
20/F, China Building
29 Queen's Road Central
Hong Kong

NOMINATING COMMITTEE

Mr. Leon O. Moulder, Jr. *(Chair)*
Dr. John Diekman
Mr. William Lis

STOCK CODE

HKEX: 9688
NASDAQ: ZLAB

AUDITOR

Deloitte Touche Tohmatsu
Registered Public Interest Entity Auditors
35/F, One Pacific Place
88 Queensway
Hong Kong

COMPANY WEBSITE

http://www.zailaboratory.com/

FINANCIAL HIGHLIGHTS

	As of	
	June 30, 2021	December 31, 2020
	US$ (in thousands)	
Unaudited consolidated balance sheet data:		
Cash and cash equivalents	**1,766,573**	442,116
Short-term investments [(1)]	**—**	744,676
Total assets	**1,895,215**	1,297,638
Total shareholders' equity	**1,671,698**	1,169,345
Total current liabilities	**193,917**	98,043
Total non-current liabilities	**29,600**	30,250

(1) The short-term investment primarily comprises of the time deposits with original maturities between three months and one year.

	Six months ended June 30,	
	2021	2020
	US$ (in thousands, except for share and per share data)	
Unaudited consolidated statements of operations data:		
Revenue	**57,038**	19,213
Expenses:		
Cost of sales	**(18,373)**	(4,980)
Research and development	**(346,076)**	(102,049)
Selling, general and administrative	**(90,252)**	(42,472)
Loss from operations	**(397,663)**	(130,288)
Interest income	**458**	2,882
Interest expenses	**—**	(114)
Other income/(expense), net	**1,179**	(691)
Loss before income tax and share of loss from equity method investment	**(396,026)**	(128,211)
Income tax expense	**—**	—
Share of loss from equity method investment	**(208)**	(406)
Net loss	**(396,234)**	(128,617)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	**90,723,132**	73,847,551
Loss per share, basic and diluted	**(4.37)**	(1.74)

HONG KONG LISTING RULES

Under Rule 19C.11 of the Listing Rules, we are exempt from certain corporate governance requirements of the Hong Kong Stock Exchange, including Appendix 14 of the Listing Rules (Corporate Governance Code and Corporate Governance Report) and Appendix 16 of the Listing Rules (Disclosure of Financial Information).

In connection with our listing on the Hong Kong Stock Exchange, the Hong Kong Stock Exchange and the SFC granted certain waivers and exemptions from strict compliance with the relevant provisions of the Listing Rules and the SFO, respectively, and the SFC also granted a ruling under the Takeovers Codes (see below).

Not a public company in Hong Kong

Section 4.1 of the Introduction to the Takeovers Code provides that the Takeovers Code apply to takeovers, mergers and share buy-backs affecting, among others, public companies in Hong Kong and companies with a primary listing in Hong Kong. According to the Note to Section 4.2 of the Introduction to the Takeovers Code, a Grandfathered Greater China Issuer within the meaning of Rule 19C.01 of the Listing Rules with a secondary listing on the Hong Kong Stock Exchange will not normally be regarded as a public company in Hong Kong under Section 4.2 of the Introduction to the Takeovers Code.

The SFC granted, a ruling that we are not a "public company in Hong Kong" for the purposes of the Takeovers Code. Therefore, the Takeovers Code do not apply to us. In the event that the bulk of trading in our Shares migrates to Hong Kong on a permanent basis such that we would be treated as having a dual-primary listing pursuant to Rule 19C.13 of the Listing Rules, the Takeovers Code will apply to us.

Disclosure of Interests under Part XV of the SFO

Part XV of the SFO imposes duties of disclosure of interests in Shares. Under the U.S. Exchange Act, which we are subject to, any person (including directors and officers of the company concerned) who acquires beneficial ownership, as determined in accordance with the rules and regulations of the SEC and which includes the power to direct the voting or the disposition of the securities, of more than 5% of a class of equity securities registered under Section 12 of the U.S. Exchange Act must file beneficial owner reports with the SEC, and such person must promptly report any material change in the information provided (including any acquisition or disposition of 1% or more of the class of equity securities concerned), unless exceptions apply. Therefore, compliance with Part XV of the SFO would subject our corporate insiders to a second level of reporting, which would be unduly burdensome to them, would result in additional costs and would not be meaningful, since the statutory disclosure of interest obligations under the U.S. Exchange Act that apply to us and our corporate insiders would provide our investors with sufficient information relating to the shareholding interests of our significant shareholders.

The SFC granted a partial exemption under section 309(2) of the SFO from the provisions of Part XV of the SFO (other than Divisions 5, 11 and 12 of Part XV of the SFO), on the conditions that (i) the bulk of trading in the Shares is not considered to have migrated to Hong Kong on a permanent basis in accordance with Rule 19C.13 of the Listing Rules; (ii) the disclosures of interest filed in the SEC are also filed with the Hong Kong Stock Exchange as soon as practicable, which will then publish such disclosure in the same manner as disclosures made under Part XV of the SFO; and (iii) we will advise the SFC if there is any material change to any of the information which has been provided to the SFC, including any significant changes to the disclosure requirements in the U.S. and any significant changes in the volume of our worldwide share turnover that takes place on the Hong Kong Stock Exchange. This exemption may be reconsidered by the SFC in the event there is a material change in information provided to the SFC.

EXEMPTIONS AND WAIVERS

Corporate communication

Rule 2.07A of the Listing Rules provides that a listed issuer may send or otherwise make available to the relevant holders of its securities any corporate communication by electronic means, provided that either the listed issuer has previously received from each of the relevant holders of its securities an express, positive confirmation in writing or the shareholders of the listed issuer have resolved in a general meeting that the listed issuer may send or supply corporate communications to shareholders by making them available on the listed issuer's own website or the listed issuer's constitutional documents contain provision to that effect, and certain conditions are satisfied.

Since our listing on the Hong Kong Stock Exchange, we made the following arrangements:

- we issue all corporate communications as required by the Listing Rules on our own website in English and Chinese, and on the Hong Kong Stock Exchange's website in English and Chinese.

- we continue to provide printed copies of notice to our shareholders at no cost.

- we have added to the "Investor Relations" page of our website (http://www.zailaboratory.com) which directs investors to all of our filings with the Hong Kong Stock Exchange.

Monthly Return

Rule 13.25B of the Listing Rules requires a listed issuer to publish a monthly return in relation to movements in its equity securities, debt securities and any other securitized instruments, as applicable, during the period to which the monthly return relates.

Pursuant to the Joint Policy Statement Regarding the Listing of Overseas Companies, or Joint Policy Statement, we sought a waiver from Rule 13.25B subject to satisfying the waiver condition that the SFC has granted a partial exemption from strict compliance with Part XV of the SFO (other than Divisions 5, 11 and 12 of Part XV of the SFO). As we have obtained a partial exemption from the SFC, the Hong Kong Stock Exchange granted a waiver from strict compliance with Rule 13.25B of the Listing Rules. We disclose information about share repurchases, if material, in our quarterly or interim earnings releases, annual reports on Form 20-F, annual reports on Form 10-K, current reports on Form 6-K and current reports on Form 8-K which are furnished or filed with the SEC in accordance with applicable U.S. rules and regulations.

For further details of other waivers granted to the Company by the Hong Kong Stock Exchange and the SFC, please refer to the company information sheet of the Company dated August 2, 2021, which is available for viewing on the Hong Kong Stock Exchange's website at www.hkexnews.hk and the Company's website at www.zailaboratory.com.

OVERVIEW

We are a commercial stage, biopharmaceutical company with a substantial presence in both Greater China and the United States. We are discovering, developing and commercializing innovative products that target medical conditions with unmet needs affecting patients in China and worldwide, particularly in the areas of oncology, autoimmune disorders, and infectious diseases. As of August 9, 2021, we have three commercialized products that have received marketing approval in one or more territories in Greater China and twelve programs in late-stage product development. For further details about our Core Products and a summary of expenditure incurred on research and development activities, please refer to the sections headed "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. — Recent Developments — Recent Business Developments" and "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. — Factors Affecting our Results of Operations" in this report and the section headed "Business — Our Products and Drug Candidates Pipeline" in the prospectus of the Company dated September 17, 2020.

Cautionary statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to develop, or ultimately market, ZEJULA and Tumor Treating Fields in other clinically relevant indications successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the securities of the Company.

THE FOLLOWING SECTION SETS OUT A RE-PRODUCTION OF FULL SET OF FORM 10-Q OF THE COMPANY FILED WITH THE SECURITIES AND EXCHANGE COMMISSION OF THE UNITED STATES ON AUGUST 9, 2021, FOR INFORMATION PURPOSE.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-38205

ZAI LAB LIMITED

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands **(State or other jurisdiction of incorporation or organization)**	**98-1144595** **(I.R.S. Employer Identification No.)**
4560 Jinke Road **Bldg. 1, Fourth Floor** **Pudong** **Shanghai, China** **(Address of principal executive offices)**	**201210** **(Zip Code)**

+86 21 6163 2588
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 1 Ordinary Share, par value $0.00006 per share	**ZLAB**	**The Nasdaq Global Market**
Ordinary Shares, par value $0.00006 per share*	**9688**	**The Stock Exchange of Hong Kong Limited**

* Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 31, 2021, 95,408,743 ordinary shares of the registrant, par value $0.00006 per share, were outstanding, of which 65,826,281 ordinary shares were held in the form of American Depositary Shares.

