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**Zai Lab Limited**

**再鼎醫藥有限公司\***

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 9688)**

## **OVERSEAS REGULATORY ANNOUNCEMENT - FORM 10-Q**

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

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

By order of the Board

**Zai Lab Limited**

**Samantha Du**

*Director, Chairperson and Chief Executive Officer*

Hong Kong, November 8, 2023

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

*\* For identification only*

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

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FORM 10-Q

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(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38205



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

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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)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>American Depositary Shares, each representing 10 Ordinary Shares, par value \$0.000006 per share</b>	<b>ZLAB</b>	<b>The Nasdaq Global Market</b>
<b>Ordinary Shares, par value \$0.000006 per share*</b>	<b>9688</b>	<b>The Stock Exchange of Hong Kong Limited</b>

\* 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 November 1, 2023, 988,387,430 ordinary shares of the registrant, par value \$0.000006 per share, were outstanding, of which 754,401,320 ordinary shares were held in the form of American Depositary Shares.

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**For the Third Quarter of 2023**

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## SPECIAL NOTES REGARDING THE COMPANY

### Forward-Looking Statements

This report contains certain forward-looking statements, including statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; capital allocation and investment strategy; clinical development programs and related clinical trials; clinical trial data, data readouts, and presentations; risks and uncertainties associated with drug development and commercialization; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our products and product candidates and those of our collaboration partners; the anticipated benefits and potential of investments, collaborations, and business development activities; and our future financial and operating results. All statements, other than statements of historical fact, included in this report are forward-looking statements, and can be identified by words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this report and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the following:

- Our ability to successfully commercialize and generate revenue from our approved products;
- Our ability to obtain funding for our operations and business initiatives;
- The results of our clinical and pre-clinical development of our product candidates;
- The content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates;
- Changes in United States and China trade policies and relations, as well as relations with other countries, and/or changes in regulations and/or sanctions;
- Actions the Chinese government may take to intervene in or influence our operations;
- Economic, political, and social conditions in mainland China, as well as governmental policies;
- Uncertainties in the Chinese legal system, including with respect to the anti-corruption enforcement efforts in China and 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;
- 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;
- Business disruptions caused by pandemics such as COVID-19, international war or conflict such as the Russia/Ukraine and Israel/Hamas wars, natural disasters, extreme weather events, and other significant disruptions outside of our control;

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

These factors should not be construed as exhaustive and should be read with the other cautionary statements and information in our Annual Report on Form 10-K for the year ended December 31, 2022 (the “2022 Annual Report”), Quarterly Report on Form 10-Q for the first quarter of 2023 (the “Q1 2023 Form 10-Q”), Quarterly Report on Form 10-Q for the second quarter of 2023 (the “Q2 2023 Form 10-Q”), and this report. Forward-looking statements are based on our management’s beliefs and assumptions and information currently available to our management. These statements, like all statements in this report, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this report.

### **Usage of Terms**

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

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

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

### **Disclosures Relating to Our Chinese Operations**

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

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

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

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

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

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

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

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

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

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

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

## **PART I – FINANCIAL INFORMATION**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes included in this report and the audited consolidated financial information and the accompanying notes included in our 2022 Annual Report.*

## Item 1. Financial Statements.

### Zai Lab Limited

#### Unaudited Condensed Consolidated Balance Sheets

(in thousands of U.S. dollars (“\$”), except for number of shares and per share data)

	Notes	September 30, 2023	December 31, 2022
<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents	3	788,806	1,008,470
Short-term investments		31,600	—
Accounts receivable (net of allowance for credit loss of \$12 and \$11 as of September 30, 2023 and December 31, 2022, respectively)		41,596	39,963
Notes receivable		23,679	8,608
Inventories, net	4	44,229	31,621
Prepayments and other current assets		29,821	35,674
<b>Total current assets</b>		<b>959,731</b>	<b>1,124,336</b>
Restricted cash, non-current		1,792	803
Long term investments		4,466	6,431
Prepayments for equipment		144	1,396
Property and equipment, net	5	55,282	57,863
Operating lease right-of-use assets		16,398	19,512
Land use rights, net		3,057	6,892
Intangible assets, net		1,568	1,511
Long-term deposits		1,256	1,396
<b>Total assets</b>		<b>1,043,694</b>	<b>1,220,140</b>
<b>Liabilities and shareholders' equity</b>			
<b>Current liabilities:</b>			
Accounts payable		55,020	65,974
Current operating lease liabilities		6,886	7,050
Other current liabilities	8	62,990	66,818
<b>Total current liabilities</b>		<b>124,896</b>	<b>139,842</b>
Deferred income		27,686	21,360
Non-current operating lease liabilities		9,808	13,343
Other non-current liabilities		325	—
<b>Total liabilities</b>		<b>162,715</b>	<b>174,545</b>
<b>Commitments and contingencies (Note 15)</b>			
<b>Shareholders' equity</b>			
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 973,930,280 and 962,455,850 shares issued as of September 30, 2023 and December 31, 2022, respectively; 969,037,150 and 960,219,570 shares outstanding as of September 30, 2023 and December 31, 2022, respectively)		6	6
Additional paid-in capital		2,954,362	2,893,120
Accumulated deficit		(2,100,551)	(1,861,360)
Accumulated other comprehensive income		47,952	25,685
Treasury Stock (at cost, 4,893,130 and 2,236,280 shares as of September 30, 2023 and December 31, 2022, respectively)		(20,790)	(11,856)
<b>Total shareholders' equity</b>		<b>880,979</b>	<b>1,045,595</b>
<b>Total liabilities and shareholders' equity</b>		<b>1,043,694</b>	<b>1,220,140</b>

*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 September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
<b>Revenues:</b>					
Product revenue, net	6	69,228	56,963	200,889	150,633
Collaboration revenue		—	577	—	1,806
Total revenues		69,228	57,540	200,889	152,439
<b>Expenses:</b>					
Cost of sales		(25,479)	(20,044)	(70,579)	(53,094)
Research and development		(58,767)	(99,524)	(183,920)	(219,462)
Selling, general, and administrative		(68,552)	(66,555)	(198,982)	(186,947)
Gain on sale of intellectual property		—	—	10,000	—
Loss from operations		(83,570)	(128,583)	(242,592)	(307,064)
Interest income		9,172	3,872	29,493	5,235
Foreign currency gain (loss)		4,852	(40,442)	(26,315)	(73,052)
Other income (expense), net	13	394	3,963	223	(6,415)
Loss before income tax and share of loss from equity method investment		(69,152)	(161,190)	(239,191)	(381,296)
Income tax expense	7	—	—	—	—
Share of loss from equity method investment		—	—	—	(221)
Net loss		(69,152)	(161,190)	(239,191)	(381,517)
Net loss attributable to ordinary shareholders		(69,152)	(161,190)	(239,191)	(381,517)
Loss per share - basic and diluted	9	(0.07)	(0.17)	(0.25)	(0.40)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		968,767,730	959,085,960	965,060,570	957,439,910
Loss per American Depositary Shares (“ADS”) - basic and diluted		(0.71)	(1.68)	(2.48)	(3.98)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted		96,876,773	95,908,596	96,506,057	95,743,991

