Zai Lab Limited

再鼎醫藥有限公司 *

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9688)

OVERSEAS REGULATORY ANNOUNCEMENT — FORM 10-Q

This announcement is issued by Zai Lab Limited (the "**Company**") pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Please refer to the attached for the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 which the Company has filed with the U.S. Securities and Exchange Commission on August 7, 2023 (U.S. Eastern Time)/August 8, 2023 (Shanghai and Hong Kong Time). For further details, please refer to the exhibits to the Form 10-Q which are available for viewing on the website of the U.S. Securities and Exchange Commission at www.sec.gov and the website of the Company at www.zailaboratory.com.

By order of the Board
Zai Lab Limited
Samantha Du
Director, Chairperson and Chief Executive Officer

Hong Kong, August 8, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Samantha Du as a director, and Dr. Kai-Xian Chen, Dr. John Diekman, Richard Gaynor, M.D., Ms. Nisa Leung, Mr. William Lis, Mr. Scott W. Morrison, Mr. Leon O. Moulder, Jr., Mr. Michel Vounatsos and Mr. Peter Wirth as independent directors.

* *For identification only*

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, 2023

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	**98-1144595**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
4560 Jinke Road **Bldg. 1, Fourth Floor, Pudong** **Shanghai** **China**	**201210**
314 Main Street **4th Floor, Suite 100** **Cambridge, MA, USA**	**02142**
(Address of Principal Executive Offices)	(Zip Code)

+86 216163 2588
+1 857 706 2604
(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 10 Ordinary Shares, par value $0.000006 per share	**ZLAB**	**The Nasdaq Global Market**
Ordinary Shares, par value $0.000006 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 August 1, 2023, 983,887,430 ordinary shares of the registrant, par value $0.000006 per share, were outstanding, of which 749,901,320 ordinary shares were held in the form of American Depositary Shares.

Zai Lab Limited
Quarterly Report on Form 10-Q
For the Second Quarter of 2023

		Page
PART I.	**FINANCIAL INFORMATION**	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets as of June 30, 2023 and December 31, 2022	1
	Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2023 and 2022	2
	Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2023 and 2022	3
	Condensed Consolidated Statements of Shareholders' Equity for the Three and Six Months Ended June 30, 2023 and 2022	4
	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2023 and 2022	6
	Notes to Unaudited Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	26
Item 4.	Controls and Procedures	27
PART II.	**OTHER INFORMATION**	28
Item 1.	Legal Proceedings	28
Item 1A.	Risk Factors	28
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	28
Item 3.	Defaults upon Senior Securities	28
Item 4.	Mine Safety Disclosures	28
Item 5.	Other Information	28
Item 6.	Exhibits	29
Signatures		30

SPECIAL NOTES REGARDING THE COMPANY

Forward-Looking Statements

This report contains certain forward-looking statements, including statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; capital allocation and investment strategy; clinical development programs and related clinical trials; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our products and product candidates and those of our collaboration partners; the anticipated benefits and potential of investments, collaborations, and business development activities; and our future financial and operating results. All statements, other than statements of historical fact, included in this report are forward-looking statements, and can be identified by words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "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. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this report and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. 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 following:

- Our ability to successfully commercialize and generate revenue from our approved products;
- Our ability to obtain funding for our operations and business initiatives;
- The results of our clinical and pre-clinical development of our product candidates;
- The content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates;
- Changes in United States and China trade policies and relations, as well as relations with other countries, and/or changes in regulations and/or sanctions;
- Actions the Chinese government may take to intervene in or influence our operations;
- Economic, political, and social conditions in mainland China, as well as governmental policies;
- Uncertainties in the Chinese legal system, including with respect to the Counter-Espionage Law, the Data Security Law, the Cyber Security Law, the Cybersecurity Review Measures, the Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, the Measures on Security Assessment of Cross-Border Data Transfer (the "Security Assessment Measures"), and other future laws and regulations or amendments to such laws and regulations;
- The effects of the COVID-19 pandemic, particularly in mainland China where our operations and product markets are primarily located;
- Approval, filing, or procedural requirements imposed by the China Securities Regulatory Commission ("CSRC") or other Chinese regulatory authorities in connection with issuing securities to foreign investors under Chinese law;
- Any violation or liability under the U.S. Foreign Corrupt Practices Act ("FCPA") or Chinese anti-corruption laws;
- Restrictions on currency exchange;
- Limitations on the ability of our Chinese subsidiaries to make payments to us;
- Chinese requirements on the ability of residents in mainland China to establish offshore special purpose companies;
- Chinese regulations regarding acquisitions of companies based in mainland China by foreign investors;
- Any issues that our Chinese manufacturing facilities may have with operating in conformity with established Good Manufacturing Practices ("GMPs") and international best practices, and with passing U.S. Food and Drug Administration ("FDA"), China National Medical Products Administration ("NMPA"), and European Medicines Agency inspections;
- Expiration of, or changes to, financial incentives or discretionary policies granted by local governments in mainland China;
- Restrictions or limitations on the ability of overseas regulators to conduct investigations or collect evidence within mainland China;
- Unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders if we were to be classified as a Chinese resident enterprise for Chinese income tax purposes;

- Failure to comply with applicable Chinese, U.S., and Hong Kong regulations that could lead to government enforcement actions, fines, other legal or administrative sanctions, and/or harm to our business or reputation;
- Review by the U.S. Committee on Foreign Investment ("CFIUS") in our investments or other delays or obstacles for closing transactions;
- Any inability to renew our current leases on desirable terms or otherwise locate desirable alternatives for our leased properties;
- Our ability to generate revenues from our approved commercial products;
- Any inability of third parties on whom we rely to conduct our pre-clinical and clinical trials to successfully carry out their contractual duties or meet expected deadlines; and
- Any inability to obtain or maintain sufficient patent protection for our products and product candidates.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and information in our Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Annual Report"), Quarterly Report on Form 10-Q for the three months ended March 31, 2023 (the "Q1 2023 Form 10-Q"), and this report. Forward-looking statements are based on our management's beliefs and assumptions and information currently available to our management. These statements, like all statements in this report, 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 report.

Usage of Terms

Unless the context requires otherwise, references in this report to "Greater China" refer to mainland China, Hong Kong Special Administrative Region ("Hong Kong" or "HK"), Macau Special Administrative Region ("Macau"), and Taiwan, collectively; references to "Zai Lab," the "Company," "we," "us," and "our" refer to Zai Lab Limited, a holding company, and its subsidiaries, on a consolidated basis; and references to "Zai Lab Limited" refer to Zai Lab Limited, a holding company. Zai Lab Limited is the entity in which investors hold their interest.

Our operating subsidiaries consist of Zai Lab (Hong Kong) Limited, domiciled in Hong Kong; Zai Auto Immune (Hong Kong) Limited, domiciled in Hong Kong; Zai Anti Infectives (Hong Kong) Limited, domiciled in Hong Kong; Zai Lab (Shanghai) Co., Ltd., domiciled in mainland China; Zai Lab International Trading (Shanghai) Co., Ltd., domiciled in mainland China; Zai Lab (Suzhou) Co., Ltd., domiciled in mainland China; Zai Biopharmaceutical (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab Trading (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab (Taiwan) Limited, domiciled in Taiwan; Zai Lab (AUST) Pty. Ltd., domiciled in Australia; and Zai Lab (US) LLC, domiciled in the United States. As of the date of this report, Zai Anti Infectives (Hong Kong) Limited has non-substantial business operations.

We own various registered trademarks, trademark applications, and unregistered trademarks and service marks, including various forms of the "ZAI LAB" and "再鼎医药" brands, as well as domain names incorporating some or all of these trademarks and our corporate logo. All other trade names, trademarks, and service marks of other companies appearing in this report are the property of their respective holders. Solely for convenience, some of the trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of, any other company.

Disclosures Relating to Our Chinese Operations

Zai Lab Limited is an exempted company incorporated in the Cayman Islands on March 28, 2013 with limited liability. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. We have substantial operations in mainland China. Below is a summary of certain risks related to our Chinese operations. For more information on these risks and other risks relating to our ADSs and ordinary shares (considered individually or together, "our securities") and for material regulations that may affect our business and an investment in our securities, see Item 1A. Risk Factors and Item 1. Business – Government Regulation in our 2022 Annual Report.

