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 made 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.

On November 12, 2024 (U.S. Eastern Time)/November 12, 2024 (Shanghai and Hong Kong Time), the Company filed a Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "**Form 10-Q**") with the U.S. Securities and Exchanges Commission (the "**SEC**"). For details, please refer to the attached for the Form 10-Q which has been published on the website of the SEC at www.sec.gov and the website of the Company at www.zailaboratory.com.

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

Hong Kong, November 12, 2024

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, Dr. Richard Gaynor, Ms. Nisa Leung, Mr. William Lis, Mr. Scott W. Morrison, Mr. Leon O. Moulder, Jr., Mr. Michel Vounatsos and Mr. Peter Wirth as independent directors.

** For identification only*

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38205

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

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

+86 216163 2588
+1 857 706 2604
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

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

As of November 6, 2024, 996,087,670 ordinary shares of the registrant, par value $0.000006 per share, were outstanding, of which 762,979,490 ordinary shares were held in the form of American Depositary Shares.

Zai Lab Limited
Quarterly Report on Form 10-Q
For the Third Quarter of 2024

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, commercial products, and pipeline programs; the market for our commercial and pipeline products; 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; our profitability and timeline to profitability; 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 U.S. 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 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 ("EMA") 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 American Depositary Share ("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;
- 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, 2023 (the "2023 Annual Report"), our Quarterly Reports on Form 10-Q, and our other filings with the U.S. Securities and Exchange Commission. 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 trademarks, including various forms of the Zai Lab brand (in English and Chinese), as well as several domain names that incorporate such trademarks. Trademarks and trade names 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.

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 2023 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, 2024	December 31, 2023
Assets			
Current assets			
Cash and cash equivalents	3	616,086	790,151
Restricted cash, current		100,000	—
Short-term investments		—	16,300
Accounts receivable (net of allowance for credit losses of $14 and $17 as of September 30, 2024 and December 31, 2023, respectively)		49,970	59,199
Notes receivable		19,278	6,134
Inventories, net	4	39,548	44,827
Prepayments and other current assets		35,667	22,995
Total current assets		860,549	939,606
Restricted cash, non-current		1,118	1,113
Long term investments		3,153	9,220
Prepayments for equipment		32	111
Property and equipment, net	5	50,765	53,734
Operating lease right-of-use assets		12,833	14,844
Land use rights, net		3,012	3,069
Intangible assets, net	6	51,669	13,389
Long-term deposits		975	1,209
Value added tax recoverable		1,240	—
Total assets		**985,346**	**1,036,295**
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable		120,652	112,991
Current operating lease liabilities		6,585	7,104
Short-term debt	10	112,994	—
Other current liabilities	11	46,084	82,972
Total current liabilities		286,315	203,067
Deferred income		24,924	28,738
Non-current operating lease liabilities		6,113	8,047
Other non-current liabilities		325	325
Total liabilities		**317,677**	**240,177**
Commitments and contingencies (Note 16)			
Shareholders' equity			
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 989,268,370 and 977,151,270 shares issued as of September 30, 2024 and December 31, 2023, respectively; 984,356,170 and 972,239,070 shares outstanding as of September 30, 2024 and December 31, 2023, respectively)		6	6
Additional paid-in capital		3,031,628	2,975,302
Accumulated deficit		(2,371,399)	(2,195,980)
Accumulated other comprehensive income		28,270	37,626
Treasury Stock (at cost, 4,912,200 shares as of both September 30, 2024 and December 31, 2023)		(20,836)	(20,836)
Total shareholders' equity		**667,669**	**796,118**
Total liabilities and shareholders' equity		**985,346**	**1,036,295**