*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 \$)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Net loss	(69,152)	(161,190)	(239,191)	(381,517)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	(4,228)	35,062	22,267	63,194
Comprehensive loss	(73,380)	(126,128)	(216,924)	(318,323)

*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		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total
	Number of Shares	Amount				Shares	Amount	
Balance at December 31, 2022	962,455,850	6	2,893,120	(1,861,360)	25,685	(2,236,280)	(11,856)	1,045,595
Issuance of ordinary shares upon vesting of restricted shares	732,040	0	0	—	—	—	—	—
Exercise of share options	4,009,460	0	1,673	—	—	—	—	1,673
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,272,330)	(5,130)	(5,130)
Share-based compensation	—	—	16,661	—	—	—	—	16,661
Net loss	—	—	—	(49,144)	—	—	—	(49,144)
Foreign currency translation	—	—	—	—	(8,413)	—	—	(8,413)
Balance at March 31, 2023	967,197,350	6	2,911,454	(1,910,504)	17,272	(3,508,610)	(16,986)	1,001,242
Issuance of ordinary shares upon vesting of restricted shares	6,117,040	0	0	—	—	—	—	—
Exercise of share options	41,000	0	88	—	—	—	—	88
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,280,500)	(3,540)	(3,540)
Share-based compensation	—	—	20,511	—	—	—	—	20,511
Net loss	—	—	—	(120,895)	—	—	—	(120,895)
Foreign currency translation	—	—	—	—	34,908	—	—	34,908
Balance at June 30, 2023	973,355,390	6	2,932,053	(2,031,399)	52,180	(4,789,110)	(20,526)	932,314
Issuance of ordinary shares upon vesting of restricted shares	394,890	0	0	—	—	—	—	—
Exercise of share options	180,000	0	317	—	—	—	—	317
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(104,020)	(264)	(264)
Share-based compensation	—	—	21,992	—	—	—	—	21,992
Net loss	—	—	—	(69,152)	—	—	—	(69,152)
Foreign currency translation	—	—	—	—	(4,228)	—	—	(4,228)
Balance at September 30, 2023	973,930,280	6	2,954,362	(2,100,551)	47,952	(4,893,130)	(20,790)	880,979

	Ordinary Shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total
	Number of Shares	Amount				Shares	Amount	
Balance at December 31, 2021	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956
Issuance of ordinary shares upon vesting of restricted shares	514,800	0	0	—	—	—	—	—
Exercise of share options	1,156,660	0	297	—	—	—	—	297
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(15,150)	(68)	(68)
Share-based compensation	—	—	12,410	—	—	—	—	12,410
Net loss	—	—	—	(82,394)	—	—	—	(82,394)
Foreign currency translation	—	—	—	—	(2,193)	—	—	(2,193)
Balance at March 31, 2022	957,035,440	6	2,838,655	(1,500,468)	(25,838)	(398,080)	(4,347)	1,308,008
Issuance of ordinary shares upon vesting of restricted shares	683,700	0	0	—	—	—	—	—
Exercise of share options	2,801,000	0	4,322	—	—	—	—	4,322
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,627,230)	(6,782)	(6,782)
Share-based compensation	—	—	14,225	—	—	—	—	14,225
Net loss	—	—	—	(137,933)	—	—	—	(137,933)
Foreign currency translation	—	—	—	—	30,325	—	—	30,325
Balance at June 30, 2022	960,520,140	6	2,857,202	(1,638,401)	4,487	(2,025,310)	(11,129)	1,212,165
Issuance of ordinary shares upon vesting of restricted shares	230,250	0	0	—	—	—	—	—
Exercise of share options	1,079,330	0	1,052	—	—	—	—	1,052
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(79,470)	(327)	(327)
Share-based compensation	—	—	19,107	—	—	—	—	19,107
Net loss	—	—	—	(161,190)	—	—	—	(161,190)
Foreign currency translation	—	—	—	—	35,062	—	—	35,062
Balance at September 30, 2022	961,829,720	6	2,877,361	(1,799,591)	39,549	(2,104,780)	(11,456)	1,105,869

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 \$)**

	Nine Months Ended September 30,	
	2023	2022
<b>Cash flows from operating activities</b>		
Net loss	(239,191)	(381,517)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss (gain)	1	(3)
Inventory write-down	746	480
Depreciation and amortization expenses	6,570	6,100
Amortization of deferred income	(2,547)	(2,041)
Share-based compensation	59,164	45,742
Share of loss from equity method investment	—	221
Loss from fair value changes of equity investment with readily determinable fair value	1,965	12,067
Loss (gain) on disposal of property and equipment	139	(11)
Gain on disposal of land use right	(408)	—
Noncash lease expenses	6,630	5,820
Gain from sale of intellectual property	(10,000)	—
Foreign currency remeasurement loss	26,315	73,052
Changes in operating assets and liabilities:		
Accounts receivable	(2,823)	16,483
Notes receivable	(15,563)	(3,861)
Inventories	(14,408)	(13,235)
Prepayments and other current assets	5,126	(5,860)
Long-term deposits	140	(459)
Value added tax recoverable	—	21,432
Accounts payable	(9,494)	(28,850)
Other current liabilities	227	1,628
Operating lease liabilities	(5,794)	(6,008)
Deferred income	9,619	470
Other non-current liabilities	325	—
Net cash used in operating activities	(183,261)	(258,350)
<b>Cash flows from investing activities</b>		
Purchases of short-term investments	(134,000)	(260,274)
Proceeds from maturity of short-term investment	102,400	705,274
Purchase of property and equipment	(6,990)	(20,172)
Proceeds from the sale of property and equipment	122	—
Purchase of intangible assets	(658)	(439)
Proceeds from sale of intellectual property	10,000	—
Proceeds from disposal of land use right	3,893	—
Net cash (used in) provided by investing activities	(25,233)	424,389
<b>Cash flows from financing activities</b>		
Proceeds from exercises of stock options	1,899	5,640
Taxes paid related to settlement of equity awards	(8,725)	(7,171)
Net cash used in financing activities	(6,826)	(1,531)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(3,355)	(9,132)
Net (decrease) increase in cash, cash equivalents and restricted cash	(218,675)	155,376
Cash, cash equivalents and restricted cash - beginning of period	1,009,273	964,903
Cash, cash equivalents and restricted cash - end of period	790,598	1,120,279
<b>Supplemental disclosure on non-cash investing and financing activities</b>		
Payables for purchase of property and equipment	2,625	3,234
Payables for intangible assets	98	32
Payables for treasury stock	31	32
Receivables for stock option exercise under equity incentive plans	—	31
Right-of-use asset acquired under operating leases	3,296	12,861
<b>Supplemental disclosure of cash flow information</b>		
Cash and cash equivalents	788,806	1,119,476
Restricted cash, non-current	1,792	803
Total cash and cash equivalents and restricted cash	790,598	1,120,279

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

## **Zai Lab Limited**

### **Notes to the unaudited condensed consolidated financial statements**

#### **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 that address medical conditions with significant unmet needs, including in the areas of oncology, autoimmune disorders, infectious disease, and neuroscience.