Zai Lab Limited is not a Chinese operating company, but a holding company incorporated in the Cayman Islands.

Zai Lab Limited is not a Chinese operating company, but a holding company incorporated in the Cayman Islands. As a holding company, we conduct a substantial portion of our operations through wholly owned subsidiaries based in mainland China. Our investors do not hold direct investments in our Chinese operating companies. In July 2021, the Chinese government provided new guidance on Chinese companies raising capital outside of mainland China, including through arrangements called variable interest entities ("VIEs"). Currently, our corporate structure contains no VIEs, and the life sciences industry in which we operate is not subject to foreign ownership limitations in mainland China. However, there are uncertainties with respect to the Chinese legal system, and there may be changes in laws, regulations, and policies, including how those laws, regulations, and policies will be interpreted or implemented, that may affect our business or an investment in our business. If, in the future, the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently, the value of our securities may decline or become worthless.

There are significant legal and operational risks associated with conducting a substantial portion of our operations in mainland China, including with respect to changes in the legal, political, and economic policies of the Chinese government, relations between mainland China and the United States, or Chinese or U.S. regulations, that may materially and adversely affect our business, financial condition, results of operations, ability to raise capital or continue to offer our securities, and the market price of our securities.

There are significant legal and operational risks associated with conducting a substantial portion of our operations in mainland China, including with respect to changes in the legal, political, and economic policies of the Chinese government, relations between mainland China and the United States, or Chinese or U.S. regulations. For example, geopolitical events, such as developments with respect to Taiwan, continue to cause heightened tensions between the United States and China. In addition, new laws and regulations, including the Counter-Espionage Law, Personal Information Protection Law, Data Security Law, Cyber Security Law and Cybersecurity Review Measures, Measures on Security Assessment of Cross-Border Data Transfer, and regulations and guidelines relating to the multi-level protection scheme, have imposed, and may continue to impose, additional restrictions or obligations and compliance-related costs on our business. In addition, our business, or our directors or employees, may be subject to enforcement actions or penalties if it is determined that we, or they, have not complied with applicable laws and regulations. Such legal and operational risks may materially and adversely affect our business, financial condition, results of operations, ability to raise capital or continue to offer our securities, and the market price of our securities.

We are or may be required to obtain certain permissions from Chinese authorities to operate in mainland China, issue our securities to foreign investors, and transfer certain scientific data.

The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. As a result, we are or may be required to obtain certain approvals or permissions from Chinese authorities to operate in mainland China, transfer certain scientific data, and issue our securities to foreign investors.

For example, we are required to obtain certain approvals from Chinese authorities to operate our Chinese subsidiaries. To operate our general business activities in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the State Administration for Market Regulation ("SAMR"). Each of our Chinese subsidiaries has obtained such a business license. Our Chinese subsidiaries are also required to obtain certain licenses and permits, including but not limited to the following: Pharmaceutical Manufacturing Permits, Pharmaceutical Distribution Permits, and Medical Device Distribution Permits to manufacture and/or distribute drugs and/or applicable medical devices. No application for any such material license or permit has been denied.

Further, we are required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or controlled by those foreign parties. In addition, we may be subject to additional such requirements pursuant to the Security Assessment Measures, which may affect our Chinese subsidiaries or clinical trials. The Security Assessment Measures may require us to complete security assessments for certain cross-border data transfers, obtain prior approval from the Cyberspace Administration of China ("CAC") for transfers out of mainland China of certain important or personal data, or obtain prior clearance or approval from the Human Genetic Resources Administration Office of China ("HGRAC") for certain transfers of data derived from human organs, tissues, or cells of Chinese individuals that contain human genetic materials. If we are not able to obtain or maintain the necessary permissions or approvals, our ability to operate in mainland China may be restricted or prohibited, and the value of our securities could significantly decline or become worthless.

Although we are not currently required to obtain prior approval or permission from the CSRC or any other Chinese regulatory authority to issue our securities to foreign investors, the CSRC has promulgated a new set of regulations that consists of the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (the "Trial Measures") and five supporting guidelines, which became effective in March 2023. Pursuant to the Trial Measures, we may be required to submit filings to the CSRC following the submission of future overseas listings and the completion of future offerings of our equity securities to foreign investors. If we are not able to complete the necessary filings for future securities offerings, our ability to raise capital may be adversely affected.

The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could impose additional requirements, require additional approvals or permissions in the future, and result in additional related expenditures and efforts on our part to comply with such regulations or interpretations. Also, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations, and policies, including how those laws, regulations, and policies will be interpreted or implemented, our business and an investment in our securities could be adversely affected.

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 report and the audited consolidated financial information and the accompanying notes included in our 2022 Annual Report.

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	June 30, 2023	December 31, 2022
Assets			
Current assets:			
Cash and cash equivalents	3	859,155	1,008,470
Short-term investments		15,500	—
Accounts receivable (net of allowance for credit loss of $14 and $11 as of June 30, 2023 and December 31, 2022, respectively)		47,283	39,963
Notes receivable		20,781	8,608
Inventories, net	4	36,353	31,621
Prepayments and other current assets		38,433	35,674
Total current assets		1,017,505	1,124,336
Restricted cash, non-current		1,791	803
Long term investments		5,128	6,431
Prepayments for equipment		665	1,396
Property and equipment, net	5	56,410	57,863
Operating lease right-of-use assets		18,537	19,512
Land use rights, net		3,067	6,892
Intangible assets, net		1,690	1,511
Long-term deposits		1,580	1,396
Total assets		**1,106,373**	**1,220,140**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		67,031	65,974
Current operating lease liabilities		7,299	7,050
Other current liabilities	8	59,024	66,818
Total current liabilities		133,354	139,842
Deferred income		28,625	21,360
Non-current operating lease liabilities		11,755	13,343
Other non-current liabilities		325	—
Total liabilities		**174,059**	**174,545**
Commitments and contingencies (Note 15)			
Shareholders' equity			
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 973,355,390 and 962,455,850 shares issued as of June 30, 2023 and December 31, 2022, respectively; 968,566,280 and 960,219,570 shares outstanding as of June 30, 2023 and December 31, 2022, respectively)		6	6
Additional paid-in capital		2,932,053	2,893,120
Accumulated deficit		(2,031,399)	(1,861,360)
Accumulated other comprehensive income		52,180	25,685
Treasury Stock (at cost, 4,789,110 and 2,236,280 shares as of June 30, 2023 and December 31, 2022, respectively)		(20,526)	(11,856)
Total shareholders' equity		**932,314**	**1,045,595**
Total liabilities and shareholders' equity		**1,106,373**	**1,220,140**

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 $, except for number of shares and per share data)

	Notes	Three Months Ended June 30,		Six Months Ended June 30,	
		2023	2022	2023	2022
Revenues:					
Product revenue, net	6	68,864	47,575	131,661	93,670
Collaboration revenue		—	601	—	1,230
Total revenues		68,864	48,176	131,661	94,900
Expenses:					
Cost of sales		(23,763)	(17,407)	(45,100)	(33,051)
Research and development		(76,682)	(66,084)	(125,153)	(119,938)
Selling, general, and administrative		(67,920)	(63,401)	(130,430)	(120,392)
Gain on sale of intellectual property		10,000	—	10,000	—
Loss from operations		(89,501)	(98,716)	(159,022)	(178,481)
Interest income		10,090	1,175	20,321	1,363
Foreign currency loss		(40,079)	(34,895)	(31,167)	(32,610)
Other expense, net	13	(1,405)	(5,497)	(171)	(10,378)
Loss before income tax and share of loss from equity method investment		(120,895)	(137,933)	(170,039)	(220,106)
Income tax expense	7	—	—	—	—
Share of loss from equity method investment		—	—	—	(221)
Net loss		(120,895)	(137,933)	(170,039)	(220,327)
Net loss attributable to ordinary shareholders		(120,895)	(137,933)	(170,039)	(220,327)
Loss per share - basic and diluted	9	(0.13)	(0.14)	(0.18)	(0.23)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		964,817,310	957,684,820	963,140,360	956,603,250
Loss per American Depositary Shares (“ADS”) - basic and diluted		(1.25)	(1.44)	(1.77)	(2.30)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted		96,481,731	95,768,482	96,314,036	95,660,325

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 $)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Net loss	(120,895)	(137,933)	(170,039)	(220,327)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	34,908	30,325	26,495	28,132
Comprehensive loss	(85,987)	(107,608)	(143,544)	(192,195)