Zai Lab Limited
Quarterly Report on Form 10-Q

PART I—FINANCIAL INFORMATION

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or SEC, on March 1, 2021.

This discussion contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potentially," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the risk factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K and those "Risk Factors" discussed below in Part II, Item 1A. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Financial Statements

Zai Lab Limited

Unaudited condensed consolidated balance sheets

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Notes	As of June 30, 2021 $	As of December 31, 2020 $
Assets			
Current assets:			
Cash and cash equivalents	3	1,766,573	442,116
Short-term investments	5	—	744,676
Accounts receivable (net of allowance of $5 and $1 as of June 30, 2021 and December 31, 2020, respectively)		18,029	5,165
Inventories	6	11,114	13,144
Prepayments and other current assets		12,887	10,935
Total current assets		1,808,603	1,216,036
Restricted cash, non-current	4	743	743
Investments in equity investees	7	1,070	1,279
Prepayments for equipment		1,846	274
Property and equipment, net	8	31,642	29,162
Operating lease right-of-use assets		17,015	17,701
Land use rights, net		7,849	7,908
Intangible assets, net		1,733	1,532
Long term deposits		891	862
Value added tax recoverable		23,823	22,141
Total assets		**1,895,215**	**1,297,638**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		125,621	62,641
Current operating lease liabilities		6,371	5,206
Other current liabilities	11	61,925	30,196
Total current liabilities		193,917	98,043
Deferred income		17,632	16,858
Non-current operating lease liabilities		11,968	13,392
Total liabilities		**223,517**	**128,293**
Commitments and contingencies (Note 17)			
Shareholders' equity			
Ordinary shares (par value of $0.00006 per share; 500,000,000 shares authorized, 94,758,189 and 87,811,026 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively)		6	5
Additional paid-in capital		2,799,318	1,897,467
Accumulated deficit		(1,109,837)	(713,603)
Accumulated other comprehensive loss		(16,865)	(14,524)
Treasury Stock (at cost, 6,086 and nil shares as of June 30, 2021 and December 31, 2020, respectively)		(924)	—
Total shareholders' equity		**1,671,698**	**1,169,345**
Total liabilities and shareholders' equity		**1,895,215**	**1,297,638**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Zai Lab Limited

Unaudited condensed consolidated statements of operations

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Notes	Three Months Ended June 30,		Six Months Ended June 30,	
		2021	2020	2021	2020
		$	$	$	$
Revenue	9	36,935	10,995	57,038	19,213
Expenses:					
Cost of sales		(10,868)	(2,896)	(18,373)	(4,980)
Research and development		(142,224)	(68,307)	(346,076)	(102,049)
Selling, general and administrative		(54,414)	(23,758)	(90,252)	(42,472)
Loss from operations		(170,571)	(83,966)	(397,663)	(130,288)
Interest income		244	1,227	458	2,882
Interest expenses		—	(55)	—	(114)
Other income (expense), net		7,406	2,434	1,179	(691)
Loss before income tax and share of loss from equity method investment		(162,921)	(80,360)	(396,026)	(128,211)
Income tax expense	10	—	—	—	—
Share of loss from equity method investment		(403)	(269)	(208)	(406)
Net loss		(163,324)	(80,629)	(396,234)	(128,617)
Net loss attributable to ordinary shareholders		(163,324)	(80,629)	(396,234)	(128,617)
Loss per share - basic and diluted	12	(1.76)	(1.08)	(4.37)	(1.74)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		93,045,531	74,738,563	90,723,132	73,847,551

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Zai Lab Limited

Unaudited condensed consolidated statements of comprehensive loss

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
Net loss	(163,324)	(80,629)	(396,234)	(128,617)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(5,241)	(1,173)	(2,341)	2,366
Comprehensive loss	(168,565)	(81,802)	(398,575)	(126,251)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Zai Lab Limited

Unaudited condensed consolidated statements of shareholders' equity

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Ordinary Shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Treasury Stock		Total
	Number of Shares	Amount				Shares	Amount	
		$	$	$	$		$	$
Balance at December 31, 2020	87,811,026	5	1,897,467	(713,603)	(14,524)	—	—	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	81,600	0	0	—	—	—	—	—
Exercise of shares option	58,364	0	702	—	—	—	—	702
Issuance of ordinary shares in connection with collaboration and license arrangement (Note 15)	568,182	0	62,250	—	—	—	—	62,250
Issuance cost adjustment for secondary listing	—	—	65	—	—	—	—	65
Share-based compensation	—	—	7,318	—	—	—	—	7,318
Net loss	—	—	—	(232,910)	—	—	—	(232,910)
Foreign currency translation	—	—	—	—	2,900	—	—	2,900
Balance at March 31, 2021	88,519,172	5	1,967,802	(946,513)	(11,624)	—	—	1,009,670
Issuance of ordinary shares upon vesting of restricted shares	32,100	0	0	—	—	—	—	0
Exercise of shares option	490,517	0	3,289	—	—	—	—	3,289
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $879	5,716,400	1	817,995	—	—	—	—	817,996
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(6,086)	(924)	(924)
Share-based compensation	—	—	10,232	—	—	—	—	10,232
Net loss	—	—	—	(163,324)	—	—	—	(163,324)
Foreign currency translation	—	—	—	—	(5,241)	—	—	(5,241)
Balance at June 30, 2021	94,758,189	6	2,799,318	(1,109,837)	(16,865)	(6,086)	(924)	1,671,698
Balance at December 31, 2019	68,237,247	4	734,734	(444,698)	4,620	—	—	294,660
Issuance of ordinary shares upon vesting of restricted shares	80,200	0	0	—	—	—	—	—
Exercise of shares option	49,278	0	346	—	—	—	—	346
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $740	6,300,000	0	280,568	—	—	—	—	280,568
Share-based compensation	—	—	6,463	—	—	—	—	6,463
Net loss	—	—	—	(47,988)	—	—	—	(47,988)
Foreign currency translation	—	—	—	—	3,539	—	—	3,539
Balance at March 31, 2020	74,666,725	4	1,022,111	(492,686)	8,159	—	—	537,588
Issuance of ordinary shares upon vesting of restricted shares	36,000	0	0	—	—	—	—	0
Exercise of shares option	179,613	0	2,729	—	—	—	—	2,729
Issuance cost for follow-on public offering	—	—	(13)	—	—	—	—	(13)
Share-based compensation	—	—	6,964	—	—	—	—	6,964
Net loss	—	—	—	(80,629)	—	—	—	(80,629)
Foreign currency translation	—	—	—	—	(1,173)	—	—	(1,173)
Balance at June 30, 2020	74,882,338	4	1,031,791	(573,315)	6,986	—	—	465,466

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. "0" in above table means less than 1,000 dollars.

Zai Lab Limited

Unaudited condensed consolidated statements of cash flows

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Six Months Ended June 30,	
	2021	2020
	$	$
Operating activities		
Net loss	(396,234)	(128,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for doubtful accounts	4	2
Inventory write-down	290	7
Depreciation and amortization expenses	2,975	2,107
Amortization of deferred income	(156)	(156)
Share-based compensation	17,550	13,427
Noncash research and development expenses (Note 15)	62,250	—
Share of loss from equity method investment	208	406
Loss on disposal of property and equipment	4	1
Noncash lease expenses	2,779	2,114
Changes in operating assets and liabilities:		
Accounts receivable	(12,868)	(3,235)
Inventories	1,740	(571)
Prepayments and other current assets	(1,952)	(948)
Long term deposits	(29)	(335)
Value added tax recoverable	(1,682)	(2,422)
Accounts payable	62,980	9,732
Other current liabilities	28,077	4,697
Operating lease liabilities	(2,214)	(1,539)
Deferred income	930	13,011
Net cash used in operating activities	(235,348)	(92,319)
Cash flows from investing activities:		
Purchases of short-term investments	—	(205,000)
Proceeds from maturity of short-term investments	743,902	200,000
Purchase of property and equipment	(5,647)	(1,303)
Purchase of intangible assets	(427)	(218)
Net cash provided by (used in) investing activities	737,828	(6,521)
Cash flows from financing activities:		
Repayment of short-term borrowings	—	(2,130)
Proceeds from exercises of stock options	3,992	3,075
Proceeds from issuance of ordinary shares upon public offerings	818,874	281,295
Payment of public offering costs	(1,323)	(740)
Employee taxes paid related to net share settlement of equity awards	(594)	—
Net cash provided by financing activities	820,949	281,500
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	1,028	12
Net increase in cash, cash equivalents and restricted cash	1,324,457	182,672
Cash, cash equivalents and restricted cash - beginning of period	442,859	76,442
Cash, cash equivalents and restricted cash - end of period	1,767,316	259,114
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	1,720	984
Payables for intangible assets	58	—
Payables for public offering costs	555	—
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	1,766,573	258,604
Restricted cash, non-current	743	510
Total cash and cash equivalents and restricted cash	1,767,316	259,114
Interest paid	—	122

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

1. Organization and principal activities

Zai Lab Limited (the "Company") was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (collectively referred to as the "Group") are focused on developing and commercializing therapies that address medical conditions with unmet medical needs including, in particular, oncology, autoimmune disorders and infectious diseases.

The Group's principal operations and geographic markets are in mainland China (hereinafter referred to as "China"), Hong Kong, Macau and Taiwan (hereinafter collectively referred to as "Greater China"). The Group has a substantial presence in Greater China and the United States.