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

#### **2. Basis of Presentation and Consolidation and Significant Accounting Policies**

##### ***(a) Basis of Presentation***

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

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

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

##### ***(b) Principles of Consolidation***

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

##### ***(c) Use of Estimates***

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, accrual of rebates, recognition of research and development expenses to the appropriate financial reporting period based on the progress of the research and development projects, fair value of share-based compensation expenses, and recoverability of deferred tax assets. These estimates, judgments, and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Actual results could differ from these estimates.

## Zai Lab Limited

### Notes to the unaudited condensed consolidated financial statements

#### (d) Fair Value Measurements

Equity investments with readily determinable fair value are measured using level 1 inputs and were \$4.5 million and \$6.4 million as of September 30, 2023 and December 31, 2022, respectively. The unrealized gains and losses from fair value changes are recognized in other income (expenses), net in the condensed 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 September 30, 2023 and December 31, 2022, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximated its fair value based on the nature of the assessment of the ability to recover these amounts.

#### (e) Recent Accounting Pronouncements

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

### 3. Cash and Cash Equivalents

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

	September 30, 2023	December 31, 2022
Cash	787,725	1,007,423
Cash equivalents (i)	1,081	1,047
	<u>788,806</u>	<u>1,008,470</u>
Denominated in:		
US\$	764,765	957,824
RMB (ii)	21,056	45,486
Hong Kong dollar ("HK\$")	2,352	4,378
Australian dollar ("A\$")	553	598
Taiwan dollar ("TW\$")	80	184
	<u>788,806</u>	<u>1,008,470</u>

- (i) Cash equivalents represent short-term and highly liquid investments in a money market fund.
- (ii) Certain cash and bank balances denominated in RMB were deposited with banks in mainland China. The conversion of these RMB-denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the Chinese government.

### 4. Inventories, Net

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

	September 30, 2023	December 31, 2022
Finished goods	21,417	12,156
Raw materials	22,812	19,029
Work in progress	—	436
Inventories, net	<u>44,229</u>	<u>31,621</u>

## Zai Lab Limited

### Notes to the unaudited condensed consolidated financial statements

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. The Company recorded write-downs in inventory, which were included in cost of sales, of \$0.1 million and \$0.7 million during the three and nine months ended September 30, 2023, respectively, and \$0.3 million and \$0.5 million during the three and nine months ended September 30, 2022 respectively.

#### 5. Property and Equipment, Net

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

	September 30, 2023	December 31, 2022
Office equipment	1,024	977
Electronic equipment	8,757	7,416
Vehicle	196	202
Laboratory equipment	19,858	18,726
Manufacturing equipment	16,865	17,055
Leasehold improvements	11,153	11,300
Construction in progress	25,019	24,251
	82,872	79,927
Less: accumulated depreciation	(27,590)	(22,064)
Property and equipment, net	55,282	57,863

Depreciation expense was \$1.8 million and \$6.1 million for the three and nine months ended September 30, 2023, respectively, and \$2.1 million and \$5.7 million for the three and nine months ended September 30, 2022, respectively.

#### 6. Revenue

##### *Product Revenue*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenue - gross	74,018	60,446	220,240	168,095
Less: Rebates and sales returns	(4,790)	(3,483)	(19,351)	(17,462)
Product revenue - net	69,228	56,963	200,889	150,633

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.

## Zai Lab Limited

### Notes to the unaudited condensed consolidated financial statements

The following table presents the Company's net revenue by product (\$ in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
ZEJULA	41,593	39,214	127,230	102,863
Optune	11,562	10,662	38,596	35,051
QINLOCK	5,702	5,541	14,535	9,123
NUZYRA	5,483	1,546	15,588	3,596
VYVGART	4,888	—	4,940	—
Product revenue - net	69,228	56,963	200,889	150,633

### 7. Income Tax

No provision for income taxes has been required to be accrued because the Company is in a cumulative loss position 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 September 30, 2023 and December 31, 2022. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

### 8. Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Payroll	26,046	31,689
Accrued professional service fee	9,578	4,080
Payables for purchase of property and equipment	2,625	5,269
Accrued rebate to distributors	8,121	8,443
Tax payables	13,792	13,283
Others (i)	2,828	4,054
Total	62,990	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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss attributable to ordinary shareholders	(69,152)	(161,190)	(239,191)	(381,517)
Denominator:				
Weighted average number of ordinary shares - basic and diluted	968,767,730	959,085,960	965,060,570	957,439,910
Net loss per share - basic and diluted	(0.07)	(0.17)	(0.25)	(0.40)

## Zai Lab Limited

### Notes to the unaudited condensed consolidated financial statements

As a result of the Company's net loss for the three and nine months ended September 30, 2023 and 2022, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	September 30,	
	2023	2022
Share options	107,249,960	90,511,530
Non-vested restricted shares	32,359,260	34,103,830

### 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 an insignificant amount during the three and nine months ended September 30, 2023 and an insignificant amount and \$0.3 million during the three and nine months ended September 30, 2022, respectively.

### 11. Share-Based Compensation

During the nine months ended September 30, 2023, the Company granted share options to purchase up to 23,768,090 ordinary shares and restricted shares representing 8,836,580 ordinary shares under the 2022 Plan. The share options granted have a contractual term of ten years. Share options granted since April 2023 generally vest ratably over a four-year period, and share options granted prior to April 2023 generally vest ratably over a five-year period, with 25% or 20% of the awards vesting on each anniversary of the grant date, respectively, subject to continued employment with the Company on the vesting date. 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. For a description of the Company's equity incentive plans and more details on the terms of the share-based awards, see Note 15 to our 2022 Annual Report.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Selling, general and administrative	14,041	11,298	35,880	27,221
Research and development	7,951	7,809	23,284	18,521
Total	21,992	19,107	59,164	45,742

As of September 30, 2023, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of \$114.6 million and \$115.4 million, respectively, which the Company expects to recognize over a weighted-average period of 3.24 years and 2.98 years, respectively.

