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 19**

For the quarterly period ended March 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 19**

For the transition period from _____ to _____

Commission File Number: 001-38205

ZAI LAB LIMITED
(Exact Name of Registrant as Specified in its Charter)

Cayman Islands **(State or Other Jurisdiction of Incorporation or Organization)**	**98-1144595** **(I.R.S. Employer Identification No.)**
4560 Jinke Road **Bldg. 1, Fourth Floor, Pudong** **Shanghai** **China**	**201210**
314 Main Street **4th Floor, Suite 100** **Cambridge, MA, USA** **(Address of Principal Executive Offices)**	**02142** **(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 May 3, 2023, 979,087,430 ordinary shares of the registrant, par value $0.000006 per share, were outstanding, of which 743,576,320 ordinary shares were held in the form of American Depositary Shares.

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

SPECIAL NOTES REGARDING THE COMPANY

Forward-Looking Statements

This report contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "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. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information, that are not statements of historical facts or guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions, and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the following:

- The effects of the COVID-19 pandemic, particularly in mainland China where our operations and product markets are primarily located;
- 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;
- 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 by residents in mainland China;
- 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 filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2023 (the "2022 Annual Report") and in 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 on March 31, 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	March 31, 2023	December 31, 2022
Assets			
Current assets:			
Cash and cash equivalents	3	879,844	1,008,470
Short-term investments		50,550	—
Accounts receivable (net of allowance for credit loss of $13 and $11 as of March 31, 2023 and December 31, 2022, respectively)		43,346	39,963
Notes receivable		17,381	8,608
Inventories, net	4	38,405	31,621
Prepayments and other current assets		42,772	35,674
Total current assets		1,072,298	1,124,336
Restricted cash, non-current		1,003	803
Long term investments (including the fair value measured investment of $6,872 and $6,431 as of March 31, 2023 and December 31, 2022, respectively)		6,872	6,431
Prepayments for equipment		1,721	1,396
Property and equipment, net	5	58,309	57,863
Operating lease right-of-use assets		20,148	19,512
Land use rights, net		6,920	6,892
Intangible assets, net		1,479	1,511
Long-term deposits		1,324	1,396
Total assets		**1,170,074**	**1,220,140**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		66,361	65,974
Current operating lease liabilities		7,318	7,050
Other current liabilities	8	50,881	66,818
Total current liabilities		124,560	139,842
Deferred income		30,968	21,360
Non-current operating lease liabilities		12,979	13,343
Other non-current liabilities		325	—
Total liabilities		**168,832**	**174,545**
Commitments and contingencies (Note 15)			
Shareholders' equity			
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 967,197,350 and 962,455,850 shares issued as of March 31, 2023 and December 31, 2022, respectively; 963,688,740 and 960,219,570 shares outstanding as of March 31, 2023 and December 31, 2022, respectively)		6	6
Additional paid-in capital		2,911,454	2,893,120
Accumulated deficit		(1,910,504)	(1,861,360)
Accumulated other comprehensive income		17,272	25,685
Treasury Stock (at cost, 3,508,610 and 2,236,280 shares as of March 31, 2023 and December 31, 2022, respectively)		(16,986)	(11,856)
Total shareholders' equity		**1,001,242**	**1,045,595**
Total liabilities and shareholders' equity		**1,170,074**	**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 March 31, 2023	2022
Revenues:			
Product revenue, net	6	62,797	46,095
Collaboration revenue		—	629
Total revenues		62,797	46,724
Expenses:			
Cost of sales		(21,337)	(15,643)
Research and development		(48,472)	(53,854)
Selling, general, and administrative		(62,510)	(56,991)
Loss from operations		(69,522)	(79,764)
Interest income		10,232	188
Foreign currency gain		8,912	2,285
Other income (expenses), net	13	1,234	(4,882)
Loss before income tax and share of loss from equity method investment		(49,144)	(82,173)
Income tax expense	7	—	—
Share of loss from equity method investment		—	(221)
Net loss		(49,144)	(82,394)
Net loss attributable to ordinary shareholders		(49,144)	(82,394)
Loss per share - basic and diluted	9	(0.05)	(0.09)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		961,444,780	955,499,030
Loss per American Depositary Shares (“ADS”) - basic and diluted		(0.51)	(0.86)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted		96,144,478	95,549,903