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,	
		2024	2023	2024	2023
Revenues					
Product revenue, net	7	101,847	69,228	289,102	200,889
Collaboration revenue	7	418	—	816	—
Total revenues		102,265	69,228	289,918	200,889
Expenses					
Cost of product revenue		(36,569)	(25,479)	(105,336)	(70,579)
Cost of collaboration revenue		(348)	—	(433)	—
Research and development		(65,982)	(58,767)	(182,252)	(183,920)
Selling, general, and administrative		(67,219)	(68,552)	(216,123)	(198,982)
Gain on sale of intellectual property		—	—	—	10,000
Loss from operations		(67,853)	(83,570)	(214,226)	(242,592)
Interest income		9,029	9,172	28,017	29,493
Interest expense		(745)	—	(1,350)	—
Foreign currency gains (losses)		14,457	4,852	8,281	(26,315)
Other income, net	14	3,441	394	3,859	223
Loss before income tax		(41,671)	(69,152)	(175,419)	(239,191)
Income tax expense	8	—	—	—	—
Net loss		(41,671)	(69,152)	(175,419)	(239,191)
Loss per share - basic and diluted	9	(0.04)	(0.07)	(0.18)	(0.25)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		981,687,390	968,767,730	976,941,030	965,060,570

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

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Comprehensive Loss

(in thousands of $)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net loss	(41,671)	(69,152)	(175,419)	(239,191)
Other comprehensive income, net of tax of nil:				
Foreign currency translation adjustments	(14,503)	(4,228)	(9,356)	22,267
Comprehensive loss	(56,174)	(73,380)	(184,775)	(216,924)

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

Zai Lab Limited

Unaudited Condensed Consolidated Statements of Shareholders' Equity

(in thousands of $, except for number of shares)

	Ordinary Shares					Treasury Stock		
	Number of Shares	Amount	Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income	Shares	Amount	Total
Balance at December 31, 2023	977,151,270	6	2,975,302	(2,195,980)	37,626	(4,912,200)	(20,836)	796,118
Issuance of ordinary shares upon vesting of restricted shares	1,046,440	0	0	—	—	—	—	—
Share-based compensation	—	—	17,980	—	—	—	—	17,980
Net loss	—	—	—	(53,471)	—	—	—	(53,471)
Foreign currency translation	—	—	—	—	1,542	—	—	1,542
Balance at March 31, 2024	978,197,710	6	2,993,282	(2,249,451)	39,168	(4,912,200)	(20,836)	762,169
Issuance of ordinary shares upon vesting of restricted shares	8,087,630	0	0	—	—	—	—	—
Exercise of share options	25,000	0	44	—	—	—	—	44
Share-based compensation	—	—	18,638	—	—	—	—	18,638
Net loss	—	—	—	(80,277)	—	—	—	(80,277)
Foreign currency translation	—	—	—	—	3,605	—	—	3,605
Balance at June 30, 2024	986,310,340	6	3,011,964	(2,329,728)	42,773	(4,912,200)	(20,836)	704,179
Issuance of ordinary shares upon vesting of restricted shares	393,850	0	0	—	—	—	—	—
Exercise of share options	2,564,180	0	2,869	—	—	—	—	2,869
Share-based compensation	—	—	16,795	—	—	—	—	16,795
Net loss	—	—	—	(41,671)	—	—	—	(41,671)
Foreign currency translation	—	—	—	—	(14,503)	—	—	(14,503)
Balance at September 30, 2024	989,268,370	6	3,031,628	(2,371,399)	28,270	(4,912,200)	(20,836)	667,669