2. Basis of presentation and consolidation and significant accounting policies

(a) Basis of presentation

The unaudited condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's unaudited condensed consolidated financial statements for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2020 condensed consolidated balance sheets data were derived from audited financial statements, but do not include all disclosures required by U.S. GAAP. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

(b) Principles of consolidation

The unaudited condensed consolidated financial statements include the financial statements of the Company and its subsidiaries. All intercompany transactions and balances among the Company and its subsidiaries are eliminated upon consolidation.

(c) Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, revenue recognition, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets and a lack of marketability discount of the ordinary shares issued in connection with collaboration and license arrangement (Note 15). Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

(d) Fair value measurements

The Group applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 - Unobservable inputs which are supported by little or no market activity.

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

ASC 820 describes three main approaches to measure the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Group primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, accounts payable and other payables. As of June 30, 2021 and December 31, 2020, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, accounts payable and other payable approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature of the assessment of the ability to recover these amounts.

(e) Recent accounting pronouncements

Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group adopted this standard on January 1, 2021. There was no material impact to the Group's financial position or results of operations upon adoption.

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

3. Cash and cash equivalents

	As of	
	June 30, 2021	December 31, 2020
	$	$
Cash at bank and in hand	1,465,757	441,283
Cash equivalents (note (i))	300,816	833
	1,766,573	442,116
Denominated in:		
US$	907,662	297,813
RMB (note (ii))	36,222	23,898
Hong Kong dollar ("HK$")	822,182	119,695
Australian dollar ("A$")	471	710
Taiwan dollar ("TW$")	36	—
	1,766,573	442,116

Note:

(i) Cash equivalents represent short-term and highly liquid investments in a money market fund.

(ii) Certain cash and bank balances denominated in RMB were deposited with banks in China. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the government of the People's Republic of China ("PRC").

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

4. Restricted cash, non-current

The Group's restricted cash balance of $743 and $743 as of June 30, 2021 and December 31, 2020, respectively, was long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Group.

5. Short-term investments

Short-term investments are primarily comprised of time deposits with original maturities between three months and one year.

As of June 30, 2021, the Group held no short-term investments. As of December 31, 2020, the Group's short-term investments consisted entirely of short-term held to maturity debt instruments with high credit ratings, which were determined to have remote risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of December 31, 2020.

6. Inventories

The Group's inventory balance of $11,114 and $13,144 as of June 30, 2021 and December 31, 2020, respectively, mainly consisted of finished goods purchased from Tesaro, Inc., now GlaxoSmithKline (GSK), for distribution in Hong Kong, and from NovoCure Limited ("Novocure") and Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong and China, as well as finished goods, work in process and certain raw materials for ZEJULA commercialization in China.

	As of	
	June 30, 2021	December 31, 2020
	$	$
Finished goods	4,477	3,041
Raw materials	6,269	10,103
Work in process	368	—
Inventories	11,114	13,144

The Group writes down inventory for any excess or obsolete inventories or when the Group believes that the net realizable value of inventories is less than the carrying value. During the three and six months ended June 30, 2021, the Group recorded write-downs of $277 and $290, respectively, in cost of revenues. During the three months and six months ended June 30, 2020, the Group recorded write-downs of $7 and $7, respectively, in cost of revenues.

7. Investments in equity investees

In June 2017, the Group entered into an agreement with three third parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group was RMB26,250 in cash, which was paid by the Group in 2017 and 2018, representing 20% and 18% of the equity interest of JING as of December 31, 2020 and June 30, 2021, respectively. The Group accounts for this investment using the equity method of accounting due to the fact that the Group can exercise significant influence on the investee. The Group recorded its gain on deemed disposal in this investee of nil and $463 for the three months and six months ended June 30, 2021, and recorded loss of $403 and $671 for its portion of JING's net loss for the three months and six months ended June 30, 2021, respectively. The Group recorded share of loss in this investee of $269 and $406 for the three and six months ended June 30, 2020, respectively.

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

8. Property and equipment, net

Property and equipment consist of the following:

	As of	
	June 30, 2021	December 31, 2020
	$	$
Office equipment	444	430
Electronic equipment	3,269	2,646
Vehicle	218	143
Laboratory equipment	13,384	11,933
Manufacturing equipment	12,838	12,198
Leasehold improvements	9,889	9,641
Construction in progress	4,699	2,423
	44,741	39,414
Less: accumulated depreciation	(13,099)	(10,252)
Property and equipment, net	31,642	29,162

Depreciation expenses for the three and six months ended June 30, 2021 were $1,407 and $2,747, respectively. Depreciation expenses for the three and six months ended June 30, 2020 were $968 and $1,974, respectively.

9. Revenue

The Group's revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The table below presents the Group's net product sales for the three and six months ended June 30, 2021 and 2020.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
Product revenue - gross	41,380	11,478	87,935	20,415
Less: Rebate and sales return	(4,445)	(483)	(30,897)	(1,202)
Product revenue - net	36,935	10,995	57,038	19,213

Sales rebates are offered to distributors in China and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes and level of distributor inventories.

The following table disaggregates net revenue by product for the three and six months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
ZEJULA	23,366	7,446	35,972	13,791
Optune	9,535	3,549	16,665	5,422
QINLOCK	4,034	—	4,401	—
Product revenue - net	36,935	10,995	57,038	19,213

10. Income Tax

No provision for income taxes has been required to be accrued because the Company and all of its subsidiaries are in cumulative loss positions for all the periods presented.

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of June 30, 2021 and December 31, 2020. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

11. Other current liabilities

Other current liabilities consist of the following:

	As of	
	June 30, 2021	December 31, 2020
	$	$
Payroll	12,474	13,694
Professional service fee	9,610	3,128
Payables for purchase of property and equipment	1,720	788
Accrued rebate to distributors	22,416	7,067
Others (note (i))	15,705	5,519
Total	61,925	30,196

Note:

(i) Others are mainly payables to employees for exercising the share-based compensations, tax payables and payables related to travel and business entertainment expenses.

12. Loss per share

Basic and diluted net loss per share for each of the period presented are calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
Numerator:				
Net loss attributable to ordinary shareholders	(163,324)	(80,629)	(396,234)	(128,617)
Denominator:				
Weighted average number of ordinary shares- basic and diluted	93,045,531	74,738,563	90,723,132	73,847,551
Product revenue - net	(1.76)	(1.08)	(4.37)	(1.74)

As a result of the Group's net loss for the six months ended June 30, 2021 and 2020, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	As of	
	June 30, 2021	June 30, 2020
Share options	8,629,440	9,808,561
Non-vested restricted shares	632,535	710,068

13. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of June 30, 2021:

Company Name	Relationship with the Group
MEDx (Suzhou) Translational Medicine Co., Ltd.	Significant influence held by Samantha Du's (Director, Chairwoman and Chief Executive Officer of the Company) immediate family

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

For the three and six months ended June 30, 2021, the Group incurred $104 and $207 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for product research and development services, respectively. The Group incurred $129 and $184 research and development expense for the three and six months ended June 30, 2020, respectively. All of the transactions are carried out with normal business terms and are on arms' length basis.

14. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool"). Subsequently, the Board of Directors approved the increase in the Option Pool to 7,369,767 ordinary shares.

In connection with the completion of the initial public offering (the "IPO"), the Board of Directors approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan.

For the six months ended June 30, 2020, the Group granted 960,878 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $44.94 to $82.13 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five- or three-year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

For the six months ended June 30, 2021, the Group granted 512,088 share options to certain management and employees of the Group at the exercise price ranging from $130.96 to $180.00 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

The weighted-average grant-date fair value of the options granted in the six months ended June 30, 2021 and 2020 were $81.37 and $33.51 per share, respectively. The Group recorded compensation expense related to the options of $12,776 and $10,355 for the six months ended June 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
Selling, general and administrative	4,123	2,804	7,382	5,548
Research and development	3,104	2,630	5,394	4,807
Total	7,227	5,434	12,776	10,355

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

As of June 30, 2021, there was $97,837 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 1.48 years which is determined based on the number of shares and unrecognized years.

Non-vested restricted shares

For the six months ended June 30, 2020, 50,000 ordinary shares were authorized for grant to the independent directors. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the six months ended June 30, 2020, 45,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the six months ended June 30, 2021, 19,260 ordinary shares were authorized for grant to the independent directors. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the six months ended June 30, 2021, 203,575 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

The Group measured the fair value of the non-vested restricted shares as of respective grant dates and recognized the amount as compensation expense over the deemed service period using a graded vesting attribution model on a straight-line basis.

As of June 30, 2021, there was $40,562 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of $4,774 and $3,072 for the six months ended June 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	$	$	$	$
Selling, general and administrative	1,839	1,046	3,050	2,114
Research and development	1,166	484	1,724	958
Total	3,005	1,530	4,774	3,072

15. Licenses and collaborative arrangement

The following is a description of the Group's significant ongoing collaboration agreements for the three and six months ended June 30, 2021.