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 March 31,	
	2023	**2022**
Net loss	(49,144)	(82,394)
Other comprehensive income (loss), net of tax of nil:		
Foreign currency translation adjustments	(8,413)	(2,193)
Comprehensive loss	(57,557)	(84,587)

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 shares options	4,009,460	0	1,673	—	—	—	—	1,673
Receipt of employees' shares 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
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 shares options	1,156,660	0	297	—	—	—	—	297
Receipt of employees' shares 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

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 $)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	(49,144)	(82,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss (gain)	1	(1)
Inventory write-down	377	138
Depreciation and amortization expenses	2,657	2,013
Amortization of deferred income	(582)	(708)
Share-based compensation	16,661	12,410
Share of loss from equity method investment	—	221
(Gain) Loss from fair value changes of equity investment with readily determinable fair value	(441)	6,939
Loss (gain) on disposal of property and equipment	64	(11)
Non-cash lease expenses	2,464	2,017
Foreign currency remeasurement gain	(8,912)	(2,285)
Changes in operating assets and liabilities:		
Accounts receivable	(2,852)	14,080
Notes receivable	(8,599)	(3,513)
Inventories	(6,686)	(1,475)
Prepayments and other current assets	(6,470)	1,531
Long-term deposits	72	(71)
Value added tax recoverable	—	3,092
Accounts payable	(327)	(28,002)
Other current liabilities	(15,593)	(8,837)
Operating lease liabilities	(2,141)	(2,389)
Deferred income	9,839	118
Other non-current liabilities	325	—
Net cash used in operating activities	(69,287)	(87,127)
Cash flows from investing activities		
Purchases of short-term investments	(100,000)	(120,274)
Proceeds from maturity of short-term investment	49,450	100,000
Disposal of property and equipment	112	25
Purchases of property and equipment	(3,513)	(9,743)
Purchases of intangible assets	(3)	(152)
Net cash used in investing activities	(53,954)	(30,144)
Cash flows from financing activities		
Proceeds from exercises of stock options	1,197	297
Employee taxes paid related to settlement of equity awards	(5,083)	(39)
Net cash (used in) provided by financing activities	(3,886)	258
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(1,299)	(130)
Net decrease in cash, cash equivalents and restricted cash	(128,426)	(117,143)
Cash, cash equivalents and restricted cash - beginning of period	1,009,273	964,903
Cash, cash equivalents and restricted cash - end of period	880,847	847,760
Supplemental disclosure on non-cash investing and financing activities		
Payables for purchase of property and equipment	4,232	668
Payables for intangible assets	268	73
Payables for treasury stock	—	55
Receivables for stock option exercise under equity incentive plans	476	—
Right-of-use asset acquired under operating leases	2,662	4,596
Receivables for dispose of property and equipment	10	—
Supplemental disclosure of cash flow information		
Cash and cash equivalents	879,844	846,957
Restricted cash, non-current	1,003	803
Total cash and cash equivalents and restricted cash	880,847	847,760

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 products and product candidates 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 filed with the SEC on March 1, 2023 (the "2022 Annual Report"). The December 31, 2022 condensed consolidated balance sheet data included in this report were derived from the audited financial statements included 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 amount in the prior period of the condensed consolidated financial statement has 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 $6.9 million and $6.4 million as of March 31, 2023 and December 31, 2022, respectively. The unrealized gains and losses from fair value changes are recognized in other income (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 March 31, 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

There were no standards adopted since the 2022 Annual Report.

(f) Significant Accounting Policies

For a more complete discussion of the Company's significant accounting policies, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the 2022 Annual Report.