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

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,	
	2024	**2023**
Cash flows from operating activities		
Net loss	(175,419)	(239,191)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit losses	(3)	1
Inventory write-down	814	746
Depreciation and amortization expenses	8,824	6,570
Amortization of deferred income	(2,518)	(2,547)
Share-based compensation	53,413	59,164
Loss from fair value changes of equity investment with readily determinable fair value	6,067	1,965
Losses on disposal of property and equipment	451	139
Gain on disposal of land use right	—	(408)
Noncash lease expenses	6,104	6,630
Gain from sale of intellectual property	—	(10,000)
Debt issuance costs	700	—
Foreign currency remeasurement impact	(8,281)	26,315
Changes in operating assets and liabilities:		
Accounts receivable	9,712	(2,823)
Notes receivable	(12,901)	(15,563)
Inventories	4,403	(14,408)
Prepayments and other current assets	(10,767)	5,126
Long-term deposits	234	140
Value added tax recoverable	(1,223)	—
Accounts payable	6,545	(9,494)
Other current liabilities	(36,854)	227
Operating lease liabilities	(6,853)	(5,794)
Deferred income	(1,548)	9,619
Other non-current liabilities	—	325
Net cash used in operating activities	(159,100)	(183,261)
Cash flows from investing activities		
Purchases of short-term investments	—	(134,000)
Proceeds from maturity of short-term investment	16,300	102,400
Purchases of property and equipment	(3,057)	(6,990)
Proceeds from the sale of property and equipment	29	122
Acquisition of intangible assets	(40,711)	(658)
Proceeds from sale of intellectual property	—	10,000
Proceeds from disposal of land use right	—	3,893
Net cash used in investing activities	(27,439)	(25,233)
Cash flows from financing activities		
Proceeds from short-term debt	111,738	—
Repayment of short-term bank borrowings	(282)	—
Payments of debt issuance costs	(700)	—
Proceeds from exercises of stock options	1,321	1,899
Taxes paid related to settlement of equity awards	—	(8,725)
Net cash provided by (used in) financing activities	112,077	(6,826)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	402	(3,355)
Net decrease in cash, cash equivalents and restricted cash	(74,060)	(218,675)
Cash, cash equivalents and restricted cash - beginning of period	791,264	1,009,273
Cash, cash equivalents and restricted cash - end of period	717,204	790,598
Supplemental disclosure on non-cash investing and financing activities		
Payables for purchase of property and equipment	2,612	2,625
Payables for acquisition of intangible assets	11,358	98
Payables for treasury stock	—	31
Right-of-use asset acquired under operating leases	3,945	3,296
Receivables for stock option exercise under equity incentive plans	1,593	—
Supplemental disclosure of cash flow information		
Cash paid for interest	1,169	—

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

1. Organization and Principal Activities

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

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.

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 U.S. generally accepted accounting principles ("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, 2023 (the "2023 Annual Report"). The December 31, 2023 condensed consolidated balance sheet data included in this report were derived from the audited financial statements in the 2023 Annual Report.

The accompanying unaudited 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, 2024.

(b) Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of Zai Lab Limited and its subsidiaries, which are wholly owned. 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, fair value of share-based compensation expenses, and recoverability of deferred tax assets. These estimates, judgments, and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Actual results could differ from these estimates.

(d) Fair Value Measurements

Equity investments with readily determinable fair value are measured using level 1 inputs and were $3.2 million and $9.2 million as of September 30, 2024 and December 31, 2023, respectively. The unrealized losses from fair value changes are recognized in other income, net in the unaudited condensed consolidated statements of operations.

Financial instruments of the Company primarily include cash and cash equivalents, current restricted cash, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, non-current restricted cash,

accounts payable, short-term debt, and other current liabilities. As of September 30, 2024 and December 31, 2023, the carrying values of cash and cash equivalents, current restricted cash, short-term investments, accounts receivable, prepayments and other current assets, accounts payable, short-term debt, and other current liabilities approximated their fair value due to the short-term maturity of these instruments, and the carrying value of notes receivable and non-current restricted cash approximated their fair value based on the assessment of the ability to recover these amounts.

(e) Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures (Topic 280). This ASU requires all public entities, including public entities with a single reportable segment, to disclose the title and position of the Chief Operating Decision Maker ("CODM") and the significant segment expenses and any additional measures of a segment's profit or loss used by the CODM to allocate resources and assess performance. This ASU is effective on a retrospective basis for fiscal years beginning after December 15, 2023 and for interim periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this ASU and expects to adopt it for the year ending December 31, 2024.

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures (Topic 740). This ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. This ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in additional disclosure in the consolidated financial statements, once adopted. The Company is currently evaluating the impact of this ASU and expects to adopt it for the year ending December 31, 2025.

The Company did not adopt any new accounting standards in the nine months ended September 30, 2024 that had a material impact on the consolidated financial statements. For additional information on the Company's significant accounting policies, refer to the notes to the consolidated financial statements in the 2023 Annual Report.