### 12. License and Collaboration Agreements

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

#### Significant License and Collaboration Arrangements

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

## Zai Lab Limited

### Notes to the unaudited condensed consolidated financial statements

upfront or milestone fees under our significant license and collaboration agreements during the nine months ended September 30, 2023.

#### *License and Collaboration Agreement with Entasis Therapeutics Holdings Inc. (“Entasis”) (SUL-DUR)*

Under the terms of our license and collaboration agreement with Entasis for SUL-DUR, the Company paid a \$3.0 million development milestone in the third quarter of 2023, which was accrued in the second quarter of 2023. As of September 30, 2023, the Company may be required to pay an additional aggregate amount of up to \$88.6 million in development, regulatory, and sales-based milestones.

#### *License Agreement with BMS (Formerly Turning Point Therapeutics Inc (“Turning Point”)) (Reprotrectinib)*

Under the terms of our license agreement with BMS for reprotrectinib, the Company paid a \$5.0 million development milestone in the third quarter of 2023, which was accrued in the second quarter of 2023. As of September 30, 2023, the Company may be required to pay an additional aggregate amount of up to \$141.0 million in development, regulatory, and sales-based milestones.

#### Other License and Collaboration Arrangements That Are Not Individually Significant

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

### 13. Other Income (Expenses), Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Government grants	671	3,422	754	5,048
Loss on equity investments with readily determinable fair value	(661)	489	(1,965)	(12,067)
Others miscellaneous gain	384	52	1,434	604
Total	<u>394</u>	<u>3,963</u>	<u>223</u>	<u>(6,415)</u>

### 14. Restricted Net Assets

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

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

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

## **Zai Lab Limited**

### **Notes to the unaudited condensed consolidated financial statements**

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 September 30, 2023 and December 31, 2022, amounts restricted were the paid-in capital of the Company's Chinese subsidiaries, which were \$506.0 million and \$456.0 million, respectively.

#### **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 \$2.5 million as of September 30, 2023 and were expected to be incurred within one year.

##### ***(b) Legal Proceedings***

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

##### ***(c) Indemnifications***

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

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

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

### Overview

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

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and selling, general and administrative costs associated with our operations. Developing high quality product candidates requires significant investment in our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and positive cash flow from operations over the next several years depends upon our ability to successfully market our commercial products and to successfully expand the indications for these products and develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. For example, our licensing and collaboration agreements may require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

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

### Recent Developments

#### *Commercial Products*

- **VYVGART** (efgartigimod, FcRn): In September 2023, we launched VYVGART (efgartigimod alfa injection) as an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (“gMG”) who are anti-acetylcholine receptor (“AChR”) antibody positive, increasing our number of commercial products to five. We are in the negotiation process for VYVGART’s inclusion on the National Reimbursement Drug List (“NRDL”) to help support increased patient access for this therapy.
- **ZEJULA** (niraparib, PARP): In September 2023, we conducted the final overall survival (“OS”) analysis for the Phase III NORA study in Chinese patients with platinum-sensitive recurrent ovarian cancer, which supports the NMPA’s full approval of ZEJULA for patients with recurrent ovarian cancer in China. The final OS results showed that niraparib maintenance treatment in the recurrent setting provides a favorable trend in OS irrespective of gBRCA mutation status compared with placebo.

## Product Candidates

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

### Oncology

- **ZEJULA** (niraparib, PARP): In July 2023, we announced the publication in JAMA Oncology of data from the pivotal Phase III PRIME study evaluating ZEJULA as a first-line maintenance therapy in Chinese patients with newly diagnosed advanced ovarian cancer and demonstrating that an individual starting dose (“ISD”) of 200 or 300mg based on baseline bodyweight and platelet count can bring significant benefit to patients with an improved safety and tolerability profile of ZEJULA compared to a fixed 300mg starting dose. The data demonstrated that maintenance treatment with ZEJULA can significantly extend progression-free survival (“PFS”) versus a placebo and can reduce the risk of disease progression or death by 55% among patients with newly diagnosed advanced ovarian cancer, regardless of postoperative residual disease or biomarker status. For example, with a median follow-up of 27.5 months, median PFS (“mPFS”) with ZEJULA versus placebo in the intention-to-treat (“ITT”) population was 24.8 versus 8.3 months (hazard ratio (“HR”), 0.45; 95% confidence interval (“CI”), 0.34–0.60;  $p < .001$ ). At the time of data cut-off, OS data were not yet mature in the ITT population. Utilization of an individual starting dose demonstrated a tolerable safety profile in the maintenance setting. Grade  $\geq 3$  treatment-emergent adverse events (“TEAEs”) and serious adverse events (“SAEs”) were reported in 54.5% versus 17.8% and 18.8% vs 8.5% in ZEJULA-treated and placebo-treated patient, respectively. Similar proportions of ZEJULA-treated and placebo-treated patients (6.7% vs 5.4%) discontinued therapy due to TEAEs. The findings are consistent with prior studies that indicate that ZEJULA monotherapy as first-line maintenance treatment can provide statistically and clinically meaningful benefit in a broad population of patients, regardless of postoperative residual disease or biomarker status.
- **Tumor Treating Fields (TTFields or Optune):**
  - *Pancreatic Cancer:* In July 2023, NovoCure Limited (“NovoCure”) announced the results of a pre-specified interim analysis for the Phase III PANOVA-3 clinical trial evaluating the safety and efficacy of TTFields therapy together with nab-paclitaxel and gemcitabine for the treatment of patients with unresectable, locally advanced pancreatic cancer. An independent data monitoring committee (“DMC”) reviewed the safety and efficacy data for all patients in the fully enrolled clinical trial. The interim analysis resulted in a DMC recommendation that the clinical trial proceed to final analysis. Zai Lab participated in the Greater China portion of the study.
  - *Ovarian Cancer:* In August 2023, NovoCure announced that the Phase III INNOVATE-3 clinical trial of TTFields together with paclitaxel in patients with platinum-resistant ovarian cancer did not meet its primary endpoint of OS at the final analysis. We did not participate in this study.
- **KRAZATI<sup>®</sup> (Adagrasib, KRAS<sup>G12C</sup>):**
  - *First-Line Non-Small Cell Lung Cancer (“NSCLC”):* In October 2023, our partner Mirati Therapeutics, Inc. (“Mirati”) announced updated results from the KRYSTAL-7 Phase II study evaluating adagrasib combined with pembrolizumab in first-line KRAS<sup>G12C</sup>-mutated NSCLC at the European Society of Medical Oncology Congress (“ESMO”) 2023. The results demonstrate a manageable safety profile and early signs of durability of adagrasib in combination with a checkpoint inhibitor in the first-line NSCLC setting. We are participating in the study in Greater China.