3. Cash and Cash Equivalents

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

	March 31, 2023	December 31, 2022
Cash at bank and in hand	878,786	1,007,423
Cash equivalents (i)	1,058	1,047
	879,844	1,008,470
Denominated in:		
US$	836,981	957,824
RMB (ii)	38,278	45,486
Hong Kong dollar ("HK$")	3,864	4,378
Australian dollar ("A$")	588	598
Taiwan dollar ("TW$")	133	184
	879,844	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 Company's net inventory balance was $38.4 million and $31.6 million as of March 31, 2023 and December 31, 2022, respectively, and mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline ("GSK"), for distribution in Hong Kong, from NovoCure Limited ("NovoCure") for distribution in Hong Kong and mainland China, and from Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong, mainland China and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China.

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

	March 31, 2023	December 31, 2022
Finished goods	17,832	12,156
Raw materials	20,521	19,029
Work in Progress	52	436
Inventories, net	38,405	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 cost of sales of $0.4 million and $0.1 million for the first quarter of 2023 and 2022, respectively.

5. Property and Equipment, Net

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

	March 31, 2023	December 31, 2022
Office equipment	998	977
Electronic equipment	8,315	7,416
Vehicle	205	202
Laboratory equipment	19,491	18,726
Manufacturing equipment	16,763	17,055
Leasehold improvements	11,470	11,300
Construction in progress	25,546	24,251
	82,788	79,927
Less: accumulated depreciation	(24,479)	(22,064)
Property and equipment, net	58,309	57,863

Depreciation expense was $2.5 million and $1.9 million for the first quarter of 2023 and 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 March 31,	
	2023	2022
Product revenue - gross	71,212	53,310
Less: Rebates and sales returns	(8,415)	(7,215)
Product revenue - net	62,797	46,095

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 March 31,	
	2023	2022
ZEJULA	42,680	29,597
Optune	13,342	12,797
QINLOCK	1,306	2,959
NUZYRA	5,469	742
Product revenue - net	62,797	46,095

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 March 31, 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):

	March 31, 2023	December 31, 2022
Payroll	11,472	31,689
Accrued professional service fee	7,148	4,080
Payables for purchase of property and equipment	4,232	5,269
Accrued rebate to distributors	11,536	8,443
Tax payables	13,001	13,283
Others (i)	3,492	4,054
Total	50,881	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 March 31,	
	2023	2022
Numerator:		
Net loss attributable to ordinary shareholders	(49,144)	(82,394)
Denominator:		
Weighted average number of ordinary shares - basic and diluted	961,444,780	955,499,030
Net loss per share - basic and diluted	(0.05)	(0.09)

As a result of the Company's net loss for the first quarter of 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.

	March 31	
	2023	2022
Share options	86,242,060	80,514,330
Non-vested restricted shares	32,154,670	9,846,360

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 nil and $0.1 million during the first quarter of 2023 and 2022, respectively.

11. Share-Based Compensation

In March 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan"), pursuant to which the Board of Directors could grant options to purchase ordinary shares to management including officers, directors, employees, and individual advisors who rendered services to the Company. In August 2017, in connection with the completion of the Company's initial public offering on Nasdaq (the "IPO"), the Board of Directors approved the 2017 Equity Incentive Plan (the "2017 Plan"). All equity-based awards subsequent to the IPO would be granted under the 2017 Plan. The 2017 Plan provided for an automatic annual increase to the number of ordinary shares reserved under the 2017 Plan on each January 1st between January 1, 2018 and January 1, 2027 equal to the lesser of 4% of the number of ordinary shares outstanding as of the close of business on the immediately prior December 31st or such number as approved by the Board on or prior to such date each year.

On June 22, 2022, at the 2022 Annual General Meeting of Shareholders of the Company, the Company's shareholders approved the 2022 Equity Incentive Plan (the "2022 Plan"), which was previously approved by the Board of Directors on April 20, 2022, conditioned on and subject to (i) the dual primary listing of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the "Hong Kong Stock Exchange") and (ii) the granting of a waiver on Note 1 to Rule 17.03(9) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. The Company's voluntary conversion of its secondary listing status to primary listing status on the Hong Kong Stock Exchange became effective on June 27, 2022, and the waiver was granted to the Company in connection with the primary conversion. As such, the 2022 Plan became effective on June 27, 2022, and the aggregate number of shares that may be delivered in satisfaction of awards under the 2022 Plan is 97,908,743 ordinary shares as of June 22, 2022. No new grants will be made under the 2015 Plan or the 2017 Plan as of the effective date of the 2022 Plan.