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 $, except for number of shares)

	Ordinary Shares					Treasury Stock		
	Number of Shares	Amount	Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Shares	Amount	Total
Balance at December 31, 2022	962,455,850	6	2,893,120	(1,861,360)	25,685	(2,236,280)	(11,856)	1,045,595
Issuance of ordinary shares upon vesting of restricted shares	732,040	0	0	—	—	—	—	—
Exercise of share options	4,009,460	0	1,673	—	—	—	—	1,673
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,272,330)	(5,130)	(5,130)
Share-based compensation	—	—	16,661	—	—	—	—	16,661
Net loss	—	—	—	(49,144)	—	—	—	(49,144)
Foreign currency translation	—	—	—	—	(8,413)	—	—	(8,413)
Balance at March 31, 2023	967,197,350	6	2,911,454	(1,910,504)	17,272	(3,508,610)	(16,986)	1,001,242
Issuance of ordinary shares upon vesting of restricted shares	6,117,040	0	0	—	—	—	—	—
Exercise of share options	41,000	0	88	—	—	—	—	88
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,280,500)	(3,540)	(3,540)
Share-based compensation	—	—	20,511	—	—	—	—	20,511
Net loss	—	—	—	(120,895)	—	—	—	(120,895)
Foreign currency translation	—	—	—	—	34,908	—	—	34,908
Balance at June 30, 2023	973,355,390	6	2,932,053	(2,031,399)	52,180	(4,789,110)	(20,526)	932,314

	Ordinary Shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total
	Number of Shares	Amount				Shares	Amount	
Balance at December 31, 2021	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956
Issuance of ordinary shares upon vesting of restricted shares	514,800	0	0	—	—	—	—	—
Exercise of share options	1,156,660	0	297	—	—	—	—	297
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(15,150)	(68)	(68)
Share-based compensation	—	—	12,410	—	—	—	—	12,410
Net loss	—	—	—	(82,394)	—	—	—	(82,394)
Foreign currency translation	—	—	—	—	(2,193)	—	—	(2,193)
Balance at March 31, 2022	957,035,440	6	2,838,655	(1,500,468)	(25,838)	(398,080)	(4,347)	1,308,008
Issuance of ordinary shares upon vesting of restricted shares	683,700	0	0	—	—	—	—	—
Exercise of share options	2,801,000	0	4,322	—	—	—	—	4,322
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,627,230)	(6,782)	(6,782)
Share-based compensation	—	—	14,225	—	—	—	—	14,225
Net loss	—	—	—	(137,933)	—	—	—	(137,933)
Foreign currency translation	—	—	—	—	30,325	—	—	30,325
Balance at June 30, 2022	960,520,140	6	2,857,202	(1,638,401)	4,487	(2,025,310)	(11,129)	1,212,165

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 $)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	(170,039)	(220,327)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss (gain)	3	(3)
Inventory write-down	623	193
Depreciation and amortization expenses	4,652	3,874
Amortization of deferred income	(1,716)	(1,386)
Share-based compensation	37,172	26,634
Share of loss from equity method investment	—	221
Loss from fair value changes of equity investment with readily determinable fair value	1,304	12,556
Loss (gain) on disposal of property and equipment	260	(11)
Gain on disposal of land use right	(404)	—
Noncash lease expenses	4,383	3,825
Gain from sale of intellectual property	(10,000)	—
Foreign currency remeasurement loss	31,167	32,610
Changes in operating assets and liabilities:		
Accounts receivable	(8,863)	20,422
Notes receivable	(12,714)	(3,633)
Inventories	(6,627)	(4,582)
Prepayments and other current assets	87	48
Long-term deposits	(184)	(78)
Value added tax recoverable	—	23,602
Accounts payable	3,037	(17,718)
Other current liabilities	(6,761)	(3,100)
Operating lease liabilities	(3,596)	(3,849)
Deferred income	9,902	(1,325)
Other non-current liabilities	325	—
Net cash used in operating activities	(127,989)	(132,027)
Cash flows from investing activities		
Purchases of short-term investments	(100,000)	(260,274)
Proceeds from maturity of short-term investment	84,500	130,000
Purchase of property and equipment	(5,234)	(13,488)
Proceeds from the sale of property and equipment	112	—
Purchase of intangible assets	(630)	(107)
Proceeds from sale of intellectual property	10,000	—
Net cash used in investing activities	(11,252)	(143,869)
Cash flows from financing activities		
Proceeds from exercises of stock options	1,762	4,619
Taxes paid related to settlement of equity awards	(7,141)	(6,859)
Net cash used in financing activities	(5,379)	(2,240)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(3,707)	(5,144)
Net decrease in cash, cash equivalents and restricted cash	(148,327)	(283,280)
Cash, cash equivalents and restricted cash - beginning of period	1,009,273	964,903
Cash, cash equivalents and restricted cash - end of period	860,946	681,623
Supplemental disclosure on non-cash investing and financing activities		
Payables for purchase of property and equipment	4,344	1,661
Payables for intangible assets	96	270
Payables for treasury stock	1,531	17
Receivables for stock option exercise under equity incentive plans	—	12
Right-of-use asset acquired under operating leases	3,313	8,451
Receivables for disposal of land use right	3,867	—
Supplemental disclosure of cash flow information		
Cash and cash equivalents	859,155	680,820
Restricted cash, non-current	1,791	803
Total cash and cash equivalents and restricted cash	860,946	681,623

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

1. Organization and Principal Activities

Zai Lab Limited was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Act of the Cayman Islands (as amended). Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs, including in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience.

The Company's principal operations and geographic markets are in Greater China. The Company has a substantial presence in Greater China and the United States. The accompanying unaudited condensed consolidated financial statements are the financial statements of the Company.

2. Basis of Presentation and Consolidation and Significant Accounting Policies

(a) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"), regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this report should be read in conjunction with the consolidated financial statements and accompanying notes included in the Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Annual Report"). The December 31, 2022 condensed consolidated balance sheet data included in this report were derived from the audited financial statements in the 2022 Annual Report.

In the third quarter of 2022, we began to separately present the amount of foreign currency remeasurement gain (loss) on our statements of cash flows. This amount was previously included in changes in other current liabilities. This change did not have any impact on net cash used in operating activities. Corresponding amounts in the prior periods of the condensed consolidated financial statement have been presented to conform to the current period presentation.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the year ending December 31, 2023.

(b) Principles of Consolidation

The unaudited condensed consolidated financial statements include the financial statements of the Company. All intercompany transactions and balances 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, judgments, 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 revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, accrual of rebates, recognition of research and development expenses to the appropriate financial reporting period based on the progress of the research and development projects, fair value of share-based compensation expenses, and recoverability of deferred tax assets. These estimates, judgments, and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Actual results could differ from these estimates.

(d) Fair Value Measurements

Equity investments with readily determinable fair value are measured using level 1 inputs and were $5.1 million and $6.4 million as of June 30, 2023 and December 31, 2022, respectively. The unrealized gains and losses from fair value changes are recognized in other expenses, net in the consolidated statements of operations.

Financial instruments of the Company primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities. As of June 30, 2023 and December 31, 2022, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, 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 approximated its fair value based on the nature of the assessment of the ability to recover these amounts.

(e) Recent Accounting Pronouncements

The Company has not adopted any new accounting standards since December 31, 2022. For a discussion of the Company's significant accounting policies, see the discussion in Note 2 above and the notes to the consolidated financial statements in the 2022 Annual Report.

3. Cash and Cash Equivalents

The following table presents the Company's cash and cash equivalents ($ in thousands):

	June 30, 2023	December 31, 2022
Cash	858,089	1,007,423
Cash equivalents (i)	1,066	1,047
	859,155	1,008,470
Denominated in:		
US$	832,974	957,824
RMB (ii)	21,968	45,486
Hong Kong dollar ("HK$")	3,485	4,378
Australian dollar ("A$")	578	598
Taiwan dollar ("TW$")	150	184
	859,155	1,008,470

(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 mainland 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 Chinese government.

4. Inventories, Net

The following table presents the Company's inventories, net ($ in thousands):

	June 30, 2023	December 31, 2022
Finished goods	16,687	12,156
Raw materials	19,320	19,029
Work in progress	346	436
Inventories, net	36,353	31,621

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. The Company recorded write-downs in inventory, which were included in cost of sales, of $0.2 million and $0.6 million during the three and six months ended June 30, 2023, respectively, and $0.1 million and $0.2 million during the three and six months ended June 30, 2022 respectively.