License and collaboration agreement with GSK

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, Inc., a company later acquired by GSK, pursuant to which it obtained an exclusive sublicense under certain patents and know-how of GSK (including such patents and know-how licensed from Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., and AstraZeneca UK Limited) to develop, manufacture and commercialize GSK's proprietary PARP inhibitor, niraparib, in China, Hong Kong and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer). The Group also obtained the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of niraparib being developed by GSK in the licensed territory. Under the agreement, the Group agreed not to research, develop or commercialize certain competing products, and the Group also granted GSK the right of first refusal to license certain immuno-oncology assets developed by the Group. In February 2018, the Group entered into an amendment with GSK that eliminated GSK's option to co-market niraparib in the licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $15,000 and one milestone payment of $1,000, and accrued one development milestone payment of $3,500 to GSK. On top of those, if the Group achieves other specified regulatory, development and commercialization milestones, the Group may be additionally required to pay further milestone payments up to $36,000 to GSK. In addition, if the Group successfully develops and commercializes the licensed products, the Group will pay GSK tiered royalties on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement at any time by providing written notice of termination to GSK.

License and collaboration agreements with MacroGenics Inc. ("MacroGenics")

In November 2018, the Group entered into a collaboration agreement with MacroGenics, pursuant to which it obtained an exclusive license under certain patents and know-how of MacroGenics to develop and commercialize margetuximab, tebotelimab (MGD-013) and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, each as an active ingredient in all human fields of use, except to the extent limited by any applicable third party agreement of MacroGenics in Greater China.

Under the terms of the agreement, the Group paid an upfront license fee of $25,000 and two milestone payments in total of $4,000 to MacroGenics. The Group also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of $136,000, and tiered royalties at percentage rates for net sales of Margetuximab, tebotelimab and TRIDENT molecule in the territory.

The Group has the right to terminate this agreement at any time by providing written notice of termination to MacroGenics.

In June 2021, the Group entered into a collaboration and license agreement with MacroGenics, pursuant to which the Group and MacroGenics made four collaboration programs involving up to four immuno-oncology molecules. The first collaboration program covers a lead research molecule that incorporates MacroGenics' DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors. The second collaboration program will cover a target to be designated by MacroGenics. For both molecules, the Group received commercial rights in Greater China, Japan, and Korea and MacroGenics received commercial rights in all other territories. For the lead molecule, the Group receives an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share. The Group also obtained exclusive, global licenses from MacroGenics to develop, manufacture and commercialize two additional molecules. For these four programs, each company will contribute intellectual property to generate either CD3- or CD47-based bispecific antibodies.

Under the terms of the agreement, the Group accrued an upfront payment of $25,000 to MacroGenics. In addition, MacroGenics is also eligible to receive up to $1,386,000 in potential development, regulatory and commercial milestone payments for the four programs. If products from the collaboration are commercialized, MacroGenics would also receive royalties on annual net sales in the Group's territories.

Pursuant to the collaboration and license agreement, the Group also agreed to make an equity investment of $30,000 in MacroGenics' common stock at $31.30 per share (see Note 18).

The Group has the right to terminate this agreement at any time by providing written notice of termination to MacroGenics.

License and collaboration agreement with Deciphera

In June 2019, the Group entered into a license agreement with Deciphera, pursuant to which it obtained an exclusive license under certain patents and know-how of Deciphera to develop and commercialize products containing ripretinib in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in Greater China.

Under the terms of the agreement, the Group paid Deciphera an upfront license fee of $20,000 and three milestone payments of $12,000. The Group also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $173,000, and certain tiered royalties (from low-to-high teens on a percentage basis and subject to certain reductions) based on the net sales of the licensed products in the territory.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Deciphera.

License agreements with Turning Point Therapeutics Inc ("Turning Point")

In July 2020, the Group entered into an exclusive license agreement with Turning Point pursuant to which Turning Point exclusively licensed to the Group the rights to develop and commercialize products containing repotrectinib as an active ingredient in all human therapeutic indications, in Greater China.

Under the terms of the agreements, the Group paid an upfront payment of $25,000 and one milestone payment of $2,000, and accrued two milestone payments totaling $3,000 to Turning Point. Turning Point is also eligible to receive up to $146,000 in development, regulatory and sales milestones. Turning Point will also be eligible to receive certain tiered royalties (from mid-to-high teens on a percentage basis and subject to certain reductions) based on annual net sales of repotrectinib in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Turning Point.

In January 2021, the Group entered into a license agreement with Turning Point, which expanded their collaboration. Under the terms of the new agreement, the Group obtained exclusive rights to develop and commercialize TPX-0022, Turning Point's MET, SRC and CSF1R inhibitor, in Greater China.

The Group paid an upfront license fee in the amount of $25,000 to Turning Point. The Group also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $336,000. Turning Point will also be eligible to receive certain tiered royalties (from mid-teens to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of TPX-0022 in Greater China. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology product candidate discovered by the Group.

License and collaboration agreement with Five Prime Therapeutics, Inc. ("Five Prime")

In December 2017, the Group entered into a license and collaboration agreement with Five Prime (a company later acquired by Amgen Inc.), pursuant to which it obtained an exclusive license under certain patents and know-how of Five Prime to develop and commercialize products containing Five Prime's proprietary afucosylated FGFR2b antibody known as bemarituzumab (FPA144) as an active ingredient in the treatment or prevention of any disease or condition in humans in Greater China.

Under the terms of the agreement, the Group made an upfront payment of $5,000 and a milestone payment of $2,000 to Five Prime. Additionally, the Group also agreed to pay further development and regulatory milestone payments of up to an aggregate of $37,000 to Five Prime and certain tiered royalties (from high-teens to low-twenties on a percentage basis and subject to certain reductions) based on the number of patients the Group enrolls in the bemarituzumab study.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Five Prime.

License agreement with Cullinan Pearl Corp. ("Cullinan")

In December 2020, the Group entered into a license agreement with Cullinan, a subsidiary of Cullinan Management, Inc., formerly Cullinan Oncology, LLC, pursuant to which it obtained an exclusive license under certain patents and know-how of Cullinan to develop, manufacture and commercialize products containing CLN-081 as an active ingredient in all uses in humans and animals in Greater China.

Under the terms of the agreement, the Group paid an upfront payment of $20,000 to Cullinan. Cullinan is also eligible to receive up to $211,000 in development, regulatory and sales-based milestone payments. Cullinan is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on annual net sales of CLN-081 in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Cullinan.

License agreement with Takeda Pharmaceutical Company Limited ("Takeda")

In December 2020, the Group entered into an exclusive license agreement with Takeda. Under the terms of the license agreement, Takeda exclusively licensed to the Group the right to exploit products in the licensed field during the term.

Under the terms of the agreement, the Group paid an upfront payment of $6,000 to Takeda. Takeda is also eligible to receive up to $481,500 in development, regulatory and sales-based milestone payments. Takeda is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on net sales of each product sold by selling party during each year of the applicable royalty term.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Takeda.

Collaboration and license agreement with argenx BV ("argenx")

In January 2021, the Group entered into a collaboration and license agreement with argenx. The Group received an exclusive license to develop and commercialize products containing argenx's proprietary antibody fragment, known as efgartigimod, in Greater China. The Group is responsible for the development of the licensed compound and licensed product and will have the right to commercialize such licensed product in the territory.

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Group and argenx. As the upfront payment to argenx, the Group issued 568,182 ordinary shares of the Company to argenx with par value $0.00006 per share on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $62,250 in the aggregate. The Group recorded this upfront payment in research and development expenses.

In addition, the Group made a non-creditable, non-refundable development cost-sharing payment of $75,000 to argenx. Argenx is also eligible to receive a cash payment of $25,000 upon the first regulatory approval of a licensed product by the U.S. Food and Drug Administration for myasthenia gravis and tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed product in the territory.

Collaboration and license agreement with Mirati Therapeutics, Inc. ("Mirati")

In May 2021, the Group entered into a collaboration and license agreement with Mirati. The Group obtained the right to research, develop, manufacture and exclusively commercialize adagrasib in Greater China. The Group will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRASG12C mutation. Mirati has an option to co-commercialize in Greater China and retains full and exclusive rights to adagrasib in all countries outside of Greater China.

Under the terms of the agreement, the Group accrued an upfront payment of $65,000 to Mirati. Mirati is also eligible to receive up to $273,000 in development, regulatory and sales-based milestone payments. Mirati is also eligible to receive high-teen- to low-twenties-percent tiered royalties based on annual net sales of adagrasib in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Mirati.

Full details of the licenses and collaborative arrangements are included in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 1, 2021 and this Quarterly Report on Form 10-Q. As noted above, the Group has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Group up to an aggregate of approximately $4,541,502 in future milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the product candidates, which may be before the Group has commercialized the product or received any revenue from sales of such product candidate, which may never occur.

16. Restricted net assets

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its Chinese subsidiary. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's Chinese subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the unaudited condensed consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Group's PRC subsidiary.

In accordance with the Company Law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's Chinese subsidiary was established as domestic invested enterprise and therefore is subject to the above-mentioned restrictions on distributable profits.

During the three and six months ended June 30, 2021 and 2020, no appropriation to statutory reserves was made because the Group's Chinese subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the restrictions discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's Chinese subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulations in China may further restrict the Group's Chinese subsidiary from transferring funds to the Group in the form of dividends, loans and advances. As of June 30, 2021 and December 31, 2020, amounts restricted are the paid-in capital of the Group's Chinese subsidiaries, which amounted to $306,010 and $205,858, respectively.

17. Commitments and Contingencies

(a) Purchase commitments

As of June 30, 2021, the Group's commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statement were $28,191 and $49 which are expected to be incurred within one year and within one to two years, respectively.