The options granted have a contractual term of ten years and generally vest ratably over a five-year period, with 20% of the awards vesting on each anniversary of the grant date, subject to continued employment with the Company on the vesting date. 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 shares underlying restricted share grants represent shares not yet vested until they have met related consideration or vesting requirements, which are generally continued employment/service to the Company or satisfaction of specified performance conditions. The restricted shares will be released from the restrictions once they vest. Upon termination of the award holders' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited unless otherwise set forth in an agreement between the Company and the award holder.

Upon each settlement date of certain share-based awards, shares were withheld to cover the required withholding tax, which was based on the value of a share on the settlement date as determined by the applicable price of the ADSs on the trading day of the applicable settlement date. The remaining shares after the withholding were delivered to the recipient. The amount remitted to the tax authorities for employee tax obligations was reflected as a financing activity on the consolidated statements of cash flows. These shares withheld by the Company as a result of the net settlement were accounted for as treasury stock and considered issued but not outstanding.

During the first quarter of 2023, the Company granted 92,640 share options and 266,570 non-vested restricted shares under the 2022 Plan. The share options were granted at an exercise price of $3.99 per share. The share options granted were valued using the Black-Scholes model, and the grant-date fair value was $2.70 per share.

The following table presents the stock-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 March 31,	
	2023	2022
Selling, general and administrative	10,063	6,992
Research and development	6,598	5,418
Total	16,661	12,410

As of March 31, 2023, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of $90.9 million and $117.6 million, respectively, which the Company expects to recognize over a weighted-average period of 3.39 years and 3.38 years, respectively.

12. License and Collaboration Agreements

The Company may enter into collaboration agreements with third parties to license intellectual property. 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 first quarter of 2023, the Company did not enter into any new significant license or collaboration agreements, and the Company did not pay or accrue any material upfront or milestone fees for our existing significant license and collaboration agreements.

13. Other Income (Expenses), Net

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

	Three Months Ended March 31,	
	2023	2022
Government grants	—	1,576
Gain (loss) on equity investments with readily determinable fair value	441	(6,939)
Others miscellaneous gain	793	481
Total	1,234	(4,882)

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 first quarter of 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 March 31, 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 $6.0 million as of March 31, 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 included in "Item 1. Financial Statements" in this report.

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 four commercial products – ZEJULA, Optune, QINLOCK, and NUZYRA – that have received marketing approval in one or more territories in Greater China and thirteen programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires 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 four 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. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and 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. We recorded $1.0 million of research and development expense related to upfront license fees and development milestones during the first quarter of 2023. 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 access to our commercial products, including through increased sales for ZEJULA, new NRDL listings for QINLOCK and NUZYRA and increased supplemental insurance plan listings for Optune:

- **Sales Growth for ZEJULA:** Net product revenues for ZEJULA continued to increase in the first quarter of 2023, growing 44% compared to the first quarter of 2022.
- **National Drug Reimbursement List (NRDL) Implementation:** In January 2023, QINLOCK was included in the NRDL for fourth-line treatment of advanced gastrointestinal stromal tumor patients and NUZYRA was included for the treatment of adults with community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. The updated NRDL officially took effect on March 1, 2023.
- **Supplemental Insurance Plan Coverage:** As of March 31, 2023, Optune was listed in 96 regional customized health insurance plans guided by provincial or municipal governments throughout mainland China, or supplemental insurance plans, up from 87 as of December 31, 2022 and 37 as of March 31, 2021.