3. Cash and Cash Equivalents

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

	September 30, 2024	December 31, 2023
Cash	614,937	789,051
Cash equivalents (i)	1,149	1,100
	616,086	790,151
Denominated in:		
US$	575,116	762,436
Renminbi ("RMB") (ii)	40,092	25,093
Hong Kong dollar ("HK$")	53	1,974
Australian dollar ("A$")	580	587
Taiwan dollar ("TW$")	245	61
	616,086	790,151

(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, 2024	December 31, 2023
Finished goods	22,460	22,702
Raw materials	15,397	17,655
Work in progress	1,691	4,470
Inventories, net	39,548	44,827

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 product revenue, of an insignificant amount and $0.8 million in the three and nine months ended September 30, 2024, respectively, and $0.1 million and $0.7 million in the three and nine months ended September 30, 2023, respectively.

5. Property and Equipment, Net

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

	September 30, 2024	December 31, 2023
Office equipment	1,059	1,047
Electronic equipment	9,527	9,161
Vehicle	201	199
Laboratory equipment	20,793	20,140
Manufacturing equipment	17,944	17,680
Leasehold improvements	11,544	11,371
Construction in progress	26,050	24,272
	87,118	83,870
Less: accumulated depreciation	(36,353)	(30,136)
Property and equipment, net	50,765	53,734

Depreciation expense was $2.1 million and $6.6 million in the three and nine months ended September 30, 2024, respectively, and $1.8 million and $6.1 million in the three and nine months ended September 30, 2023, respectively.

6. Intangible Assets, Net

The following table presents the components of the Company's intangible assets, net ($ in thousands):

	September 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Finite-lived intangible assets						
Commercial products (i)	52,050	(1,881)	50,169	11,351	(186)	11,165
Software	4,215	(2,715)	1,500	4,340	(2,116)	2,224
Total	**56,265**	**(4,596)**	**51,669**	**15,691**	**(2,302)**	**13,389**

(i) The increase in the net carrying value is primarily driven by $33.0 million of regulatory milestone fees for repotrectinib and SUL-DUR (see *Note 13*) and $6.0 million of commercial development costs.

Intangible assets for commercial products include capitalized post-approval milestone fees and commercial manufacturing development costs. The Company is amortizing commercial products as cost of product revenue over the estimated remaining useful life of the related products. Externally purchased software is amortized over three to five years on a straight-line basis.

Amortization expense was $0.7 million and $2.3 million in the three and nine months ended September 30, 2024, respectively, and $0.2 million and $0.5 million in the three and nine months ended September 30, 2023, respectively.

7. Revenues

Product Revenue, Net

The Company's product revenue is derived from the sales of its commercial products primarily in mainland China. The table below presents the Company's gross and net product revenue ($ in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product revenue - gross	107,678	74,018	307,401	220,240
Less: Rebates and sales returns	(5,831)	(4,790)	(18,299)	(19,351)
Product revenue - net	101,847	69,228	289,102	200,889

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
ZEJULA	48,227	41,593	138,727	127,230
OPTUNE	7,715	11,562	32,779	38,596
QINLOCK	8,643	5,702	21,774	14,535
NUZYRA	9,997	5,483	32,205	15,588
VYVGART	27,265	4,888	63,617	4,940
Product revenue - net	101,847	69,228	289,102	200,889

Collaboration Revenue

Collaboration revenue was $0.4 million and $0.8 million in the three and nine months ended September 30, 2024, respectively, and related to promotional activities in mainland China. We had no such collaboration revenue in the prior year periods.

8. 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, 2024 and December 31, 2023. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

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,	
	2024	2023	2024	2023
Numerator:				
Net loss	(41,671)	(69,152)	(175,419)	(239,191)
Denominator:				
Weighted average number of ordinary shares - basic and diluted	981,687,390	968,767,730	976,941,030	965,060,570
Net loss per share - basic and diluted	(0.04)	(0.07)	(0.18)	(0.25)

As a result of the Company's net loss in the three and nine months ended September 30, 2024 and 2023, 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,	
	2024	2023
Share options	105,188,950	107,249,960
Non-vested restricted shares	32,875,090	32,359,260