(b) Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 15).

18. Subsequent Event

In July 2021, the Group made an equity investment in MacroGenics in a private placement with total contributions amounting to $30,000 and obtained 958,467 newly issued common shares of MacroGenics at $31.30 per share.

In July and August 2021, the Group granted 11,701 share options to certain management and employees of the Group at exercise prices ranging from $144.61 to $178.37 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

In July and August 2021, 32,341 ordinary shares were authorized for grant to certain management and employees of the Group. One-fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In August 2021, the Group entered into a global discovery, development and commercialization collaboration with Schrödinger, Inc., or Schrödinger, pursuant to which the parties will jointly conduct a research program focused on a novel DNA damage repair program in the area of oncology. Following the selection of a development candidate, the Group will assume primary responsibility for global development, manufacturing and commercialization of the program.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We are a commercial stage, biopharmaceutical company with a substantial presence in both Greater China and the United States. We are discovering, developing and commercializing innovative products that target medical conditions with unmet needs affecting patients in China and worldwide, particularly in the areas of oncology, autoimmune disorders, and infectious diseases. As of August 9, 2021, we have three commercialized products that have received marketing approval in one or more territories in Greater China and twelve programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and to generate positive cash flow from operations over the next several years depends upon our ability to successfully market our current three commercial products ZEJULA, Optune and QINLOCK®, and our other product candidates that we are able to successfully commercialize. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our unaudited condensed consolidated financial statements and totaled $269.2 million for the six months ended June 30, 2021. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

Furthermore, as we pursue our strategy of growth and development, we anticipate that our financial results will fluctuate from quarter to quarter based upon the balance between the successful marketing of our commercial products and our significant research and development expenses. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

Recent Developments

Recent Business Developments

On April 12, 2021, we achieved first-patient-in for the Phase 3 pivotal LUNAR trial.

On April 13, 2021, we announced in a joint press release with our partner, Novocure, an update regarding Novocure's Phase 3 pivotal LUNAR trial of Tumor Treating Fields in stage 4 non-small cell lung cancer (NSCLC) following platinum failure. Following a routine review of the study by an independent data monitoring committee (DMC), Novocure was informed that the pre-specified interim analysis for the LUNAR trial would be accelerated given the length of accrual and the number of events observed to date. The interim analysis included data from 210 patients accrued to the LUNAR trial through February 2021. After review of the interim analysis report, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity. On May 18, 2021, Novocure announced the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) supplement, reducing the enrollment requirement for its LUNAR trial to 276 patients with 12 months follow-up. In addition, in April 2021, we achieved first-patient-in for the LUNAR trial in Greater China.

On April 23, 2021, we announced the closing of a global offering of American depositary shares and ordinary shares, including the full exercise of the greenshoe option, for total gross proceeds to us of $857.5 million. This offering was the first ever dual-tranche offering on both Nasdaq and the Stock Exchange of Hong Kong.

On May 24, 2021, we announced the first patient treated in the METIS Phase 3 pivotal trial of Tumor Treating Fields in brain metastases from NSCLC in Greater China.

On June 1, 2021, we announced that we entered into a collaboration and license agreement with Mirati for adagrasib, a small-molecule KRASG12C inhibitor, in Greater China (mainland China, Hong Kong, Macau and Taiwan). Under the terms of the agreement, we obtained the right to research, develop, manufacture and exclusively commercialize adagrasib in Greater China. We will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRAS G12C mutation.

On June 4, 2021, our partner, Cullinan, announced additional details pertaining to Cullinan's ongoing Phase 1/2a trial of CLN-081 in NSCLC patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations, including that CLN-081 continues to demonstrate acceptable overall safety and tolerability with encouraging GI toxicity profile.

On June 15, 2021, we announced that we entered into an exclusive collaboration and license agreement with MacroGenics, pursuant to which we agreed to collaboratively develop and commercialize up to four bispecific antibody-based molecules with MacroGenics based on the MacroGenics' proprietary DART® and TRIDENT® multi-specific technology platforms. Under the agreement, each party agrees to contribute specified intellectual property to enable the research, development, manufacture and commercialization of up to four future CD3 or CD47-based bispecific molecules. We were granted exclusive rights in Greater China, Japan, and Korea for two programs and exclusive global rights for two other programs.

On August 4, 2021, we announced that we entered into a global discovery, development and commercialization collaboration with Schrödinger, pursuant to which we will jointly conduct a research program focused on a novel DNA damage repair program in the area of oncology. Schrödinger is a recognized leader in providing physics-based computational software platforms used in drug discovery. The research program will be conducted jointly by the scientific teams of our two companies. Following the selection of a development candidate, we will assume primary responsibility for global development, manufacturing and commercialization of the program.

Recent Regulatory Developments

PRC Medical Device Regulations

The sale and marketing of imported medical device products in China are subject to notifications (for Class I devices) or registrations (for Class II and III devices) with China's National Medical Products Administration (NMPA). We launched Optune in China in June 2020 after the NMPA approved Optune in May 2020 in combination with temozolomide for the treatment of patients with newly diagnosed GBM and also as a monotherapy for the treatment of patients with recurrent GBM. Optune is regulated as a Class III imported medical device in China, and we act as the Chinese legal agent for our collaboration partner, Novocure, who is the foreign marketing authorization holder (MAH) for Optune in China. We are preparing to submit to the NMPA a Marketing Authorization Application for Optune Lua for the treatment of unresectable, locally advanced or metastatic malignant pleural mesothelioma.

The Chinese State Council passed new Medical Device Regulations (State Council Order #739), or Order #739, to replace the existing Medical Device Regulations (State Council Order #680), or Order #680. Order #739 was published by the National Medical Products Administration (NMPA) and became effective on June 1, 2021. Order #739 largely follows the legislative structure of Order #680. We, as the Chinese legal agent for Optune in China, are subject to the statutory compliance requirements under Order #739. The following updates from Order #739 we believe are the most relevant to our compliance obligations and our business operations in China:

- *Chinese legal agent*. Under Order #739, foreign device MAHs will still need to appoint a Chinese legal entity to submit regulatory applications and correspond with regulatory authorities. Nevertheless, the local appointees may only need to play a secondary role to assist the foreign device MAHs in the performance of compliance obligations under Order #739.

- *Liabilities for non-compliance*. Order #739 significantly increases MAH's liabilities for non-compliance. Order #739 also introduces personal liability on the legal representatives, main responsible persons, directly responsible supervisors or other personnel of MAHs. While Order #680 does not differentiate the liability of local legal agents from the foreign device MAHs, Order #739 makes it clear that local appointees will assume a lesser degree of liability compared to the foreign device MAHs. If local appointees fail to perform the statutory responsibilities and obligations on behalf of the MAHs, they will be subject to administrative fines up to RMB 0.5 million, and their responsible personnel will only be subject to a five-year debarment. In comparison, foreign MAHs who refuse to fulfill the administrative penalties may be subject to a ten-year import ban.
- *MAH system*. The MAH system will be rolled out nationwide. MAHs will be responsible for the safety and effectiveness of their products during the entire product life cycle. They must establish a quality management system and ensure its effectiveness, define and implement a post-approval study and risk control plan, conduct adverse event monitoring and re-evaluation, establish and implement the product tracing and recall system, and fulfill other statutory obligations imposed by the NMPA.
- *Encouraging innovations*. As a core theme of its drafting philosophy, Order #739 encourages innovations in medical device technologies and will continue to allow the "fast track approval process" to accelerate the product launch timeline for innovative devices. Under Order #739, imported medical devices that are "first-in-class" and have Chinese invention patent(s) covering their core technologies do not need to be approved outside of China before the NMPA's marketing authorization.
- *Clinical evidence*. The NMPA will allow versatile clinical evidence to demonstrate product safety and effectiveness. Such evaluation can be based on clinical study data or analysis of clinical literature and clinical data on predicate devices.
- *Expanded access*. Expanded access to investigational devices will be made available for patients in the study sites upon ethics committee approval and the patients' giving informed consent, provided that the investigational devices are used for critical, life-threatening diseases without an effective treatment method and can confer clinical benefits on patients based on medical judgment.

To implement Order #739, from March to June of 2021, the NMPA also published draft administrative regulations on the registration, manufacturing, distribution, Good Clinical Practices and company-led type tests for medical devices for public comment.

PRC Biosecurity Law

On April 15, 2021, the PRC Biosecurity Law took effect.

PRC Patent Law

On June 1, 2021, the fourth amendment to the PRC Patent Law took effect.

On July 3, 2021, the Implementing Measure to Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "Measures"), jointly issued by the NMPA and the China National Intellectual Property Administration jointly, took effect. The Measures give practical guidance on the patent linkage system in China, where the drug originators are permitted to list on a public registration system certain patents that are relevant to approved drugs. Generic and biosimilar drug applicants must then make certifications when applying for drug approval in respect of the listed patents. Where the certification is a type IV certification which alleges the invalidity of the listed patents or alleges that the scope of the listed patents does not cover the generic or biosimilar drug that is the subject of the drug approval application, drug originators have an opportunity to pursue administrative or judicial litigation to determine patent infringement prior to commercial sale, and in the case of chemical generics, obtain a 9-month approval stay on the chemical generic drug approval application. Upon successful litigation prior to the approval of the generic or biosimilar drug, the drug originators may delay the grant of the approval of a chemical generic drug until after patent expiry or have the approval of a biosimilar drug be conditioned upon patent expiry.