- *Second-line+ NSCLC*: In September 2023, Mirati presented two-year follow-up data from a pooled analysis of the Phase I/Ib Cohort and Phase 2 Cohort A for the KRYSTAL-1 study in previously treated patients with KRAS<sup>G12C</sup>-mutated NSCLC at the 2023 World Conference on Lung Cancer (“WCLC”). In the pooled analysis, adagrasib demonstrated durable efficacy and a manageable long-term safety profile. We are participating in the ongoing confirmatory Phase III KRYSTAL-12 study in previously treated patients with KRAS<sup>G12C</sup>-mutated NSCLC in Greater China.
- **Repotrectinib (ROS1/TRK):**
  - *NTRK-Positive Solid Tumors*: In August 2023, the Center for Drug Evaluation (“CDE”) of the China National Medical Products Administration (“NMPA”) granted Breakthrough Therapy Designation (“BTD”) for repotrectinib, a next generation tyrosine kinase inhibitor (“TKI”), for the treatment of patients with advanced solid tumors that have a neurotrophic tropomyosin-receptor kinase (“NTRK”) gene fusion who have progressed following treatment with TRK TKIs. This BTD was supported by data from both global and Chinese patients enrolled in the Phase I/II TRIDENT-1 study.
  - *ROS1-Positive NSCLC*: In August 2023, our partner Bristol Myers Squibb (“BMS”) announced updated results from the registrational TRIDENT-1 study, demonstrating that repotrectinib continued to demonstrate high response rates and durable responses, including robust intracranial responses in patients with ROS1-positive locally advanced or metastatic NSCLC. For example, median duration of response (“DOR”) and median progression-free survival (“PFS”) was disclosed for the first time in the pooled Phase I and Phase II population of patients with ROS1-positive NSCLC: In TKI-naïve patients (n=71) with median follow-up of 24.0 months, confirmed objective response rate by Blinded Independent Central Review was 79%, median DOR and PFS were 34.1 months and 35.7 months, respectively. Based on results from the TRIDENT-1 trial, the FDA accepted the New Drug Application (“NDA”) submitted by BMS for repotrectinib for the treatment of patients with ROS1-positive NSCLC and granted Priority Review, with a Prescription Drug User Fee Act (“PDUFA”) goal date of November 27, 2023. The NDA we submitted to the NMPA for repotrectinib for patients with ROS-1 positive NSCLC has been accepted with priority review.
- **TIVDAK<sup>®</sup> (Tisotumab Vedotin, Antibody Drug Conjugate (“ADC”))**: In October 2023, our partner Seagen Inc. (“Seagen”) and Genmab A/S presented results from the Phase III innovaTV 301 global trial in recurrent or metastatic cervical cancer patients with disease progression on or after front-line therapy who received TIVDAK, compared with chemotherapy alone, met its primary endpoint of OS. An Independent Data Monitoring Committee determined that OS crossed the pre-specified efficacy boundary at interim analysis. The key secondary endpoints of investigator-assessed progression-free survival and objective response rate also demonstrated statistical significance. The safety profile of TIVDAK in innovaTV 301 was consistent with the known safety profile of TIVDAK as presented in the U.S. prescribing information, and no new safety signals were observed. We are participating in the global trial and extension study in Greater China.
- **Bemarituzumab (FGFR2b)**: In July 2023, we enrolled the first patient in China in the global Phase III FORTITUDE-101 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy, in first-line gastric cancer with FGFR2b overexpression.
- **ZL-1211 (Claudin18.2)**: Based on a review of the competitive landscape and market opportunity, we have decided to terminate internal development of this product.

### Autoimmune Disorders, Infectious Disease, and Neuroscience

- **Efgartigimod (FcRn):** In September 2023, the CDE of the NMPA granted BTD for efgartigimod alfa injection (subcutaneous injection) (“efgartigimod SC”) for the treatment of patients with chronic inflammatory demyelinating polyneuropathy (“CIDP”). This BTD was supported by data from both global and Chinese patients enrolled in the ADHERE study. The ADHERE study met its primary endpoint ( $p=0.000039$ ), demonstrating a significantly lower risk of relapse with efgartigimod SC compared to placebo. efgartigimod SC demonstrated a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo, and 67% of patients in open-label Stage A demonstrated evidence of clinical improvement, indicating that IgG autoantibodies play a significant role in the underlying biology of CIDP. The safety and tolerability profile was consistent with previous clinical trials and the confirmed safety profile of VYVGART. We participated in the Greater China portion of the study.
- **KarXT (xanomeline-trospium, M1/M4 agonist):**
  - *Schizophrenia:* In September 2023, our partner Karuna Therapeutics, Inc. (“Karuna”) announced that it had submitted an NDA to the FDA for the treatment of schizophrenia, supported by data from three positive registrational trials. We continue to enroll patients in our registrational bridging study in mainland China.
  - *Alzheimer’s disease psychosis (ADP):* Karuna initiated the Phase III ADEPT-2 and ADEPT-3 trials in ADP in the third quarter of 2023. We plan to participate in these studies in Greater China next year.

### *Corporate Updates*

We continued to strengthen our organizational structure to support the evolving needs of our business. For example:

- The Company promoted Dr. Yajing Chen to Chief Financial Officer, effective July 7, 2023. Dr. Chen previously served as our Senior Vice President and Deputy Chief Financial Officer, helping to oversee finance, planning and forecasting, accounting, tax, treasury, and procurement matters since joining the Company in September 2021. She is a seasoned finance executive with more than 20 years of experience in the life sciences industry as well as a Ph.D. trained scientist. She joined the Company from AstraZeneca where she held various roles of increasing responsibility from 2006 to 2021, including Chief Financial Officer for the U.S. Oncology Business Unit from 2019 to 2021 and Finance Controller of the Global Oncology Business Unit from 2016 to 2019. Her scientific background combined with her significant executive management experience, finance expertise at leading global companies, and business acumen provide a unique and valuable perspective to the Company and will help drive our next phase of growth. Dr. Chen succeeds Billy Cho, who stepped down from his role and left the Company on July 7, 2023.
- The Company appointed Dr. Robert Brown as Chief Medical Officer, Oncology in September 2023 to help accelerate the growth and development for our global oncology pipeline. Dr. Brown is an oncology drug development leader, with more than 16 years of translational, research, and clinical development expertise in the areas of oncology, immunology, and neurology. Dr. Brown reports to Dr. Rafael Amado, President, Head of Global Oncology Research and Development at Zai Lab, and provides strategic leadership and support with respect to the clinical development of our oncology pipeline.