5. Property and Equipment, Net

The following table presents the components of the Company's property and equipment, net ($ in thousands):

	June 30, 2023	December 31, 2022
Office equipment	985	977
Electronic equipment	8,457	7,416
Vehicle	195	202
Laboratory equipment	19,672	18,726
Manufacturing equipment	16,595	17,055
Leasehold improvements	11,036	11,300
Construction in progress	25,092	24,251
	82,032	79,927
Less: accumulated depreciation	(25,622)	(22,064)
Property and equipment, net	56,410	57,863

Depreciation expense was $1.8 million and $4.3 million for the three and six months ended June 30, 2023, respectively, and $1.7 million and $3.6 million for the three and six months ended June 30, 2022, respectively.

6. Revenue

Product Revenue

The Company's product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The table below presents the Company's product revenue ($ in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Product revenue - gross	75,010	54,339	146,222	107,649
Less: Rebates and sales returns	(6,146)	(6,764)	(14,561)	(13,979)
Product revenue - net	68,864	47,575	131,661	93,670

Sales rebates are offered to distributors in mainland 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 presents the Company's net revenue by product ($ in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
ZEJULA	42,957	34,052	85,637	63,649
Optune	13,692	11,592	27,034	24,389
QINLOCK	7,527	623	8,833	3,582
NUZYRA	4,636	1,308	10,105	2,050
VYVGART	52	—	52	—
Product revenue - net	68,864	47,575	131,661	93,670

7. 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 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, 2023 and December 31, 2022. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

8. Other Current Liabilities

The following table presents the Company's other current liabilities ($ in thousands):

	June 30, 2023	December 31, 2022
Payroll	18,976	31,689
Accrued professional service fee	7,922	4,080
Payables for purchase of property and equipment	4,344	5,269
Accrued rebate to distributors	8,514	8,443
Tax payables	15,768	13,283
Others (i)	3,500	4,054
Total	59,024	66,818

(i) Others mainly include accrued travel and business-related expenses.

9. Loss Per Share

The following table presents the computation of the basic and diluted net loss per share ($ in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss attributable to ordinary shareholders	(120,895)	(137,933)	(170,039)	(220,327)
Denominator:				
Weighted average number of ordinary shares - basic and diluted	964,817,310	957,684,820	963,140,360	956,603,250
Net loss per share - basic and diluted	(0.13)	(0.14)	(0.18)	(0.23)

As a result of the Company's net loss for the three and six months ended June 30, 2023 and 2022, 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.

	June 30,	
	2023	2022
Share options	108,322,600	91,546,280
Non-vested restricted shares	33,462,670	34,356,250

10. Related Party Transactions

The Company incurred research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd ("MEDx"), over which an immediate family member of our Chief Executive Officer and Chairperson of the Board held significant influence. The Company incurred development expenses with MEDx of insignificant amounts during the three and six months ended June 30, 2023 and $0.2 million and $0.3 million during the three and six months ended June 30, 2022, respectively.

11. Share-Based Compensation

During the six months ended June 30, 2023, the Company granted share options to purchase up to 22,776,380 ordinary shares and restricted shares representing 8,326,080 ordinary shares under the 2022 Plan. The share options granted have a contractual term of ten years. Share options granted since April 2023 generally vest ratably over a four-year period, and share options granted prior to April 2023 generally vest ratably over a five-year period, with 25% or 20% of the awards vesting on each anniversary of the grant date, respectively, subject to continued employment with the Company on the vesting date. For a description of the Company's equity incentive plans and more details on the terms of the share-based awards, see Note 15 to our 2022 Annual Report.

During the six months ended June 30, 2023, the share options were granted at exercise prices ranging from $3.35 per share to $3.99 per share. The share options granted were valued using the Black-Scholes model, and the weighted-average grant-date fair value was $2.23 per share. The restricted shares granted generally vest ratably over a specified period on the anniversary of the grant date, subject to continued employment/service with the Company on the vesting date.

The following table presents the share-based compensation expense that has been reported in the Company's condensed consolidated statements of operations and comprehensive loss as follows ($ in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Selling, general and administrative	11,776	8,931	21,839	15,923
Research and development	8,735	5,294	15,333	10,712
Total	20,511	14,225	37,172	26,635

As of June 30, 2023, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of $129.2 million and $130.9 million, respectively, which the Company expects to recognize over a weighted-average period of 3.45 years and 3.21 years, respectively.

12. License and Collaboration Agreements

The Company has entered into various license and collaboration agreements with third parties to develop and commercialize product candidates.

Significant License and Collaboration Arrangements

For a description of the material terms of the Company's significant license and collaboration agreements, see Note 16 to our 2022 Annual Report. During the six months ended June 30, 2023, the Company did not enter into any new significant license or collaboration agreements. The following includes a description of payments or accruals related to upfront or milestone fees under our significant license and collaboration agreements during the six months ended June 30, 2023.

License and Collaboration Agreement with Entasis Therapeutics Holdings Inc.("Entasis") (SUL-DUR)

Under the terms of our license and collaboration agreement with Entasis for SUL-DUR, the Company accrued a $3.0 million development milestone in the second quarter of 2023, and the additional aggregate amount the Company may be required to pay for development, regulatory, and sales-based milestones decreased to $88.6 million.

License Agreement with BMS (Formerly Turning Point Therapeutics Inc ("Turning Point")) (Repotrectinib)

Under the terms of our license agreement with BMS for reprotrectinib, the Company accrued a $5.0 million development milestone in the second quarter of 2023, and the additional aggregate amount the Company may be required to pay for development, regulatory, and sales-based milestones decreased to $141.0 million.

Other License and Collaboration Arrangements That Are Not Individually Significant

The Company made an upfront payment of $10.0 million in the second quarter of 2023 for a new strategic partnership and global license agreement with MediLink Therapeutics (Suzhou) Co., Ltd. for an early-stage next generation DLL3 ADC program, ZL-1310.

13. Other Expenses, Net

The following table presents the Company's other expenses, net ($ in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Government grants	83	50	83	1,627
Loss on equity investments with readily determinable fair value	(1,744)	(5,617)	(1,304)	(12,556)
Others miscellaneous gain	256	70	1,050	551
Total	(1,405)	(5,497)	(171)	(10,378)

14. Restricted Net Assets

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its Chinese subsidiaries. Relevant Chinese laws and regulations permit payments of dividends by the Company's Chinese subsidiaries only out of its retained earnings, if any, as determined in accordance with Chinese 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 Company's Chinese subsidiaries.

In accordance with the Company Law of the People's Republic of China, 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 Chinese statutory accounts. A domestic enterprise may provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's Chinese statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's Chinese subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

No appropriation to statutory reserves was made during the three and six months ended June 30, 2023 and 2022 because the Chinese subsidiaries had substantial losses during such periods.

As a result of these Chinese laws and regulations, subject to the limits discussed above that require annual appropriations of 10% of after-tax profit to be set aside, prior to payment of dividends, as a general reserve fund, the Company's Chinese subsidiaries are restricted in their ability to transfer out a portion of their net assets.

Foreign exchange and other regulation in mainland China may further restrict the Company's Chinese subsidiaries from transferring out funds in the form of dividends, loans, and advances. As of June 30, 2023 and December 31, 2022, amounts restricted are the paid-in capital of the Company's Chinese subsidiaries, which both amounted to $456.0 million.

15. Commitments and Contingencies

(a) Purchase Commitments

The Company's commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statements were $3.9 million as of June 30, 2023 and were expected to be incurred within one year.

(b) Legal Proceedings

The Company is not currently a party to any material legal proceedings.

(c) Indemnifications

In the normal course of business, the Company enters into agreements that indemnify others for certain liabilities that may arise in connection with a transaction or certain events and activities. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2022 Annual Report and our unaudited condensed consolidated financial statements and the accompanying notes for the three and six months ended June 30, 2023 included in Item 1. Financial Statements.

Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are focused on discovering, developing, and commercializing products that address medical conditions with significant unmet needs in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. We currently have five products that have received marketing approval in one or more territories in Greater China (our "commercial products"). We have commercially launched four of those products – ZEJULA®, Optune®, QINLOCK®, and NUZYRA® – and we expect to commercially launch VYVGART® later this year. We also have thirteen programs in late-stage product development and a number of ongoing pivotal trials across our portfolio.

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 selling, general and administrative costs associated with our operations. Developing high quality product candidates requires significant investment in 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 positive cash flow from operations over the next several years depends upon our ability to successfully market our commercial products and to successfully expand the indications for these products and develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. For example, our licensing and collaboration agreements may require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

As we pursue our strategy of growth and development, we anticipate that our financial results will fluctuate from quarter to quarter and year to year depending in part on the balance between the success of our commercial products and the level of our research and development expenses. We cannot predict whether or when products in our pipeline, including new indications for our current commercial products, will receive regulatory approval. Further, if we receive such regulatory approval, we cannot predict whether or when we may be able to successfully commercialize such product or whether or when such product may become profitable.

Recent Developments

Commercial Products

We continued to increase net product revenues for each of our commercial products in the second quarter of 2023, compared to the second quarter of 2022, driven by the increased access for ZEJULA, QINLOCK, and NUZYRA as a result of their inclusion in the National Reimbursement Drug List ("NRDL") and for Optune as a result of increased supplemental insurance plan coverage.

We also received the following regulatory approvals for our commercial products during the second quarter of 2023:

- **Optune for GBM in Taiwan**: In May 2023, the Taiwan Food and Drug Administration approved the Marketing Authorization Application ("MAA") for Optune for the treatment of patients with glioblastoma multiforme ("GBM").
- **VYVGART for gMG in mainland China**: In June 2023, we received approval from the NMPA for the Biologics License Application ("BLA") for VYVGART (efgartigimod alfa injection), a first-in-class neonatal Fc receptor ("FcRn") antagonist, as an add on standard therapy for the treatment of adult patients with generalized myasthenia gravis ("gMG") who are anti-acetylcholine receptor ("AChR") antibody positive. We expect to commercially launch VYVGART in mainland China later this year.

Product Candidates

We continued to advance our product candidates through our research and development and commercial operations, including the following developments with respect to our clinical trials and regulatory approvals:

Oncology

- **ZEJULA** (niraparib, PARP): In July 2023, we announced the publication in JAMA Oncology of data from the pivotal Phase III PRIME study evaluating ZEJULA as a first-line maintenance therapy in Chinese patients with newly diagnosed advanced ovarian cancer and demonstrating that an individual starting dose ("ISD") of 200 or 300mg based on baseline bodyweight and platelet count can bring significant benefit to patients with an improved safety and tolerability profile of ZEJULA compared to a fixed 300mg starting dose. The data demonstrated that maintenance treatment with ZEJULA can significantly extend progression-free survival ("PFS") versus a placebo and can reduce the risk of disease progression or death by 55% among patients with newly diagnosed advanced ovarian cancer, regardless of postoperative residual disease or biomarker status. For example, with a median follow-up of 27.5 months, median PFS ("mPFS") with ZEJULA versus placebo in the intention-to-treat ("ITT") population was 24.8 versus 8.3 months (hazard ratio ("HR"), 0.45; 95% confidence internal ("CI"), 0.34–0.60; p<.001). At the time of data cut-off, overall survival ("OS") data were not yet mature in the ITT population. Utilization of an individual starting dose demonstrated a tolerable safety profile in the maintenance setting. Grade ≥3 treatment-emergent adverse events ("TEAEs") and serious adverse events ("SAEs") were reported in 54.5% versus 17.8% and 18.8% vs 8.5% in ZEJULA-treated and placebo-treated patient, respectively. Similar proportions of ZEJULA-treated and placebo-treated patients (6.7% vs 5.4%) discontinued therapy due to TEAEs. The findings are consistent with prior studies that indicate that ZEJULA monotherapy as first-line maintenance treatment can provide statistically and clinically meaningful benefit in a broad population of patients, regardless of postoperative residual disease or biomarker status.

- **Tumor Treating Fields (TTFields or Optune):**

  - *NSCLC:* In June 2023, we announced with our partner NovoCure Limited ("NovoCure") that the Phase III LUNAR clinical trial demonstrated a statistically significant and clinically meaningful extension in OS for patients with metastatic non-small cell lung cancer ("NSCLC") after platinum-based therapies. The LUNAR trial met its primary endpoint with a statistically significant and clinically meaningful 3-month improvement in median OS when TTFields therapy was added to standard therapies (HR: 0.74, P=0.035). Patients randomized to receive TTFields therapy together with standard therapies (n=137) demonstrated median OS of 13.2 months compared to 9.9 months in patients treated with standard therapies alone (n=139). A profound OS benefit from TTFields therapy was demonstrated in the immune checkpoint inhibitor ("ICI") subgroup. Patients randomized to receive TTFields therapy and physician's choice ICI (n=66) demonstrated a median OS of 18.5 months versus 10.8 months in patients treated with ICIs alone (n=68; HR=0.63; P=0.03), and patients randomized to receive TTFields therapy and docetaxel (n=71) had a positive survival trend with a median OS of 11.1 months versus 8.7 months in patients treated with docetaxel alone (n=71). TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events. NovoCure presented the positive results at the 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2023. We participated in the Greater China portion of the study.

  - *Pancreatic Cancer:* In July 2023, NovoCure announced the results of a pre-specified interim analysis for the Phase III PANOVA-3 clinical trial evaluating the safety and efficacy of TTFields therapy together with nab-paclitaxel and gemcitabine for the treatment of patients with unresectable, locally advanced pancreatic cancer. An independent data monitoring committee ("DMC") reviewed the safety and efficacy data for all patients in the fully enrolled clinical trial. The interim analysis resulted in a DMC recommendation that the clinical trial proceed to final analysis. Zai Lab participated in the Greater China portion of the study.

- **KRAZATI® (adagrasib, KRAS^{G12C}):** In April 2023 and May 2023, our partner Mirati Therapeutics, Inc. ("Mirati") announced the inclusion of adagrasib as the only KRAS^{G12C} inhibitor in the National Comprehensive Cancer Network ("NCCN") Guidelines for Central Nervous System ("CNS") Cancers for patients with KRAS^{G12C}-mutated NSCLC with CNS metastases and for KRAS^{G12C}-mutation positive pancreatic adenocarcinoma cancer patients, respectively. Also, in April 2023, Mirati presented updated clinical data for adagrasib as a targeted treatment for pancreatic ductal adenocarcinoma, biliary tract cancer,

and other solid tumors harboring a $KRAS^{G12C}$ mutation at the 2023 American Society of Clinical Oncology ("ASCO") Plenary series. Data was concurrently published in the Journal of Clinical Oncology. In June 2023, we completed enrollment in China for the global Phase 2 KRYSTAL-7 trial of adagrasib in combination with pembrolizumab as first-line treatment for patients with advanced $KRAS^{G12C}$-mutated NSCLC, and in July 2023, we completed enrollment in China for the global Phase 3 KRYSTAL-10 trial of adagrasib in combination with cetuximab versus chemotherapy in patients with previously treated advanced $KRAS^{G12C}$-mutated colorectal cancer.

- **Repotrectinib (ROS1/TRK):** In May 2023, our partner Bristol Myers Squibb ("BMS") announced that the FDA had accepted its New Drug Application ("NDA") for repotrectinib, a next generation tyrosine kinase inhibitor ("TKI"), for the treatment of adult patients with ROS1-positive locally advanced or metastatic NSCLC based on results from the TRIDENT-1 trial. The FDA granted the application priority review and assigned a Prescription Drug User Fee Act ("PDUFA") date of November 27, 2023. In June 2023, the NMPA accepted our NDA for repotrectinib for the same indications, after granting priority review in May 2023.

- **TIVDAK® (Tisotumab Vedotin, Antibody Drug Conjugate ("ADC")):** In April 2023, our partner Seagen Inc. ("Seagen") presented the interim analysis for the Phase II innovaTV 207 study in head and neck cancer at the 2023 American Association of Cancer Research ("AACR") Annual Meeting. At data cutoff (November 28, 2022), confirmed objective response rate ("ORR") was 40% (95% confidence interval ("CI"): 16.3, 67.7), with 1 complete response and 5 partial responses. The safety profile was generally consistent with that observed across TIVDAK monotherapy clinical studies. In addition, in February 2023, Seagen completed global target patient enrollment for the Phase III confirmatory innovaTV 301 study in second- or third-line recurrent or metastatic cervical cancer. We are participating in the global trial and ongoing extension study in Greater China.