PRC Data Security and Cybersecurity

In June 2021, China's top legislative body, the National People's Congress, passed the Data Security Law (DSL). Being the first comprehensive data security legislation in China, the DSL will take effect on September 1, 2021, and it covers a wide range of issues relating to the collection, storage, processing, use, provision, transaction and publication of data. The DSL provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection. The DSL has extraterritorial effect and it applies to any data processing activities outside China if such activities would be detrimental to the national security or public interest of China or the interests of Chinese citizens or organizations.

In July 2021, the Cyberspace Administration of China published a revised draft of the Measures on Cybersecurity Review, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

Also, recently, the National People's Congress released the second consultation draft of the Personal Information Protection Law. The draft proposes a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The draft also proposes that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold to-be-set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the draft contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year.

Factors Affecting our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of product candidates has been steadily advancing and expanding, with twelve late-stage clinical product candidates being investigated as of June 30, 2021.

To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, a secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through June 30, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, our secondary listing and our follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $235.3 million and $92.3 million, for the six months ended June 30, 2021 and June 30, 2020, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our twelve late-stage clinical product candidates and continue research and development of our clinical and pre-clinical-stage product candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. These expenditures include:

- expenses incurred for payments to contract research organizations ("CROs"), contract manufacture organizations ("CMOs"), investigators and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expenses;
- expenses for licensors;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities, depreciation and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations;
- expenses associated with the construction and maintenance of our manufacturing facilities; and
- costs associated with operating as a public company.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general and administrative expenses include product distribution and promotion costs, professional service fees for legal, intellectual property, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support increases in our commercial and research and development activities and as we continue to commercialize, develop, and manufacture our products and assets. These increases will likely include increased headcount, increased share compensation charges, increased product distribution and promotion costs, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Our Ability to Commercialize Our Product Candidates

As of June 30, 2021, twelve of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may never occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant products under these agreements as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our unaudited condensed consolidated financial statements and totaled $269.2 million for the six months ended June 30, 2021 and $98.0 million for the three months ended June 30, 2021. The upfront payments and milestone payments are recorded in research and development expense and was $51.7 million for the six months ended June 30, 2020 and $42.5 million for the three months ended June 30, 2020.

Key Components of Results of Operations

Taxation

Cayman Islands

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see "Taxation—Material Cayman Islands Taxation" in our Annual Report on Form 10-K for the year ended December 31, 2020.

People's Republic of China

Our subsidiaries incorporated in China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see "Taxation—Material People's Republic of China Taxation" in our Annual Report on Form 10-K for the year ended December 31, 2020.

Hong Kong

Our subsidiaries incorporated in Hong Kong are subject to two-tiered tax rates for the six months ended June 30, 2021 and 2020 on assessable profits earned in Hong Kong where the profits tax rate for the first HK$2 million of assessable profits is subject to profits tax rate of 8.25% and the assessable profits above HK$2 million is subject to profits tax rate of 16.5%. Our subsidiaries incorporated in Hong Kong did not have assessable profit for the six months ended June 30, 2021 and 2020.

Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Three months ended June 30,		Six months ended June 30,	
(in thousands, except share and per share data)	2021	2020	2021	2020
Comprehensive Loss Data:				
Revenue	$ 36,935	$ 10,995	$ 57,038	$ 19,213
Expenses:				
Cost of sales	(10,868)	(2,896)	(18,373)	(4,980)
Research and development	(142,224)	(68,307)	(346,076)	(102,049)
Selling, general and administrative	(54,414)	(23,758)	(90,252)	(42,472)
Loss from operations	$ (170,571)	$ (83,966)	$ (397,663)	$ (130,288)
Interest income	244	1,227	458	2,882
Interest expenses	—	(55)	—	(114)
Other income (expense), net	7,406	2,434	1,179	(691)
Loss before income tax and share of loss from equity method investment	$ (162,921)	$ (80,360)	$ (396,026)	$ (128,211)
Income tax expense	—	—	—	—
Share of loss from equity method investment	(403)	(269)	(208)	(406)
Net loss attributable to ordinary shareholders	$ (163,324)	$ (80,629)	$ (396,234)	$ (128,617)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	93,045,531	74,738,563	90,723,132	73,847,551
Net loss per share, basic and diluted	$ (1.76)	$ (1.08)	$ (4.37)	$ (1.74)

Three Months Ended June 30, 2021 Compared to Three Months Ended June 30, 2020

Revenue

Our revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The following table disaggregates net revenue by product for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
ZEJULA	$23,366	63.3	$ 7,446	67.7
Optune	9,535	25.8	3,549	32.3
QINLOCK	4,034	10.9	—	—
Total product revenue—Net	$36,935	100.0	$10,995	100.0

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the periods indicated.

	Three Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
Research and Development Expenses:				
Personnel compensation and related costs	$ 17,282	12.1	$11,596	17.0
Licensing fees	97,966	68.9	42,480	62.2
Payment to CROs/CMOs/Investigators	19,618	13.8	9,982	14.6
Other costs	7,358	5.2	4,249	6.2
Total	$142,224	100.0	$68,307	100.0

Research and development expenses increased by $73.9 million to $142.2 million for the three months ended June 30, 2021 from $68.3 million for the three months ended June 30, 2020. The increase in research and development expenses included the following:

- $5.7 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the three months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $55.5 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees; and
- $9.6 million for increased payments to CROs, CMOs and investigators in the three months ended June 30, 2021 as we advanced our drug candidate pipeline.

The following table summarizes our research and development expenses by program for the three months ended June 30, 2021 and 2020, respectively:

	Three Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
Research and Development Expenses:				
Clinical programs	$ 93,433	65.7	$52,003	76.1
Pre-clinical programs	28,545	20.1	2,227	3.3
Unallocated research and development expenses	20,246	14.2	14,077	20.6
Total	$142,224	100.0	$68,307	100.0

During the three months ended June 30, 2021, 65.7% and 20.1% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the three months ended June 30, 2020, 76.1% and 3.3% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. Although we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any given time.

Selling, General and Administrative Expenses

The following table sets forth the components of our selling, general and administrative expenses for the periods indicated.

	Three Months Ended June 30,			
(in thousands)	2021	%	2020	%
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	30,060	55.2	14,040	59.1
Professional service fees	4,806	8.8	2,543	10.7
Other costs	19,548	36.0	7,175	30.2
Total	$54,414	100.0	$23,758	100.0

Selling, general and administrative expenses increased by $30.7 million to $54.4 million for the three months ended June 30, 2021 from $23.8 million for the three months ended June 30, 2020. The increase in general and administrative expenses included the following:

- $16.0 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during the three months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $2.3 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company; and
- $12.4 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and China.

Interest Income

Interest income decreased by $1.0 million, to $0.2 million for the three months ended June 30, 2021, from $1.2 million for the three months ended June 30, 2020 primary due to the decrease of short-term investments balance.

Interest Expenses

Interest expenses is nil for the three months ended June 30, 2021, compared to $0.1 million for the three months ended June 30, 2020, as all the short-term borrowings were repaid in 2020.

Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. (“JING”), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. We recorded loss of $0.4 million and $0.3 million for its portion of JING’s net loss for the three months June 30, 2021 and 2020, respectively.

Other Income (Expense), net

Other income (expense), net increased by $5.0 million for the three months ended June 30, 2021, as compared to the three months ended June 30, 2020, primarily as a result of an increase in foreign exchange gain and partially offset by a decrease in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $163.3 million for the three months ended June 30, 2021 compared to net loss attributable to ordinary shareholders of $80.6 million for the three months ended June 30, 2020.

Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

Revenue

Our revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The amount of revenue of ZEJULA for the six months ended June 30, 2021, was adjusted by the normal process in China to compensate distributors for products recently sold at prices prior to the National Reimbursement Drug List (NRDL) implementation. The following table disaggregates net revenue by product for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
ZEJULA	$35,972	63.1	$13,791	71.8
Optune	16,665	29.2	5,422	28.2
QINLOCK	4,401	7.7	—	—
Total product revenue—Net	$57,038	100.0	$19,213	100.0

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the periods indicated.

	Six Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
Research and Development Expenses:				
Personnel compensation and related costs	$ 29,979	8.7	$ 21,600	21.2
Licensing fees	269,248	77.8	51,720	50.7
Payment to CROs/CMOs/Investigators	35,144	10.1	19,812	19.4
Other costs	11,705	3.4	8,917	8.7
Total	$346,076	100.0	$102,049	100.0

Research and development expenses increased by $244.0 million to $346.1 million for the six months ended June 30, 2021 from $102.0 million for the six months ended June 30, 2020. The increase in research and development expenses included the following:

- $8.4 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the six months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $217.5 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees; and
- $15.3 million for increased payment to CROs, CMOs and investigators in the six months ended June 30, 2021 as we advanced our drug candidate pipeline.

The following table summarizes our research and development expenses by program for the six months ended June 30, 2021 and 2020, respectively:

	Six Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
Research and Development Expenses:				
Clinical programs	$279,689	80.8	$ 72,335	70.9
Pre-clinical programs	31,045	9.0	2,915	2.9
Unallocated research and development expenses	35,342	10.2	26,799	26.2
Total	$346,076	100.0	$102,049	100.0

During the six months ended June 30, 2021, 80.8% and 9.0% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the six months ended June 30, 2020, 70.9% and 2.9% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. Although we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any given time.