### *Legal and Regulatory Developments*

Our business has been and continues to be impacted by legal and regulatory developments in the jurisdictions in which we operate, particularly in mainland China where our operations and product markets are primarily located. In July 2023, the Ministry of Science and Technology of the People’s Republic of China published an updated Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which will impact the Company’s practices in filing for an advance approval with the HGRAC. In addition, in July 2023, a revised Counter-Espionage Law intended to strengthen provisions on the protection of national security in mainland China went into effect,

which may increase our cyber security or operational costs and could subject us to investigative or enforcement actions by the Chinese government or regulatory authorities. In September 2023, the CAC released a draft regulation, under which certain low-risk data export activities will be exempted from certain transfer requirements relating to the governmental security assessment, standard contract, and privacy protection certification. While this regulation has not been finalized and is not yet effective, and may not be finalized or adopted in its current form, as drafted it would reduce our compliance burden with respect to cross-border data transfers.

## **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 several product candidates in late-stage clinical development.

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 initial public offering in September 2020 and a follow-on offering in April 2021 on the Hong Kong Stock Exchange. Through September 30, 2023, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offerings and follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$183.3 million and \$258.4 million for the nine months ended September 30, 2023 and 2022, respectively. We expect our expenditures to increase in connection with our ongoing activities, particularly as we advance our late-stage clinical product candidates, research and develop our clinical- and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. These expenditures include:

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

### **Selling, General, and Administrative Expenses**

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

### **Our Ability to Commercialize Our Product Candidates**

We have several product candidates in late-stage clinical development and various others in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such product candidates, which may not occur. Certain of our product candidates may require additional pre-clinical and/or clinical development,

regulatory approvals in multiple jurisdictions, manufacturing supply, substantial investment, and significant marketing efforts before we generate any revenue from product sales.

## License and Collaboration Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our license and collaboration agreements. We may be 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 an insignificant amount and \$19.3 million for the three and nine months ended September 30, 2023, respectively, and \$39.8 million and \$50.2 million for the three and nine months ended September 30, 2022. We may be obligated to pay up to an additional aggregate amount of approximately \$1,337.5 million in development and regulatory milestone payments and \$2,410.2 million in sales-based milestone payments that are contingent on product performance as well as certain royalties at tiered percentage rates on annual net sales. These milestones may not occur at all, or certain development and regulatory milestones may occur before the Company has commercialized or received any revenue from the licensed product. 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.

## Results of Operations

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
<b>Revenues:</b>								
Product revenue, net	69,228	56,963	12,265	22 %	200,889	150,633	50,256	33 %
Collaboration revenue	—	577	(577)	(100)%	—	1,806	(1,806)	(100)%
Total revenues	69,228	57,540	11,688	20 %	200,889	152,439	48,450	32 %
<b>Expenses:</b>								
Cost of sales	(25,479)	(20,044)	(5,435)	27 %	(70,579)	(53,094)	(17,485)	33 %
Research and development	(58,767)	(99,524)	40,757	(41)%	(183,920)	(219,462)	35,542	(16)%
Selling, general, and administrative	(68,552)	(66,555)	(1,997)	3 %	(198,982)	(186,947)	(12,035)	6 %
Gain on sale of intellectual property	—	—	—	— %	10,000	—	10,000	NM
Loss from operations	(83,570)	(128,583)	45,013	(35)%	(242,592)	(307,064)	64,472	(21)%
Interest income	9,172	3,872	5,300	137 %	29,493	5,235	24,258	463 %
Foreign currency gain (loss)	4,852	(40,442)	45,294	(112)%	(26,315)	(73,052)	46,737	(64)%
Other income (expense), net	394	3,963	(3,569)	(90)%	223	(6,415)	6,638	(103)%
Loss before income tax and share of loss from equity method investment	(69,152)	(161,190)	92,038	(57)%	(239,191)	(381,296)	142,105	(37)%
Income tax expense	—	—	—	— %	—	—	—	— %
Share of loss from equity method investment	—	—	—	— %	—	(221)	221	(100)%
<b>Net loss</b>	<b>(69,152)</b>	<b>(161,190)</b>	<b>92,038</b>	<b>(57)%</b>	<b>(239,191)</b>	<b>(381,517)</b>	<b>142,326</b>	<b>(37)%</b>
Net loss attributable to ordinary shareholders	(69,152)	(161,190)	92,038	(57)%	(239,191)	(381,517)	142,326	(37)%

*NM - Not Meaningful*

## Revenues

### Product Revenue

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Product revenue - gross	74,018	60,446	13,572	22 %	220,240	168,095	52,145	31 %
Less: Rebates and sales return	(4,790)	(3,483)	(1,307)	38 %	(19,351)	(17,462)	(1,889)	11 %
Product revenue - net	69,228	56,963	12,265	22 %	200,889	150,633	50,256	33 %

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, NUZYRA, and VYVGART 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 \$12.3 million and \$50.3 million in the three and nine months ended September 30, 2023, respectively, primarily driven by increased sales volumes, the launch of VYVGART, and decreased negative effects from the COVID-19 pandemic. Our revenue growth was slowed by the effects on hospital and physician practices from the recent industry-wide anti-corruption enforcement efforts in China. In terms of revenue growth by product, ZEJULA continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China; increased sales for Optune were supported by increased patient access in the private-pay market, increased sales for QINLOCK and NUZYRA were supported by their inclusion in the NRDL in the first quarter of 2023, and we commercially launched VYVGART for gMG in mainland China in September 2023. The effects of the COVID-19 pandemic had an adverse impact on our sales volumes for the three and nine months ended September 30, 2022 and the first quarter in 2023, due to decreased patient access to our products, such as through reduced hospital access during periods of lockdown or high infection rates, fewer newly diagnosed oncology patients, and delayed or interrupted treatments. The COVID-19 pandemic did not have a material adverse effect on our sales volume in the second and third quarters of 2023.

For the nine months ended September 30, 2023 and 2022, our net product revenue included negative adjustments of \$5.2 million and \$5.3 million, respectively, as a result of sales rebates to compensate distributors for sales of certain products at prices prior to their price reductions in connection with their inclusion on the NRDL in China. Such sales rebates to distributors on previously purchased products are customary in our industry. The negative adjustments in the nine months ended September 30, 2023 related to such sales rebates for price reductions for QINLOCK and NUZYRA in connection with their addition to the NRDL in the first quarter of 2023. The negative adjustments in the nine months ended September 30, 2022 related to such sales rebates for price reductions for ZEJULA due to its inclusion in the NRDL for certain therapies in December 2021 and for price reductions for QINLOCK and NUZYRA in the second quarter of 2022 in connection with NRDL pricing negotiations. Such negative adjustments were nil and insignificant during the three months ended September 30, 2023 and 2022, respectively.