- **Bemarituzumab (FGFR2b):** In July 2023, we enrolled the first patient in China in the global Phase III FORTITUDE-101 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy, in first-line gastric cancer with FGFR2b overexpression.

Autoimmune Disorders, Infectious Diseases, and Neuroscience

- **VYVGART (Efgartigimod, FcRn):**

  - *gMG:* In June 2023, our partner argenx BV ("argenx") announced that the FDA approved VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection for subcutaneous use in gMG. In July 2023, the NMPA accepted our BLA for efgartigimod alfa injection (subcutaneous ("SC") injection) for the treatment of adult patients with gMG.

  - *CIDP:* In July 2023, we and argenx announced positive topline results from the global registrational ADHERE study evaluating VYVGART Hytrulo in adults with chronic inflammatory demyelinating polyneuropathy ("CIDP"). The study met its primary endpoint (p=0.000039), demonstrating a significantly lower risk of relapse with VYVGART Hytrulo compared to placebo. VYVGART Hytrulo demonstrated a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo, and 67% of patients in open-label Stage A demonstrated evidence of clinical improvement, indicating that IgG autoantibodies play a significant role in the underlying biology of CIDP. The safety and tolerability profile was consistent with previous clinical trials and the confirmed safety profile of VYVGART. We participated in the Greater China portion of the study.

  - *BP:* In May 2023, we enrolled the first patient in China in the global Phase II/III BALLAD study of SC efgartigimod in adult patients with bullous pemphigoid ("BP").

- **XACDURO® (Sulbactam-Durlobactam or SUL-DUR, Asia Pacific Rights):** In May 2023, our partner Entasis Therapeutics, Inc. ("Entasis"), a wholly owned subsidiary of Innoviva, Inc., announced that the FDA approved XACDURO for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter baumannii-calcoaceticus complex. Our NDA for the treatment of infections caused by Acinetobacter baumannii, including multidrug-resistant and carbapenem-resistant *Acinetobacter baumannii* strains, is under review at the NMPA and has been granted priority review status.

- **KarXT (Xanomeline-Trospium, M1/M4-Preferring Muscarinic Agonist):** In June 2023, we enrolled the first patient in the registrational bridging study in mainland China for KarXT for the treatment of patients with schizophrenia.

Corporate Updates

We continued to enhance our portfolio through strategic partnerships and to strengthen our organizational structure to support the evolving needs of our business:

- **Business Development:** In April 2023, we entered into a strategic partnership and global license agreement with MediLink Therapeutics (Suzhou) Co., Ltd. ("MediLink"). Through this collaboration, we expanded our lung cancer franchise and global oncology pipeline with an early-stage next generation DLL3 ADC program, ZL-1310. DLL3 is an inhibitor of the Notch ligand that is overexpressed in small cell lung cancer and neuroendocrine tumors. ZL-1310 has demonstrated an encouraging pre-clinical profile. ZL-1310 is progressing to the clinical stage, and we plan to focus on advancing its global development.

- **Organizational Update:** The Company promoted Yajing Chen to Chief Financial Officer, effective July 7, 2023. Dr. Chen previously served as our Senior Vice President and Deputy Chief Financial Officer, helping to oversee finance, planning and forecasting, accounting, tax, treasury, and procurement matters since joining the Company in September 2021. She is a seasoned finance executive with more than 20 years of experience in the life sciences industry as well as a Ph.D. trained scientist. She joined the Company from AstraZeneca where she held various roles of increasing responsibility from 2006 to 2021, including Chief Financial Officer for the U.S. Oncology Business Unit from 2019 to 2021 and Finance Controller of the Global Oncology Business Unit from 2016 to 2019. Her scientific background combined with her significant executive management experience, finance expertise at leading global companies, and business acumen provide a unique and valuable perspective to the Company and will help drive our next phase of growth. Dr. Chen succeeds Billy Cho, who stepped down from his role and left the Company on July 7, 2023.

Legal and Regulatory Developments

Our business has been and continues to be impacted by legal and regulatory developments in the jurisdictions in which we operate, particularly in mainland China where our operations and product markets are primarily located. In March 2023, the People's Government of Hainan Province published revised Regulations for the Administration of the Imported Urgently Needed Drugs and Medical Devices in the Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone (the "BMTPZ"), which became effective in May 2023. Under these regulations, medical institutions in the BMTPZ meeting certain qualifications may apply to use our products that meet specified requirements, including drugs or medical devices that address specific urgent clinical needs that cannot be met with existing approved products. We have successfully used this pathway in the past, and with the revised regulation, we will continue to look for opportunities to use this pathway to accelerate our entry into the China market for product candidates in advance of NMPA approval. In July 2023, the Ministry of Science and Technology of the People's Republic of China published an updated Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which will impact the Company's practices in filing for an advance approval with the HGRAC. In addition, in July 2023, a revised Counter-Espionage Law intended to strengthen provisions on the protection of national security in mainland China went into effect, which may increase our cyber security or operational costs and could subject us to investigative or enforcement actions by the Chinese government or regulatory authorities.

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 research and development, including internal discovery activities. As a result of this commitment, our pipeline of product candidates has been advancing and expanding, with thirteen late-stage clinical product candidates being investigated as of June 30, 2023.

We have financed our activities primarily through private placements, our initial public offering in September 2017 and multiple follow-on offerings on Nasdaq and our secondary listing and initial public offering on the Hong Kong Stock Exchange in September 2020. Through June 30, 2023, we have raised approximately $164.6 million from private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offerings and follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $128.0 million and $132.0 million for the six months ended June 30, 2023 and 2022, respectively. We expect our expenditures to increase in connection with our ongoing activities, particularly as we advance the clinical development of our thirteen late-stage clinical product candidates, research and develop 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 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 and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations; and
- expenses associated with the construction and maintenance of our manufacturing facilities.

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 discover, develop, commercialize, and manufacture our products and product candidates. These increases will likely include expanded infrastructure as well as increased headcount, and share-based compensation, product distribution, promotion, and insurance costs. We also anticipate incurring additional legal, compliance, accounting, and investor and public relations expenses associated with being a public company listed on both Nasdaq and the Hong Kong Stock Exchange.

Our Ability to Commercialize Our Product Candidates

As of August 1, 2023, thirteen of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater 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 product candidates, which may not 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.

License and Collaboration Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our license and collaboration 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 sales-based milestones for the relevant products under these agreements as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products. We recorded research and development expense related to upfront license fees and development milestones of $18.3 million and $19.3 million for the three and six months ended June 30, 2023, respectively, and $10.4 million for both the three and six months ended June 30, 2022. We may be obligated to pay up to an additional aggregate amount of approximately $2,443.8 million in development and regulatory milestone payments and $3,437.4 million in sales-based milestone payments that are contingent on product performance as well as certain royalties at tiered percentage rates on annual net sales. These milestones may occur before the Company has commercialized or received any revenue from the licensed product, or they may not occur at all. If these milestones do occur, we view related payments as positive because they signify that the product is advancing toward potential commercial launch or achieving higher sales levels.

The COVID-19 Pandemic

Our results of operations have been adversely affected by the COVID-19 pandemic, including by government actions and quarantine measures taken in response in 2022 and increased infection rates in the first quarter of 2023 after COVID restrictions were lifted or eased, particularly in mainland China where our operations and product markets are primarily located. The COVID-19 pandemic did not have a material adverse effect on our business or results of operations in the second quarter of 2023.