Selling, General and Administrative Expenses

The following table sets forth the components of our selling, general and administrative expenses for the periods indicated.

	Six Months Ended June 30,			
(in thousands)	**2021**	**%**	**2020**	**%**
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	$53,472	59.2	$27,082	63.8
Professional service fees	8,389	9.3	4,570	10.7
Other costs	28,391	31.5	10,820	25.5
Total	$90,252	100.0	$42,472	100.0

Selling, general and administrative expenses increased by $47.8 million to $90.3 million for the six months ended June 30, 2021 from $42.5 million for the six months ended June 30, 2020. The increase in general and administrative expenses included the following:

- $26.4 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during the six months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $3.8 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company; and
- $17.6 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and China.

Interest Income

Interest income decreased by $2.4 million, to $0.5 million for the six months ended June 30, 2021, from $2.9 million for the six months ended June 30, 2020 primary due to the decrease of short-term investments balance.

Interest Expenses

Interest expenses is nil for the six months ended June 30, 2021, compared to $0.1 million for the six months ended June 30, 2020, as all the short-term borrowings were repaid in 2020.

Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for product discovery and development, consultation and transfer of pharmaceutical technology. We recorded the gain on deemed disposal in this investee of $0.5 million and share of loss of $0.7 million for the six months ended June 30, 2021, and recorded share of loss in this investee of $0.4 million for the six months ended June 30, 2020.

Other Income (Expense), net

Other income (expense), net increased by $1.9 million for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, primarily as a result of an increase in foreign exchange gain and partially offset by a decrease in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $396.2 million for the six months ended June 30, 2021 compared to net loss attributable to ordinary shareholders of $128.6 million for the six months ended June 30, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our financial statements in conformity with U.S. GAAP, which requires us to make judgments, estimates and assumptions. We continually evaluate these estimates and assumptions based on the most recently available information, our own historical experiences and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in our estimates. Some of our accounting policies require a higher degree of judgment than others in their application and require us to make significant accounting estimates.

The selection of critical accounting policies, the judgments and other uncertainties affecting application of those policies and the sensitivity of reported results to changes in conditions and assumptions are factors that should be considered when reviewing our financial statements. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

Revenue recognition

In 2018, we adopted ASC Topic 606 ("ASC 606"), *Revenue from Contracts with Customers,* in recognition of revenue. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Our revenue is from product sales. We recognize revenue from product sales when we have satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the customers. Cost of sales mainly consists of the acquisition cost of products and royalty fees.

We have applied the practical expedients under ASC 606 with regard to assessment of financing components and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less. We have generated product sales revenue since 2018. Our product revenues were primarily generated from the sale of ZEJULA (niraparib), Optune (Tumor Treating Fields) and QINLOCK (ripretinib) to customers.

In China, we sell the products to distributors, who ultimately sell the products to healthcare providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the product's delivery to distributors. Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes and level of distributor inventories. We regularly review the information related to these estimates and adjust the amount accordingly.

In Hong Kong, we sell the products to customers, which are typically healthcare providers such as oncology centers. We utilize a third party for warehousing services. Based on the nature of the arrangement, we have determined that we are a principal in the transaction since we are primarily responsible for fulfilling the promise to provide the products to the customers, maintain inventory risk until delivery to the customers and have latitude in establishing the price. Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

We did not recognize any contract assets and contract liabilities as of June 30, 2021 and December 31, 2020.

Share-Based Compensation

We grant share options and non-vested restricted shares to eligible employees, management and directors and account for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation*. Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determined the fair value of the stock options granted to employees using the Black-Scholes option valuation model.

We also grant share options to eligible non-employees and account for these share-based awards in accordance with ASC 718, *Compensation- Stock Compensation*. Non-employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determined the fair value of the stock options granted to non-employees using the Black-Scholes option valuation model.

Fair Value Measurements

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Include other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches, for example, to measure the fair value of assets and liabilities: (1) market approach, (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of our company primarily include cash, cash equivalents and restricted cash, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities. As of each reporting date, the carrying values of cash and cash equivalents, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature of and the assessment of the ability to recover these amounts.

Income Taxes

Current income taxes are provided on the basis of net income for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions. We follow the liability method of accounting for income taxes.

Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statements carrying amounts and tax bases of assets and liabilities by applying enacted statutory tax rates that will be in effect in the period in which the temporary differences are expected to reverse. We record a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in our consolidated financial statements in the period of change.

In accordance with the provisions of ASC 740, Income Taxes, we recognize in our financial statements the benefit of a tax position if the tax position is "more likely than not" to prevail based on the facts and technical merits of the position. Tax positions that meet the "more likely than not" recognition threshold are measured at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. We estimate our liability for unrecognized tax benefits which are periodically assessed and may be affected by changing interpretations of laws, rulings by tax authorities, changes and/or developments with respect to tax audits, and expiration of the statute of limitations. The ultimate outcome for a particular tax position may not be determined with certainty prior to the conclusion of a tax audit and, in some cases, appeal or litigation process.

We consider positive and negative evidence when determining whether some portion or all of our deferred tax assets will not be realized. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the level of our historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe it is more likely than not that we will not realize the deferred tax assets resulted from the tax loss carried forward in the future periods.

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of June 30, 2021 and December 31, 2020, we did not have any significant unrecognized uncertain tax positions.

B. Liquidity and Capital Resources

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering on the Nasdaq stock exchange, our September 2020 secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through June 30, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, subsequent follow-on offerings, and our secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $235.3 million and $92.3 million, for the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, we had cash, cash equivalents and restricted cash of $1,767.3 million. Our expenditures as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash and cash equivalents as of August 9, 2021, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this Quarterly Report are issued. However, in order to bring to fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020:

	Six months ended June 30,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (235,348)	$ (92,319)
Net cash provided by (used in) investing activities	737,828	(6,521)
Net cash provided by financing activities	820,949	281,500
Effect of foreign exchange rate changes	1,028	12
Net increases in cash, cash equivalents and restricted cash	$1,324,457	$182,672

Net cash used in operating activities

During the six months ended June 30, 2021, our operating activities used $235.3 million of cash, which resulted principally from our net loss of $396.2 million, adjusted for non-cash charges of $85.9 million, and cash provided in our operating assets and liabilities of $75.0 million. Our net non-cash charges during the six months ended June 30, 2021 primarily consisted of $62.3 million non-cash research and development expenses, a $3.0 million depreciation expense, a $17.6 million share-based compensation expense and a $2.8 million non-cash lease expense.

Net cash provided by (used in) investing activities

Net cash provided by investing activities was $737.8 million for the six months ended June 30, 2021 compared to net cash used in investing activities of $6.5 million for the six months ended June 30, 2020. The increase in cash provided by investing activities was primarily due to the proceeds from maturity of short-term investments.

Net cash provided by financing activities

Net cash provided by financing activities was $820.9 million for the six months ended June 30, 2021 compared to $281.5 million for the six months ended June 30, 2020. The increase in cash provided by financing activities was primarily due to the issuance of ADSs in our follow-on offering during the six months ended June 30, 2021.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are provided in the “Business” and “Operating and Financial Review and Prospects” sections of our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

D. Trend Information

Other than as described elsewhere in this Quarterly Report on Form 10-Q, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

E. Off-balance Sheet Arrangements

We currently do not engage in trading activities involving non-exchange traded contracts or interest rate swap transactions or foreign currency forward contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

F. Tabular Disclosure of Contractual Obligations

The following table sets forth our contractual obligations as of June 30, 2021. Amounts we pay in future periods may vary from those reflected in the table.

(in thousands)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Purchase Obligations	$28,240	$28,191	$ 49	—	—
Operating Lease Obligations	$18,847	$ 6,557	$ 6,180	$4,373	$ 1,737

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones as well as tiered royalties on net sales. We have not included these commitments on our balance sheet or in the table above because the commitments are cancellable if the milestones are not complete and achievement and timing of these obligations are not fixed or determinable.

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, please see "Part II—Item 8—Financial Statements and Supplementary Data—Recent accounting pronouncements" in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk including foreign exchange risk, credit risk, cash flow interest rate risk and liquidity risk.

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of our company included aggregated amounts of RMB 234.0 million and RMB 155.9 million, which were denominated in RMB, as of June 30, 2021 and December 31, 2020, respectively, representing 2% and 5% of the cash and cash equivalents as of June 30, 2021 and December 31, 2020, respectively.

Our business mainly operates in China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMBs, while ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, China changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China's government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, in August 2015, the PBOC significantly devalued the RMB.

A significant portion of our cash is kept in Hong Kong dollars (HK dollars) as well as U.S. dollars. The value of our ADSs will, therefore, be affected by the foreign exchange rates between U.S. dollars, HK dollars and the RMB. For example, to the extent that we need to convert U.S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or the HK dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars or HK dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us.

Since 1983, the Hong Kong Monetary Authority (HKMA) has pegged the HK dollar to the U.S. dollar at the rate of approximately HK$7.80 to US$1.00. However, there is no assurance that the HK dollar will continue to be pegged to the U.S. dollar or that the HK dollar conversion rate will remain at HK$7.80 to US$1.00. If the HK dollar conversion rate against the U.S. dollar changes and the value of the HK dollar depreciates against the U.S. dollar, our Group's assets denominated in HK dollars will be adversely affected. Additionally, if the HKMA were to repeg the HK dollar to, for example, the RMB rather than the U.S. dollar, or otherwise restrict the conversion of HK dollars into other currencies, then our Group's assets denominated in HK dollars will be adversely affected.