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, regulatory approvals, and commercialization efforts:

Oncology

- **TIVDAK® (Tisotumab Vedotin, Antibody Drug Conjugate ("ADC")):** In April 2023, Zai Lab 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.
- **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 inhibitor in the National Comprehensive Cancer Network ("NCCN") Guidelines for Central Nervous System ("CNS") Cancers for patients with $KRAS^{G12C}$-mutated non-small cell lung cancer ("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.
- **Bemarituzumab (FGFR2b):** In March 2023, we obtained Clinical Trial Application ("CTA") approval for the Phase III FORTITUDE-101 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy, in first-line gastric cancer with FGFR2b overexpression.
- **Odronextamab (CD20xCD3):** In March 2023, we completed enrollment in China for the registrational global Phase II ELM-2 trial in B-cell non-Hodgkin lymphoma.
- **ZL-2313 (BLU-945, EGFR):** In April 2023, our partner Blueprint Medicines Corporation ("Blueprint") presented novel real-world data showing first-line osimertinib had worse outcomes in EGFR L858R+ vs. ex19del+ NSCLC at the 2023 AACR Annual Meeting. Data also demonstrated additive effects of ZL-2313 with osimertinib in preclinical models of tumor progression, reinforcing the clinical need addressed by the SYMPHONY study in first-line EGFR L858R+ NSCLC.
- **ZL-1211 (Claudin18.2, Global Rights):** In April 2023, we presented new data including a translational and biomarker data analysis at the 2023 AACR Annual Meeting.

Autoimmune Disorders, Infectious Diseases, and Neuroscience

- **Sulbactam-Durlobactam (SUL-DUR, Asia Pacific Rights):** In April 2023, our partner Entasis Therapeutics, Inc. ("Entasis"), a wholly owned subsidiary of Innoviva, Inc., announced that the FDA's Antimicrobial Drugs Advisory Committee unanimously voted in support of approval of its New Drug Application ("NDA") for SUL-DUR based on a favorable benefit-risk assessment of SUL-DUR for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter baumannii-calcoaceticus complex ("Acinetobacter"). We participated in the global Phase III registrational ATTACK trial in Greater China, and the NMPA accepted our NDA in February 2023, after granting priority review in January 2023.
- **KarXT (Xanomeline-Trospium, M1/M4-Preferring Muscarinic Acetylcholine Receptor):** In March 2023, our partner Karuna Therapeutics, Inc. announced positive results from the Phase III EMERGENT-3 trial of KarXT in schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 8.4-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-20.6 KarXT vs. -12.2 placebo; $p<0.0001$) at Week 5 (Cohen's d effect size of 0.60). Consistent with prior trials, KarXT demonstrated an early and sustained statistically significant reduction of symptoms from Week 2 ($p<0.05$) through the end of the trial as assessed by PANSS total score. The pharmacokinetic ("PK") study in mainland China is ongoing, and the CTA for a registrational bridging study in mainland China was approved in January 2023.

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 a 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:** As we enter into a stage of further growth, productivity, and global opportunities, we have promoted Joshua Smiley to the role of President and Chief Operating Officer, effective April 1. Mr. Smiley joined the Company as our Chief Operating Officer in August 2022. He is responsible for our corporate strategy and for overseeing our commercial, manufacturing, business development, finance, human resources, information technology, and corporate affairs functions. In this new role, Mr. Smiley will further help our leadership team enter and better anticipate the strategic and operational needs of this next period of growth for the Company.

Legal and Regulatory Developments

The Measures for the Administration of Internet Advertising

In February 2023, the SAMR issued the Measures for the Administration of Internet Advertising, which became effective on May 1, 2023 (the "Internet Advertising Measures"). The Internet Advertising Measures reiterate requirements under the PRC Advertising Law for advance approval from local administrative authorities to advertise pharmaceutical products and impose additional restrictions on the form and content of advertisements for pharmaceutical products.

Measures on Ethics Review for Life Sciences and Medical Research Involving Human Subjects

In February 2023, the National Health Commission, together with three other government agencies, jointly released the Measures on Ethics Review for Life Sciences and Medical Research Involving Human Subjects (the "Ethics Review Measures"). The Ethics Review Measures set forth criteria and specific steps for ethics reviews for life sciences and medical research involving human subjects carried out by medical institutions, colleges and universities, or scientific research institutes located within mainland China and elaborate the content requirements for informed consent forms. Clinical trials carried out by PRC clinical trial sites and sponsored by us are generally subject to the Ethics Review Measures.