Results of Operations

The following table presents our results of operations ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Revenues:								
Product revenue, net	68,864	47,575	21,289	45 %	131,661	93,670	37,991	41 %
Collaboration revenue	—	601	(601)	(100)%	—	1,230	(1,230)	(100)%
Total revenues	68,864	48,176	20,688	43 %	131,661	94,900	36,761	39 %
Expenses:								
Cost of sales	(23,763)	(17,407)	(6,356)	37 %	(45,100)	(33,051)	(12,049)	36 %
Research and development	(76,682)	(66,084)	(10,598)	16 %	(125,153)	(119,938)	(5,215)	4 %
Selling, general, and administrative	(67,920)	(63,401)	(4,519)	7 %	(130,430)	(120,392)	(10,038)	8 %
Gain on sale of intellectual property	10,000	—	10,000	NM	10,000	—	10,000	NM
Loss from operations	(89,501)	(98,716)	9,215	(9)%	(159,022)	(178,481)	19,459	(11)%
Interest income	10,090	1,175	8,915	759 %	20,321	1,363	18,958	1391 %
Foreign currency loss	(40,079)	(34,895)	(5,184)	15 %	(31,167)	(32,610)	1,443	(4)%
Other expense, net	(1,405)	(5,497)	4,092	(74)%	(171)	(10,378)	10,207	(98)%
Loss before income tax and share of loss from equity method investment	(120,895)	(137,933)	17,038	(12)%	(170,039)	(220,106)	50,067	(23)%
Income tax expense	—	—	—	— %	—	—	—	— %
Share of loss from equity method investment	—	—	—	— %	—	(221)	221	(100)%
Net loss	(120,895)	(137,933)	17,038	(12)%	(170,039)	(220,327)	50,288	(23)%
Net loss attributable to ordinary shareholders	(120,895)	(137,933)	17,038	(12)%	(170,039)	(220,327)	50,288	(23)%

NM - Not Meaningful

Revenues

Product Revenue

The following table presents the components of the Company's product revenue ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Product revenue - gross	75,010	54,339	20,671	38 %	146,222	107,649	38,573	36 %
Less: Rebates and sales return	(6,146)	(6,764)	618	(9)%	(14,561)	(13,979)	(582)	4 %
Product revenue - net	68,864	47,575	21,289	45 %	131,661	93,670	37,991	41 %

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong, net of sales returns and rebates to distributors in mainland China with respect to the sales of these products. We had a minimal amount of revenue for VYVGART from our named patient program in mainland China in the second quarter of 2023.

Our net product revenue increased by $21.3 million and $38.0 million in the three and six months ended June 30, 2023, respectively, primarily driven by increased sales volumes and decreased negative effects from the COVID-19 pandemic. The adverse effects of the COVID-19 pandemic had a more significant impact on our sales volumes for the three and six months ended June 30, 2022 and the first quarter in 2023, due to decreased patient access to our products, such as through reduced hospital access during periods of lockdown or high infection rates, fewer newly diagnosed oncology patients, and delayed or interrupted treatments. The COVID-19 pandemic did not have a material adverse effect on our sales volume in the second quarter of 2023.

For the three and six months ended June 30, 2023, our product revenue included negative adjustments of $1.3 million and $5.2 million, respectively, to compensate distributors for sales of QINLOCK and NUZYRA at prices prior to the price reductions made in connection with their addition to the NRDL. The Company lowered the selling price of ZEJULA due to its inclusion in the NRDL in December 2021 for certain therapies. In June 2022, the Company lowered the selling price for QINLOCK and NUZYRA. Accordingly, for the three and six months ended June 30, 2022, our product revenue included negative adjustments of $3.2 million and $5.8 million, respectively, to compensate distributors for sales of ZEJULA, QINLOCK and NUZYRA at prices prior to the price reductions. Such sales rebates to distributors on previously purchased products are customary in our industry to compensate those distributors for the new NRDL selling price.

The following table presents net revenue by product ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
ZEJULA	42,957	34,052	8,905	26 %	85,637	63,649	21,988	35 %
Optune	13,692	11,592	2,100	18 %	27,034	24,389	2,645	11 %
QINLOCK	7,527	623	6,904	1108 %	8,833	3,582	5,251	147 %
NUZYRA	4,636	1,308	3,328	254 %	10,105	2,050	8,055	393 %
VYVGART	52	—	52	NM	52	—	52	NM
Total product revenue, net	68,864	47,575	21,289	45 %	131,661	93,670	37,991	41 %

NM - Not Meaningful

Cost of Sales

Cost of sales increased by $6.4 million and $12.0 million in the three and six months ended June 30, 2023, respectively. These increases were primarily due to increasing sales volumes and higher royalties.

Research and Development Expenses

The following table presents the components of our research and development expenses ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Personnel compensation and related costs	29,378	27,045	2,333	9 %	58,034	51,847	6,187	12 %
Licensing fees	18,282	10,436	7,846	75 %	19,282	10,436	8,846	85 %
CROs/CMOs/Investigators expenses	23,626	23,368	258	1 %	36,065	46,918	(10,853)	(23)%
Other costs	5,396	5,235	161	3 %	11,772	10,737	1,035	10 %
Total	76,682	66,084	10,598	16 %	125,153	119,938	5,215	4 %

Research and development expenses increased by $10.6 million and $5.2 million in the three and six months ended June 30, 2023, respectively, primarily due to:

- an increase of $7.8 million and $8.8 million, respectively, in licensing fees in connection with increased upfront and milestone payments for our license and collaboration agreements;
- an increase of $2.3 million and $6.2 million, respectively, in personnel compensation and related costs primarily due to headcount growth and grants of share options and restricted shares and the continued vesting of option and restricted share awards; and
- an increase of $0.3 million and $1.0 million, respectively, in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials.

The increase in research and development expenses in the six months ended June 30, 2023 was partially offset by a decrease of $10.9 million in CROs/CMOs/Investigators expenses due to compensation from collaboration partners related to our clinical trials.

The following table presents our research and development expenses by program ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Clinical programs	32,462	33,292	(830)	(2)%	44,989	56,144	(11,155)	(20)%
Pre-clinical programs	10,758	1,957	8,801	450 %	13,239	4,522	8,717	193 %
Unallocated research and development expenses	33,462	30,835	2,627	9 %	66,925	59,272	7,653	13 %
Total	76,682	66,084	10,598	16 %	125,153	119,938	5,215	4 %

Research and development expenses attributable to clinical programs remained relatively flat during the three months ended June 30, 2023. Research and development expenses attributable to clinical programs decreased by $11.2 million in the six months ended June 30, 2023, primarily driven by compensation from collaboration partners related to our clinical trials in the three months ended March 31, 2023.

Research and development expenses attributable to pre-clinical programs increased by $8.8 million and $8.7 million in the three and six months ended June 30, 2023, respectively, primarily driven by increased license fees.

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 presents our selling, general and administrative expenses by program ($ in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	$	%	2023	2022	$	%
Personnel compensation and related costs	42,874	41,320	1,554	4 %	83,788	79,523	4,265	5 %
Professional service fees	5,793	8,072	(2,279)	(28)%	14,348	15,505	(1,157)	(7)%
Other costs	19,253	14,009	5,244	37 %	32,294	25,364	6,930	27 %
Total	67,920	63,401	4,519	7 %	130,430	120,392	10,038	8 %

Selling, general, and administrative expenses increased by $4.5 million and $10.0 million in the three and six months ended June 30, 2023, respectively, primarily due to:

- an increase of $5.2 million and $6.9 million, respectively, in other costs mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan; and
- an increase of $1.6 million and $4.3 million, respectively, in personnel compensation and related costs which was primarily driven by headcount growth, particularly in commercial and administrative personnel, and grants of share options and restricted shares and the continued vesting of option and restricted share awards; those increases were partially offset by
- a decrease of $2.3 million and $1.2 million, respectively, in professional service fees primarily related to legal expenses.

Gain on Sale of Intellectual Property

During the second quarter of 2023, we sold certain patent rights and related know-how to a third party, resulting in a gain of $10.0 million in the three and six months ended June 30, 2023. We had no such intellectual property sales resulting in gains or losses in the prior year periods.

Interest Income

Interest income increased by $8.9 million and $19.0 million in the three and six months ended June 30, 2023, respectively, due to increased interest rates.

Foreign Currency Loss

Foreign currency loss increased by $5.2 million in the three months ended June 30, 2023, primarily driven by increased remeasurement loss due to depreciation of the Renminbi (“RMB”) against the U.S. dollar.

Foreign currency loss decreased by $1.4 million in the six months ended June 30, 2023, primarily driven by decreased remeasurement loss due to depreciation of the RMB against the U.S. dollar.

Other Expenses, Net

Other expenses, net decreased by $4.1 million in the three months ended June 30, 2023 primarily as a result of a decrease in equity investment loss in MacroGenics of $3.9 million.

Other expenses, net decreased by $10.2 million in the six months ended June 30, 2023 primarily as a result of a decrease in equity investment loss in MacroGenics of $11.3 million, partially offset by a decrease in governmental subsidies of $1.5 million.