Credit Risk

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents and short-term investment. The carrying amounts of cash and cash equivalents and short-term investment represent the maximum amount of loss due to credit risk. As of June 30, 2021 and December 31, 2020, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in China and international financial institutions outside of China which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

Inflation

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the six months ended June 30, 2021, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended) that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We may be, from time to time, subject to claims and suits arising in the ordinary course of business. Although the outcome of these and other claims cannot be predicted with certainty, management does not believe that the ultimate resolution of these matters will have a material adverse effect on our financial position or on our results of operations. We are not currently a party to, nor is our property the subject of, any actual or threatened material legal or administrative proceedings.

Item 1A. Risk Factors.

There have been no material changes from the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021, except as follows:

Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. We conduct preclinical and clinical activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ordinary shares and/or our ADSs or prevent us from selling our drug products in certain countries.

Furthermore, the SEC has issued statements primarily focused on companies with significant China-based operations, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with a Variable Interest Entity, or a VIE structure. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations by China. Further, we believe that we have robust disclosures relating to our operations in China, including the relevant risks noted in Chairman Gensler's statement. However, it is possible that the Company's periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States.

In response to the SEC's July 30 statement, the China Securities Regulatory Commission (CSRC) announced on August 1, 2021, that "[i]t is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China-based companies listed in the U.S. so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," it emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

Compliance with China's new Data Security Law, Measures on Cybersecurity Review (revised draft for public consultation), Personal Information Protection Law (second draft for consultation), regulations and guidelines relating to the multi-level protection scheme and any other future laws and regulations may entail significant expenses and could materially affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new Data Security Law promulgated by the Standing Committee of the National People's Congress of China in June 2021, or the Data Security Law, will take effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. As the Data Security Law has not yet come into effect, we may need to make adjustments to our data processing practices to comply with this law.

Additionally, China's Cyber Security Law, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopt a multi-level protection scheme (MLPS), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong—from the lowest Level 1 to the highest Level 5 pursuant to the Measures for the Graded Protection and the Guidelines for Grading of Classified Protection of Cyber Security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Recently, the Cyberspace Administration of China has taken action against several Chinese internet companies in connection with their initial public offerings on U.S. securities exchanges, for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law, the Cyber Security Law and the Measures on Cybersecurity Review, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests." On July 10, 2021, the Cyberspace Administration of China published a revised draft of the Measures on Cybersecurity Review, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

It is unclear at the present time how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and this could lead to us delisting from the U.S. stock market.

Also, recently, the National People's Congress released the second consultation draft of the Personal Information Protection Law. The draft proposes a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The draft also proposes that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold to-be-set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the draft contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement. Compliance with the Cyber Security Law and the Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market or the Stock Exchange of Hong Kong.

The audit report included in our periodic reports are prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection, we may be subject to additional Nasdaq listing criteria or other penalties and our ADSs may be delisted from the U.S. stock market.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including the independent registered public accounting firm of our company, must be registered with the PCAOB, and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Because a substantial portion of our operations are within China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

Inspections of auditors conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on Our Exchanges Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges, such as the Nasdaq, of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted.

Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act (HFCA Act), which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction and to prohibit the securities of such issuers that have has three consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020. On May 13, 2021, the PCAOB issued proposed PCAOB Rule 6100 Board Determinations under the HFCA Act for public comment. The proposed rule provides a framework for making determinations as to whether PCAOB is unable to inspect an audit firm in a foreign jurisdiction, including the timing, factors, bases, publication and revocation or modification of such determinations, and provides that such determinations may be made on a jurisdiction-wide basis in a consistent manner applicable to all firms headquartered in the jurisdiction.

Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and departments with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks.

On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act (AHFCA Act), which amends the requirements of the HFCA Act to require that the SEC identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by any non-U.S. authority and to prohibit the securities of such issuers that have had two consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq.

Under the HFCA Act (and, if passed, the AHFCA Act), our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years (or, if the AHFCA Act is passed, two consecutive years), and this ultimately could result in our ADSs being delisted which would materially adversely affect the Company.

Additionally, the Nasdaq has proposed adopting additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer, or a Restrictive Market. Under the proposed rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by the Nasdaq to be a Restrictive Market. If the Nasdaq adopts this rule, China will likely be determined to be a Restrictive Market and, as a result, the Nasdaq may impose on us additional listing criteria or deny continued listing of our securities on the Nasdaq.

There can be no assurance that we or our auditor will be able to comply with requirements imposed by Nasdaq or the U.S. regulators. We are evaluating additional business processes and control changes with the goal of meeting the requirements of the HFCA Act. However, any business processes and control changes that we may implement may not be sufficient or may take time for us to implement and they ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act (or, if passed, the AHFCA Act). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong or may incur increased costs or suffer losses in order to do so. The market price of our ADSs could be materially adversely affected as a result of anticipated negative impacts of these rules and executive, regulatory or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these rules and executive, regulatory or legislative actions are implemented and regardless of our actual operating performance. Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs and ordinary shares.

China's economic, political and social conditions, as well as governmental policies or regulatory actions, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

Substantially all of our operations (and all of our commercial operations) are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development, data protection and allocation of resources. Some of these measures may benefit the overall economy in China but may have a negative effect on us. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and/or changes in tax, cyber and data security, capital investments, cross-border transaction and other regulations that are currently or may in the future be applicable to us. Recently, Chinese regulators have announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that materially adversely affect the business environment and financial markets in China as they relate to us, our ability to operate our business, our liquidity and our access to capital.

The uncertainties in the China legal system could materially and adversely affect us.

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities markets and promote the high-quality development of the capital markets, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation-making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us.

It is especially difficult for us to accurately predict the potential impact to the Company of new legal requirements in China because the China legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, the China legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the China legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

Other Risk Factors

The following is a summary of significant risk factors and uncertainties that may affect our business which are discussed in more detail in our Annual Report on Form 10-K for the year ended December 31, 2020:

- our ability to successfully commercialize ZEJULA, Optune, QINLOCK and any other products and product candidates that we may obtain regulatory approval for;
- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration, and acquisition agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- patent terms, patent term extensions, patent office actions and expected availability and any period of regulatory exclusivity;
- the timing, outcome and impact of administrative, regulatory, legal or other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of certain business development transactions;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals of our products, product candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- reputational or financial harm to our business arising from adverse safety events, including product liability claims or lawsuits affecting our or any of our licensors' marketed products, generic or biosimilar versions of our or any of our licensors' marketed products or any other products from the same class as one of our or any of our licensors' products;
- unexpected impacts on our business operations including sales, expenses, supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;
- the potential impact of measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities or activities in new or existing manufacturing facilities;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, regulatory requirements, judicial decisions and accounting standards;
- the disruption of our business relationships with our licensors;
- the direct and indirect impact of the COVID-19 pandemic on our business and operations, our and our partners' ability to effectively travel, as needed, during the COVID-19 pandemic, and the duration and impact of COVID-19 or any of its variants that may affect, precipitate or exacerbate one or more of any of the risks and uncertainties mentioned in this section;
- our ability to effectively manage our growth;
- the disruption in the capital or credit markets which may adversely impact our ability to obtain necessary capital or credit market financing;
- the geopolitical tensions that exist between China and the United States may adversely affect our business, our ability to grow, and our access to necessary capital or credit markets;
- our ability to retain key executives and to attract, retain and motivate personnel; and
- other risks and uncertainties, including those listed under "Part I—Item 1A—Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and other information in our Annual Report on Form 10-K for the year ended December 31, 2020 and our other filings with the SEC.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
3.1	Fifth Amended and Restated Memorandum of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021)
3.2	Fifth Amended and Restated Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 24, 2021)
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.3*	Registrant's Specimen Certificate for Ordinary Shares
4.4	Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.5	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act (incorporated by reference to Exhibit 4.5 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021)
10.1*	Amendment to the Amended and Restated Employment Agreement, dated as of May 7, 2021, by and between Zai Lab (US) LLC and Tao Fu
10.2*^	Collaboration and License Agreement, dated as of May 28, 2021, by and between Zai Lab (Hong Kong) Limited and Mirati Therapeutics, Inc.
10.3*^	License and Collaboration Agreement, dated as of June 15, 2021, by and between Zai Lab (US) LLC and MacroGenics, Inc.
31.1*	Certification of Chief Executive Officer Required by Rule 13a-14(a)
31.2*	Certification of Chief Financial Officer Required by Rule 13a-14(a)
32.1**	Certification of Chief Executive Officer Required by Rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code
32.2**	Certification of Chief Financial Officer Required by Rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

Exhibit Number	Exhibit Title
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith
** Furnished herewith
^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ZAI LAB LIMITED

Dated: August 9, 2021

By: /s/ Samantha Du

Name: Samantha Du
Title: Chief Executive Officer

The following table sets out the exhibits filed with Form 10-Q of the Company dated August 9, 2021 ("**Form 10-Q**"):

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3.1	Fifth Amended and Restated Memorandum of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our annual report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021)	For further details, please review the relevant exhibits of our Form 10-Q which are available for viewing on the website of the U.S. Securities and Exchange Commission at www.sec.gov.
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zai Lab
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