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
ZEJULA	41,593	39,214	2,379	6 %	127,230	102,863	24,367	24 %
Optune	11,562	10,662	900	8 %	38,596	35,051	3,545	10 %
QINLOCK	5,702	5,541	161	3 %	14,535	9,123	5,412	59 %
NUZYRA	5,483	1,546	3,937	255 %	15,588	3,596	11,992	333 %
VYVGART	4,888	—	4,888	NM	4,940	—	4,940	NM
Total product revenue, net	69,228	56,963	12,265	22 %	200,889	150,633	50,256	33 %

NM - Not Meaningful

### Cost of Sales

Cost of sales increased by \$5.4 million and \$17.5 million in the three and nine months ended September 30, 2023, respectively. These increases were primarily due to increasing sales volumes.

## Research and Development Expenses

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Personnel compensation and related costs	27,933	28,478	(545)	(2)%	85,967	80,325	5,642	7 %
Licensing fees	9	39,769	(39,760)	(100)%	19,291	50,205	(30,914)	(62)%
CROs/CMOs/Investigators expenses	23,136	23,407	(271)	(1)%	59,201	70,325	(11,124)	(16)%
Other costs	7,689	7,870	(181)	(2)%	19,461	18,607	854	5 %
<b>Total</b>	<b>58,767</b>	<b>99,524</b>	<b>(40,757)</b>	<b>(41)%</b>	<b>183,920</b>	<b>219,462</b>	<b>(35,542)</b>	<b>(16)%</b>

Research and development expenses decreased by \$40.8 million in the three months ended September 30, 2023, primarily due to a decrease of \$39.8 million in licensing fees in connection with decreased upfront and milestone payments for our license and collaboration agreements.

Research and development expenses decreased by \$35.5 million in the nine months ended September 30, 2023, primarily due to:

- a decrease of \$30.9 million in licensing fees in connection with decreased upfront and milestone payments for our license and collaboration agreements; and
- 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 \$5.6 million in personnel compensation and related costs primarily due to grants of share options and restricted shares and the continued vesting of option and restricted share awards.

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Clinical programs	23,243	63,324	(40,081)	(63)%	68,232	119,468	(51,236)	(43)%
Pre-clinical programs	2,013	2,965	(952)	(32)%	15,252	7,487	7,765	104 %
Unallocated research and development expenses	33,511	33,235	276	1 %	100,436	92,507	7,929	9 %
<b>Total</b>	<b>58,767</b>	<b>99,524</b>	<b>(40,757)</b>	<b>(41)%</b>	<b>183,920</b>	<b>219,462</b>	<b>(35,542)</b>	<b>(16)%</b>

Research and development expenses attributable to clinical programs decreased by \$40.1 million in the three months ended September 30, 2023, primarily driven by a decrease in licensing fees related to our license and collaboration agreements. Research and development expenses attributable to pre-clinical programs decreased by \$1.0 million in the three months ended September 30, 2023 primarily due to the advancement of certain programs to clinical stages.

Research and development expenses attributable to clinical programs decreased by \$51.2 million in the nine months ended September 30, 2023, primarily driven by a decrease in licensing fees of \$41.9 million and \$11.5 million in compensation from collaboration partners related to our clinical trials in the first quarter of 2023. Research and development expenses attributable to pre-clinical programs increased by \$7.8 million in the nine months ended September 30, 2023, primarily driven by an increase in licensing fees of \$11.0 million, partially offset by cost decreases due to the advancement of certain programs to clinical stages.

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 September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
Personnel compensation and related costs	45,410	41,859	3,551	8 %	129,198	121,382	7,816	6 %
Professional service fees	4,404	9,381	(4,977)	(53)%	18,752	24,886	(6,134)	(25)%
Other costs	18,738	15,315	3,423	22 %	51,032	40,679	10,353	25 %
<b>Total</b>	<b>68,552</b>	<b>66,555</b>	<b>1,997</b>	<b>3 %</b>	<b>198,982</b>	<b>186,947</b>	<b>12,035</b>	<b>6 %</b>

Selling, general, and administrative expenses increased by \$2.0 million and \$12.0 million in the three and nine months ended September 30, 2023, respectively, primarily due to:

- an increase of \$3.6 million and \$7.8 million in personnel compensation and related costs, respectively, primarily driven by grants of share options and restricted shares and the continued vesting of option and restricted share awards; and
- an increase of \$3.4 million and \$10.4 million in other costs, respectively, mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan; partially offset by
- a decrease of \$5.0 million and \$6.1 million in professional service fees, respectively, primarily related to legal expenses.

## ***Gain on Sale of Intellectual Property***

We had a gain on sale of intellectual property of \$10.0 million in the nine months ended September 30, 2023 in connection with our sale of certain patent rights and related know-how to a third party in the second quarter of 2023. We had no such intellectual property sales resulting in gains or losses in the prior year periods.

## ***Interest Income***

Interest income increased by \$5.3 million and \$24.3 million in the three and nine months ended September 30, 2023, respectively, due to increased interest rates.

## ***Foreign Currency Gain (Loss)***

Foreign currency gain was \$4.9 million in the three months ended September 30, 2023, primarily driven by remeasurement gain due to appreciation of the Renminbi (“RMB”) against the U.S. dollar, compared to foreign currency loss of \$40.4 million in the three months ended September 30, 2022, driven by remeasurement loss due to depreciation of the RMB against the U.S. dollar.

Foreign currency loss decreased by \$46.7 million in the nine months ended September 30, 2023, primarily driven by decreased remeasurement loss due to depreciation of the RMB against the U.S. dollar.

## ***Other Income (Expenses), Net***

Other income, net decreased by \$3.6 million in the three months ended September 30, 2023, primarily due to a decrease in government grants of \$2.8 million and a shift from a \$0.5 million gain to a \$0.7 million loss in our equity investment in MacroGenics.

Other income, net was \$0.2 million in the nine months ended September 30, 2023, compared to other expense, net of \$6.4 million in the nine months ended September 30, 2022, primarily due to a decrease of \$10.1 million in our equity investment loss in MacroGenics, partially offset by a decrease of \$4.3 million in government grants.

## ***Income Tax Expense***

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

## **Critical Accounting Policies and Significant Judgments and Estimates**

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

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

### ***Revenue Recognition***

#### *Description*

In mainland China, we sell our products to distributors, who ultimately sell the products to healthcare providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the product's delivery to distributors.

#### *Judgments and Uncertainties*

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. We estimate rebates based on contracted rates, sales volumes, and level of distributor inventories.