Income Tax Expense

There was no change in our income tax expense, which was zero in the three and six months ended June 30, 2023 and 2022.

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 periodically evaluate these judgments, 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, 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

Description

In mainland China, we sell our 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.

Judgments and Uncertainties

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. We estimate rebates based on contracted rates, sales volumes, and level of distributor inventories.

Sensitivity of Estimate to Change

Actual amounts of rebates paid or billed may differ from our estimates. We regularly review the factors and judgments underlying these estimates and adjust the amounts of rebates accordingly. If actual results vary from our estimates, we also adjust these estimates accordingly, which would affect net product revenue and earnings in the period such variances become expected or known.

Research and Development Expenses

Description

Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

Pre-clinical and clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various pre-clinical and clinical trial activities on our behalf in the ongoing development of our product candidates. Expenses related to pre-clinical and clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period.

Judgments and Uncertainties

The process of estimating our research and development expenses involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule, or when contractual milestones are met; however, some require advanced payments. We make estimates of our research and development expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Sensitivity of Estimate to Change

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed

may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Share-Based Compensation

Description

Share-based awards for our employees are measured at grant date fair value and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using a straight-line method over the requisite service period, which is the vesting period.

To the extent the required vesting conditions are not met resulting in forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed.

Judgments and Uncertainties

We determine the fair value of stock options granted to employees using the Black-Scholes option valuation model. Using this model, fair value is calculated based on assumptions with respect to (i) the expected volatility of our ADS price, (ii) the periods of time over which grantees are expected to hold their options prior to exercise (expected lives), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the expected lives of the options. Expected volatility has been estimated based on actual movements in some comparable companies' stock price over the most recent historical periods equivalent to the options' expected lives. The expected term of the share options represents the average period the share options are expected to remain outstanding. As the Company does not have sufficient historical information since its IPO to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term of options granted is derived from the average midpoint between the weighted average vesting and the contractual term, also known as the simplified method. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Sensitivity of Estimate to Change

The assumptions used in this method to determine the fair value of our option shares consider historical trends, macroeconomic conditions, and projections consistent with the Company's operating strategy. Changes in these estimates can have a significant impact on the determination of fair value of the option shares. If factors change or different assumptions are used, our share-based compensation expenses could be materially different for any period.

Income Taxes

Description

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.

Judgments and Uncertainties

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.

Sensitivity of Estimate to Change

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 and 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, 2023 and 2022, we did not have any significant unrecognized uncertain tax positions.

Liquidity and Capital Resources

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering and various follow-on offerings on Nasdaq, and our September 2020 secondary listing and initial public offering on the Hong Kong Stock Exchange. Through June 30, 2023, 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 and subsequent follow-on offerings on Nasdaq and our initial public offering on the Hong Kong Stock Exchange. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $128.0 million and $132.0 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had commitments for capital expenditures of $3.9 million, mainly for the purpose of plant construction and installation. For information on our research and development activities and expenditures see the Research and Development Expenses, License and Collaboration Arrangements, and Results of Operations sections in MD&A above.

As of June 30, 2023, we had cash and cash equivalents, restricted cash, and short-term investments of $876.4 million. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash, and short-term investments, will enable us to meet our cash requirements and fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, in order to bring to fruition our research and development objectives, we may ultimately need additional funding sources, and there can be no assurances that such funding will be made available to us on acceptable terms or at all.

The following table presents information regarding our cash flows ($ in thousands):

	Six Months Ended June 30,		Change
	2023	2022	$
Net cash used in operating activities	(127,989)	(132,027)	4,038
Net cash used in investing activities	(11,252)	(143,869)	132,617
Net cash used in financing activities	(5,379)	(2,240)	(3,139)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(3,707)	(5,144)	1,437
Net decrease in cash, cash equivalents and restricted cash	(148,327)	(283,280)	134,953

Net Cash Used in Operating Activities

Net cash used in operating activities decreased by $4.0 million to $128.0 million in the six months ended June 30, 2023, primarily due to a decrease of $50.3 million in net loss, partially offset by a decrease of $35.2 million in net changes in operating assets and liabilities and a decrease of $11.1 million in adjustments to reconcile net loss to net cash used in operating activities.

Net Cash Used in Investing Activities

Net cash used in investing activities decreased by $132.6 million to $11.3 million in the six months ended June 30, 2023. The decrease was primarily due to a decrease of $160.3 million in purchases of short-term investments, an increase

of $10.0 million in proceeds from sale of intellectual property, and a decrease of $8.3 million in purchases of property and equipment, partially offset by a decrease of $45.5 million in proceeds from the maturity of short-term investments.

Net Cash Used in Financing Activities

Net cash used in financing activities increased by $3.1 million to $5.4 million in the six months ended June 30, 2023, primarily due to a decrease of $2.9 million in proceeds from exercises of stock options and an increase of $0.3 million in employee taxes paid related to net share settlement of equity awards.

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, see Part II – Item 8. Financial Statements and Supplementary Data – Recent Accounting Pronouncements in our 2022 Annual Report. The Company has not adopted any new accounting standards since December 31, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk including foreign exchange risk, credit risk, and inflation 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 the Company included aggregated amounts of RMB158.7 million and RMB316.8 million, which were denominated in RMB, representing 3% and 5% of the cash and cash equivalents as of June 30, 2023 and December 31, 2022, respectively.

While our financial statements are presented in U.S. dollars, our business mainly operates in mainland China with a significant portion of our transactions settled in RMB, and as such, we do not believe that we currently have significant direct foreign exchange risk and have not used 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 and ordinary shares will be affected by the exchange rate between the U.S. dollar and the RMB and between the HK dollar and the RMB, respectively, because the value of our business is effectively denominated in RMB, while ADSs and ordinary shares are traded in U.S. dollars and HK dollars, respectively.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in Greater 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, the Chinese government 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 the Chinese 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.

The value of our ADSs and our ordinary shares will 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 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 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 assets denominated in HK dollars will be adversely affected.

Credit Risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, short-term investments, accounts receivable, and notes receivable.

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of June 30, 2023 and December 31, 2022, we had cash and cash equivalents of $859.2 million and $1,008.5 million and short-term investments of $15.5 million and nil, respectively. As of June 30, 2023 and December 31, 2022, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and for which we monitor continued credit worthiness.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangements. We manage credit risk related to our accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and credit worthiness. Historically, we have collected receivables from customers within the credit terms with no significant credit losses incurred. As of June 30, 2023, our two largest customers accounted for approximately 31% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of June 30, 2023, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

Inflation Risk

In recent years, mainland China has not experienced significant inflation. Although the global economy, including the U.S. economy, experienced rising inflation in recent years, which can increase the costs of our products and product candidates purchased from third parties and, as a result, adversely affect our results of operations, 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 mainland China or in other countries in which our third-party partners operate.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this report. Our disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or furnish under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based upon that evaluation, our management has concluded that, as of June 30, 2023, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such item is defined in Rules 13a-15(f)) during the fiscal quarter ended June 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control 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. We are not currently a party to any material legal or administrative proceedings.

Item 1A. Risk Factors.

We are subject to risks and uncertainties that could, directly or indirectly, adversely affect our business, results of operations, financial condition, liquidity, cash flows, strategies, and/or prospects. There have been no material changes in our risk factors from those disclosed in the "Risk Factors" section of our 2022 Annual Report.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table presents acquisitions of the Company's ADSs from employees by the Company to satisfy tax withholding obligations due in connection with exercise of option shares or vesting of restricted shares during the second quarter of 2023:

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1 – 30, 2023	2,661	$ 30.70	—	—
May 1 – 31, 2023	914	$ 42.50	—	—
June 1 – 30, 2023	123,658	$ 40.51	—	—
Total	127,233			

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

During the period covered by this report, none of the Company's directors or executive officers has adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
31.1	Certification of Chief Executive Officer Required by Exchange Act Rule 13a-14(a)
31.2	Certification of Chief Financial Officer Required by Exchange Act Rule 13a-14(a)
32.1	Certification of Chief Executive Officer Required by 18 U.S.C. Section 1350
32.2	Certification of Chief Financial Officer Required by 18 U.S.C. Section 1350
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
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)

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 7, 2023

By: /s/ Yajing Chen
Name: Yajing Chen
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)