The Provisions on Supervision and Administration of Marketing Authorization Holders Concerning the Implementation of Primary Responsibilities for Drug Quality and Safety

The Provisions on Supervision and Administration of Marketing Authorization Holders Concerning the Implementation of Primary Responsibilities for Drug Quality and Safety (the "Provisions"), which were issued by the NMPA in December 2022, became effective on March 1, 2023. The Provisions require marketing authorization holders, including us, to assume primary responsibility for the safety, effectiveness, and quality of drugs during the total product life cycle, and they impose new requirements on drug quality management and drug recall systems, including maintaining a data-based traceability system, among other things.

Regulations for the Administration of the Imported Urgently Needed Drugs and Medical Devices in Bo'ao

In March 2023, the People's Government of Hainan Province published the 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 on May 1, 2023. In accordance with 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. Such medical institution would bear the primary responsibilities for the safety risks associated with the use of such urgently needed drugs and medical devices.

Counter-Espionage Law

In April 2023, the Standing Committee of the National People's Congress voted to adopt a revised Counter-Espionage Law, which will become effective on July 1, 2023. The revised Counter-Espionage Law is intended to strengthen provisions on the protection of national security in mainland China. The revised Counter-Espionage Law broadens the definition of espionage, expands protected information, and vests authorities with greater enforcement powers. There is uncertainty with respect to the scope of the new provisions and how these provisions will be interpreted or enforced by 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 March 31, 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 March 31, 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 $69.3 million and $87.1 million for the first quarter of 2023 and 2022, respectively. We expect our expenditures to increase significantly 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. We review such expenditures for prioritization and efficiency purposes. 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 assets. 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 May 3, 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 products, 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 $1.0 million and nil for the first quarter of 2023 and 2022, respectively. We may be obligated to pay up to an additional aggregate amount of approximately $5,299.4 million in development, regulatory, and sales-based milestone payments 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 government actions and quarantine measures taken in response in the first quarter of 2022 or 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. For example, the pandemic adversely affected our net product revenues in the first quarter of 2023 and 2022 through 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 pandemic has also adversely affected our manufacturing and supply chain and our research and development, sales, marketing, and clinical trial activities. The operations of our suppliers, CROs, CMOs, and other contractors and third parties on which we rely also have been adversely affected.

Results of Operations

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

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Revenues:				
Product revenue, net	62,797	46,095	16,702	36 %
Collaboration revenue	—	629	(629)	(100)%
Total revenues	62,797	46,724	16,073	34 %
Expenses:				
Cost of sales	(21,337)	(15,643)	(5,694)	36 %
Research and development	(48,472)	(53,854)	5,382	(10)%
Selling, general, and administrative	(62,510)	(56,991)	(5,519)	10 %
Loss from operations	(69,522)	(79,764)	10,242	(13)%
Interest income	10,232	188	10,044	5343 %
Foreign currency gain	8,912	2,285	6,627	290 %
Other income (expenses), net	1,234	(4,882)	6,116	(125)%
Loss before income tax and share of loss from equity method investment	(49,144)	(82,173)	33,029	(40)%
Income tax expense	—	—	—	— %
Share of loss from equity method investment	—	(221)	221	(100)%
Net loss	(49,144)	(82,394)	33,250	(40)%
Net loss attributable to ordinary shareholders	(49,144)	(82,394)	33,250	(40)%

Revenues

Product Revenue

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

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Product revenue - gross	$ 71,212	$ 53,310	$ 17,902	34 %
Less: Rebates and sales return	(8,415)	(7,215)	(1,200)	17 %
Product revenue - net	62,797	46,095	16,702	36 %

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. Our net product revenue increased by $16.7 million in the first quarter of 2023, primarily driven by increased sales volumes. Although our sales volumes increased, these volumes were negatively affected by the effects of the COVID-19 pandemic, which 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. Our product revenue for the first quarter of 2023 included a negative $3.9 million adjustment 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 in the first quarter of 2023. 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 March 31,		Change	
	2023	2022	$	%
ZEJULA	$ 42,680	$ 29,597	$ 13,083	44 %
Optune	13,342	12,797	545	4 %
QINLOCK	1,306	2,959	(1,653)	(56)%
NUZYRA	5,469	742	4,727	637 %
Total product revenue, net	$ 62,797	$ 46,095	$ 16,702	36 %