#### *Sensitivity of Estimate to Change*

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

### ***Research and Development Expenses***

#### *Description*

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

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

#### *Judgments and Uncertainties*

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

#### *Sensitivity of Estimate to Change*

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

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

### ***Share-Based Compensation***

#### *Description*

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

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

#### *Judgments and Uncertainties*

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

#### *Sensitivity of Estimate to Change*

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

### ***Income Taxes***

#### *Description*

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

## *Judgments and Uncertainties*

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

## *Sensitivity of Estimate to Change*

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts and circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of September 30, 2023 and 2022, we did not have any significant unrecognized uncertain tax positions.

## **Liquidity and Capital Resources**

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering and various follow-on offerings on Nasdaq, and our September 2020 secondary listing and initial public offering on the Hong Kong Stock Exchange. Through September 30, 2023, we have raised approximately \$164.6 million in private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering and subsequent follow-on offerings on Nasdaq and our initial public offering on the Hong Kong Stock Exchange. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$183.3 million and \$258.4 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had commitments for capital expenditures of \$2.5 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 September 30, 2023, we had cash and cash equivalents, restricted cash, and short-term investments of \$822.2 million. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash, and short-term investments, will enable us to meet our cash requirements and fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, in order to bring to fruition our research and development objectives, we may ultimately need additional funding sources, and there can be no assurances that such funding will be made available to us on acceptable terms or at all.

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

	Nine Months Ended September 30,		Change
	2023	2022	\$
Net cash used in operating activities	(183,261)	(258,350)	75,089
Net cash (used in) provided by investing activities	(25,233)	424,389	(449,622)
Net cash used in financing activities	(6,826)	(1,531)	(5,295)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(3,355)	(9,132)	5,777
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(218,675)</u>	<u>155,376</u>	<u>(374,051)</u>

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

Net cash used in operating activities decreased by \$75.1 million to \$183.3 million in the nine months ended September 30, 2023, primarily due to a decrease of \$142.3 million in net loss, partially offset by an increase of \$52.9 million in adjustments to reconcile net loss to net cash used in operating activities and a decrease of \$14.3 million in net changes in operating assets and liabilities.

### ***Net Cash Used in (Provided by) Investing Activities***

Net cash used in investing activities was \$25.2 million in the nine months ended September 30, 2023, compared to net cash provided by investing activities of \$424.4 in the nine months ended September 30, 2022. This shift was primarily due to a decrease of \$602.9 million in proceeds from the maturity of short-term investments, partially offset by a decrease of \$126.3 million in purchases of short-term investments, a decrease of \$13.2 million in purchases of property and equipment, and proceeds of \$13.9 million from a sale of intellectual property and a disposal of land use rights in the second quarter of 2023.

### ***Net Cash Used in Financing Activities***

Net cash used in financing activities increased by \$5.3 million to \$6.8 million in the nine months ended September 30, 2023, primarily due to a decrease of \$3.7 million in proceeds from exercises of stock options and an increase of \$1.6 million in taxes paid related to settlement of equity awards.

### ***Recently Issued Accounting Standards***

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk including foreign exchange risk, credit risk, and inflation risk.

#### ***Foreign Exchange Risk***

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts of RMB151.2 million and RMB316.8 million, which were denominated in RMB, representing 3% and 5% of the cash and cash equivalents as of September 30, 2023 and December 31, 2022, respectively.

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

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

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

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

### ***Credit Risk***

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of September 30, 2023 and December 31, 2022, we had cash and cash equivalents of \$788.8 million and \$1,008.5 million and short-term investments of \$31.6 million and nil, respectively. As of September 30, 2023 and December 31, 2022, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and for which we monitor continued credit worthiness.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangements. We manage credit risk related to our accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and credit worthiness. Historically, we have collected receivables from customers within the credit terms with no significant credit losses incurred. As of September 30, 2023, our two largest customers accounted for approximately 29% of our total accounts receivable collectively.

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

### ***Inflation Risk***

In recent years, mainland China has not experienced significant inflation. Although the global economy, including the U.S. economy, experienced rising inflation in recent years, which can increase the costs of our products and product candidates purchased from third parties and, as a result, adversely affect our results of operations, inflation has not had a material impact on our results of operations. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in mainland China or in other countries in which our third-party partners operate.

## **Item 4. Controls and Procedures**

### ***Management's Evaluation of our Disclosure Controls and Procedures***

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

### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as such item is defined in Rules 13a-15(f)) during the fiscal quarter ended September 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

We may be, from time to time, subject to claims and suits arising in the ordinary course of business. We are not currently a party to any material legal or administrative proceedings.

### **Item 1A. Risk Factors.**

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

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

#### **Recent Sales of Unregistered Securities**

None.

### Issuer Purchases of Equity Securities

The following table presents acquisitions of the Company's ADSs from employees by the Company to satisfy tax withholding obligations due in connection with exercise of option shares or vesting of restricted shares during the third 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
July 1 – 31, 2023	1,157	\$ 27.73	—	—
August 1 – 31, 2023	7,927	\$ 24.99	—	—
September 1 – 30, 2023	1,318	\$ 26.10	—	—
Total	10,402			

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

None.

### Item 5. Other Information.

On August 12, 2023, Joshua Smiley, the Company's President and Chief Operating Officer, adopted a new written Rule 10b5-1 trading arrangement (as defined in Item 408 of Regulation S-K), for the purchase of up to 15,000 of the Company's ADSs, each representing ten of the Company's ordinary shares. This Rule 10b5-1 trading arrangement is scheduled to terminate no later than May 13, 2024.

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

## Item 6. Exhibits.

### Exhibit Index

Exhibit Number	Exhibit Title
10.1#	<a href="#">Letter Agreement between Yajing Chen and Zai Lab (US) LLC dated July 6, 2023</a>
10.2#^	<a href="#">Letter Agreement between William Ki Chul Cho and Zai Lab (Hong Kong) Limited dated July 6, 2023</a>
31.1	<a href="#">Certification of Chief Executive Officer Required by Exchange Act Rule 13a-14(a)</a>
31.2	<a href="#">Certification of Chief Financial Officer Required by Exchange Act Rule 13a-14(a)</a>
32.1	<a href="#">Certification of Chief Executive Officer Required by 18 U.S.C. Section 1350</a>
32.2	<a href="#">Certification of Chief Financial Officer Required by 18 U.S.C. Section 1350</a>
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

# Management contract or compensatory plan, contract, or arrangement

^ Certain information contained in this exhibit has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential

## 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.

Dated: November 7, 2023

### ZAI LAB LIMITED

By: /s/ Yajing Chen

Name: Yajing Chen

Title: Chief Financial Officer

*(Principal Financial and Accounting Officer)*