Cost of Sales

Cost of sales increased by $5.7 million to $21.3 million in the first quarter of 2023 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 March 31,		Change	
	2023	2022	$	%
Personnel compensation and related costs	$ 28,655	$ 24,802	$ 3,853	16 %
Licensing fees	1,000	—	1,000	100 %
CROs/CMOs/Investigators expenses	12,439	23,550	(11,111)	(47)%
Other costs	6,378	5,502	876	16 %
Total	$ 48,472	$ 53,854	$ (5,382)	(10)%

Research and development expenses decreased by $5.4 million in the first quarter of 2023 primarily due to:

- a decrease of $11.1 million in CROs/CMOs/Investigators expenses due to compensation from collaboration partners related to our clinical trials; partially offset by
- an increase of $3.9 million 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 $1.0 million in licensing fees in connection with a milestone payment for a collaboration agreement.

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

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Clinical programs	$ 12,528	$ 22,852	$ (10,324)	(45)%
Pre-clinical programs	2,481	2,565	(84)	(3)%
Unallocated research and development expenses	33,463	28,437	5,026	18 %
Total	$ 48,472	$ 53,854	$ (5,382)	(10)%

Research and development expenses attributable to clinical programs decreased by $10.3 million during the first quarter of 2023 primarily driven by decreased CROs/CMOs/Investigators expenses due to compensation from collaboration partners related to our clinical trials.

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 March 31,		Change	
	2023	2022	$	%
Personnel compensation and related costs	$ 40,914	$ 38,203	$ 2,711	7 %
Professional service fees	11,983	7,433	4,550	61 %
Other costs	9,613	11,355	(1,742)	(15)%
Total	$ 62,510	$ 56,991	$ 5,519	10 %

Selling, general and administrative expenses increased by $5.5 million in the first quarter of 2023, primarily due to:

- an increase of $4.6 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong; and
- an increase of $2.7 million 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; partially offset by
- a decrease of $1.7 million in other costs mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan.

Interest Income

Interest income increased by $10.0 million to $10.2 million in the first quarter of 2023, due to increased interest rates.

Foreign Currency Gain

Foreign currency gain increased by $6.6 million to $8.9 million in the first quarter of 2023 primarily driven by increased remeasurement gain due to depreciation of the U.S. dollar against the Renminbi (“RMB”).

Other Income (Expenses), Net

Other income, net was $1.2 million in the first quarter of 2023, compared to other expense, net of $4.9 million in the first quarter of 2022, primarily due to the shift from $6.9 million in loss to $0.4 million in gain on equity investments with readily determinable fair value.

Income Tax Expense

There was no change in our income tax expense, which was zero in both the first quarter of 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 March 31, 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 March 31, 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 $69.3 million and $87.1 million for the first quarter of 2023 and 2022, respectively. As of March 31, 2023, we have commitments for capital expenditures of $6.0 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 March 31, 2023, we had cash and cash equivalents, restricted cash, and short-term investments of $931.4 million. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash, and short-term investments as of May 9, 2023, will enable us to 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):

	Three Months Ended March 31,		Change
	2023	2022	$
Net cash used in operating activities	$ (69,287)	$ (87,127)	$ 17,840
Net cash used in investing activities	(53,954)	(30,144)	(23,810)
Net cash (used in) provided by financing activities	(3,886)	258	(4,144)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(1,299)	(130)	(1,169)
Net decrease in cash, cash equivalents and restricted cash	$ (128,426)	$ (117,143)	$ (11,283)

Net Cash Used in Operating Activities

Net cash used in operating activities decreased by $17.8 million to $69.3 million in the first quarter of 2023, primarily due to a decrease of $33.3 million in net loss partially offset by a decrease of $8.5 million in adjustments to reconcile net loss to net cash used in operating activities and a decrease of $7.0 million in net changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities increased by $23.8 million to $54.0 million for the first quarter of 2023. The increase was primarily due to a decrease of $50.6 million in proceeds from the maturity of short-term investments, partially offset by a decrease of $20.3 million in purchases of short-term investments and a decrease of $6.2 million in purchases of property and equipment.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $3.9 million for the first quarter of 2023 compared to net cash provided by financing activities of $0.3 million for the first quarter of 2022. This change was primarily due to an increase of $5.0 million in employee taxes paid related to net share settlement of equity awards partially offset by an increase of $0.9 million in proceeds from exercises of stock options.

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, please see Part II – Item 8. Financial Statements and Supplementary Data – Recent Accounting Pronouncements in our 2022 Annual Report.

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 RMB263.0 million and RMB316.8 million, which were denominated in RMB, representing 4% and 5% of the cash and cash equivalents as of March 31, 2023 and December 31, 2022, respectively.

Our business mainly operates in mainland China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have 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 March 31, 2023 and December 31, 2022, we had cash and cash equivalents of $879.8 million and $1,008.5 million and short-term investments of $50.6 million and nil, respectively. As of March 31, 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 March 31, 2023, our two largest customers accounted for approximately 29% of our total accounts receivable collectively.

During the first quarter of 2023, certain accounts receivable balances were settled in the form of notes receivable. As of March 31, 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, has experienced rising inflation in recent quarters, 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 March 31, 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 March 31, 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.

This report should be read in conjunction with our 2022 Annual Report, which describes various material risks and uncertainties to which we are or may become subject. These risks and uncertainties could, directly or indirectly, adversely affect our business, results of operations, financial condition, liquidity, cash flows, strategies, and/or prospects.

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 to satisfy tax withholding obligations due in connection with exercise of option shares or vesting of restricted shares during the first 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
January 1 – 31, 2023	2,661	$ 30.70	—	—
February 1 – 28, 2023	914	$ 42.50	—	—
March 1 – 31, 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.

On May 9, 2023, we announced in our earnings release for the first quarter of 2023 the promotion of Joshua Smiley to President and Chief Operating Officer, effective April 1, 2023. Mr. Smiley, 53, joined the Company as our Chief Operating Officer in August 2022 following the completion of his leave with his prior employer. Mr. Smiley brings to the Company over 26 years of experience working in the biopharmaceutical industry, including experience leading finance, corporate strategy, business development, venture capital, and global business services operations. He is responsible for our corporate strategy and for overseeing our commercial, manufacturing, business development, finance, human resources, information technology, and corporate affairs functions.

Prior to joining the Company, Mr. Smiley worked for Eli Lilly and Company ("Lilly") from 1995 to March 2022. While at Lilly, he held various global leadership roles with responsibility over finance, corporate strategy, business

development, and capital markets activities, including Senior Vice President and Chief Financial Officer from January 2018 to February 2021. Prior to joining Lilly, he worked in investment banking and consulting. Mr. Smiley received a B.A. in History from Harvard University.

In connection with Mr. Smiley's promotion to President and Chief Operating Officer, and to better align his compensation with the market, the Compensation Committee of the Company's Board of Directors has increased Mr. Smiley's annual base salary to $650,000 and annual target bonus percentage to 60%, effective April 1, 2023.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
10.1#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to our Annual Report on Form 10-K (File No 001-38205) filed on March 1, 2023)
10.2#	Letter Agreement between Michel Vounatsos and Zai Lab Limited dated January 8, 2023 (incorporated by reference to Exhibit 10.42 to Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2023)
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 embedd 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)

Management contract or compensatory plan, contract, or arrangement.

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: May 9, 2023

By: /s/ Billy Cho
Name: Billy Cho
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification by the Principal Executive Officer
Pursuant to Exchange Act Rule 13a-14(a),
As Adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Samantha (Ying) Du, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of Zai Lab Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023

/s/ Samantha (Ying) Du

Samantha (Ying) Du
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification by the Principal Financial Officer
Pursuant to Exchange Act Rule 13a-14(a),
As Adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Billy Cho, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of Zai Lab Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023

/s/ Billy Cho

Billy Cho
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification by the Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350,
As Adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of Zai Lab Limited (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha (Ying) Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2023

/s/ Samantha (Ying) Du

Samantha (Ying) Du
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification by the Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350,
As Adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 of Zai Lab Limited (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2023

/s/ Billy Cho

Billy Cho
Chief Financial Officer
(Principal Financial and Accounting Officer)