10. Borrowings

The Company has debt arrangements with the Bank of China, SPD Bank, CMB, and Ningbo Bank to support its working capital needs in mainland China. The following table presents the Company's short-term debt as of September 30, 2024 ($ in thousands):

	Weighted average interest rate per annum	September 30, 2024
Bank of China Working Capital Loans	2.86 %	70,925
SPD Bank Working Capital Loans	3.45 %	14,271
China Merchant Bank Working Capital Loans	3.15 %	27,798
Total short-term debt	3.01 %	112,994

Bank of China Working Capital Loan Facility

On February 5, 2024, the Company entered into an uncommitted facility letter with the Bank of China (Hong Kong) Limited (the "BOC HK") pursuant to which the BOC HK will provide standby letters of credit for loans of up to $100.0 million for a term of one year. In connection with this agreement, the Company paid a one-time, non-refundable fee of $0.7 million in the first quarter of 2024. In accordance with this agreement, the Company also maintained restricted deposits of $100.0 million, which are presented as restricted cash-current on the unaudited condensed consolidated balance sheet, to secure the standby letters of credit. On February 6, 2024 and June 20, 2024, upon the Company's application, the BOC HK provided standby letters of credit in favor of the Bank of China Pudong Development Zone Branch (the "BOC Pudong Branch") for $50.0 million and $23.0 million, respectively, which are or may become payable by the Company's wholly-owned subsidiary, Zai Lab (Shanghai) Co., Ltd. ("Zai Lab Shanghai"). Zai Lab Shanghai entered into working capital loans with the BOC Pudong Branch under this facility in the first half of 2024, and the aggregate principal amount outstanding was RMB497.0 million (approximately $70.9 million) as of September 30, 2024. Each working capital loan has a one-year term and is subject to a floating interest rate, which is subject to adjustment every six months.

SPD Bank Working Capital Loan Facility

On February 6, 2024, the Company entered into a maximum-amount guarantee contract with the Shanghai Pudong Development Bank Co., Ltd. Zhangjiang Hi-Tech Park Sub-branch (the "SPD Bank") pursuant to which the Company will guarantee working capital loans of up to RMB300.0 million (approximately $42.0 million) from SPD Bank to Zai Lab Shanghai over a three-year period. Zai Lab Shanghai entered into working capital loan contracts with SPD Bank under this debt facility in the first quarter of 2024, and the aggregate principal amount outstanding was RMB100.0 million (approximately $14.3 million) as of September 30, 2024. Each working capital loan has a one-year term and is subject to a fixed interest rate.

Ningbo Bank Working Capital Loan Facility

On February 6, 2024, the Company's wholly-owned subsidiary, Zai Lab (Suzhou) Co., Ltd. ("Zai Lab Suzhou"), entered into a maximum credit contract with Bank of Ningbo Co., Ltd. Suzhou Sub-branch ("Ningbo Bank") as well as an Electronic Commercial Draft Discounting Master Agreement and Online Working Capital Loan Master Agreement (collectively, the "Ningbo Bank Agreements"). The Ningbo Bank Agreements permit Zai Lab Suzhou to utilize, including through discounting or working capital loan agreements and subject to the terms and conditions in related master agreements, up to RMB230.3 million (approximately $32.4 million), of which the Company is authorized to utilize up to RMB160.0 million (approximately $22.5 million). In connection with the arrangements described in the Ningbo Bank Agreements, Zai Lab Suzhou agreed to pledge interests in certain real property it owns in Suzhou. As of September 30, 2024, Zai Lab Suzhou has not entered into any discounting arrangements or working capital loans under this Ningbo Bank working capital loan facility.

China Merchants Bank Working Capital Loan Facility

On July 5, 2024, the Company issued a maximum-amount irrevocable letter of guarantee to China Merchants Bank Co., Ltd., Shanghai Branch ("CMB") pursuant to which the Company will guarantee working capital loans of up to RMB250.0 million (approximately $34.4 million) from CMB to the Company's wholly-owned subsidiary, Zai Lab Shanghai, and Zai Lab Shanghai entered into a Credit Agreement with CMB with respect to the RMB250.0 million facility. The credit facility will be available for one year. As of September 30, 2024, Zai Lab Shanghai has an aggregate principal amount outstanding of RMB194.8 million (approximately $27.8 million) under this debt facility. Each working capital loan has a one-year term and is subject to a floating interest rate, which is subject to adjustment every three months.

11. Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Accrued payroll	24,077	33,711
Accrued professional service fee	3,986	7,520
Payables for purchase of property and equipment	2,612	2,474
Accrued rebate to distributors	8,800	16,926
Tax payables	3,756	16,988
Other (i)	2,853	5,353
Total	46,084	82,972

(i) Other primarily includes accrued travel and business-related expenses.

12. Share-Based Compensation

During the nine months ended September 30, 2024, the Company granted share options to purchase up to 20,747,480 ordinary shares and restricted shares representing 17,293,410 ordinary shares under its equity incentive plans. 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/service 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* of the 2023 Annual Report.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general and administrative	10,404	14,041	31,861	35,880
Research and development	6,391	7,951	21,552	23,284
Total	16,795	21,992	53,413	59,164

As of September 30, 2024, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of $80.4 million and $83.3 million, respectively, which the Company expects to recognize over a weighted-average period of 2.83 years and 2.68 years, respectively.

13. 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* of the 2023 Annual Report. During the nine months ended September 30, 2024, the Company did not enter into any new significant license or collaboration agreements. The following includes a description of milestone fees incurred in the nine months ended September 30, 2024 under the Company's significant license and collaboration agreements.

License and Collaboration Agreement with Innoviva (SUL-DUR)

Under the terms of the Company's license and collaboration agreement with Entasis Therapeutics Holdings Inc., a wholly owned subsidiary of Innoviva, Inc. ("Innoviva"), the Company recorded an $8.0 million regulatory milestone in the second quarter of 2024, which was capitalized as an intangible asset. As of September 30, 2024, the Company may be required to pay an additional aggregate amount of up to $80.6 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from high single digits to low-teens on annual net sales of the licensed products in the licensed territory.

License Agreement with BMS (Repotrectinib)

Under the terms of the Company's license agreement with Turning Point Therapeutics, Inc., a company later acquired by Bristol Myers Squibb ("BMS"), the Company recorded $25.0 million for regulatory milestones in the second

quarter of 2024, which was capitalized as an intangible asset. As of September 30, 2024, the Company may be required to pay an additional aggregate amount of up to $116.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid- to high-teens on annual net sales of the licensed products in the licensed territory.

License Agreement with BMS (Xanomeline and Trospium Chloride)

Under the terms of the Company's license agreement with Karuna Therapeutics, Inc. (a company later acquired by BMS), the Company recorded a $10.0 million development milestone into research and development expenses in the third quarter of 2024. As of September 30, 2024, the Company may be required to pay an additional aggregate amount of up to $132.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of the licensed products in Greater China.

Other License and Collaboration Arrangements That Are Not Individually Significant

The Company recorded an upfront payment of $12.0 million into research and development expenses in the third quarter of 2024 for a license and collaboration agreement that is not individually significant.

14. Other Income, Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Government grants	3,861	671	7,186	754
Loss on equity investments with readily determinable fair value	(920)	(661)	(6,067)	(1,965)
Others miscellaneous gain	500	384	2,740	1,434
Total	3,441	394	3,859	223

15. 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 in the three and nine months ended September 30, 2024 and 2023 because the Chinese subsidiaries had substantial losses during such periods.

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

Foreign exchange and other regulation in mainland China may further restrict the Company's subsidiaries in mainland China from transferring out funds in the form of dividends, loans, and advances. As of September 30, 2024 and December 31, 2023, amounts restricted included the paid-in capital of the Company's subsidiaries in mainland China and were $506.0 million.

16. Commitments and Contingencies

(a) Purchase Commitments

As of September 30, 2024, the Company's commitments related to purchase of property and equipment and the commercial manufacturing development activities that are contracted but not yet reflected in the unaudited condensed consolidated financial statements were $8.6 million 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

You should read the following discussion and analysis of our financial condition and results of operations together with our 2023 Annual Report and our unaudited condensed consolidated financial statements and the accompanying notes for the three and nine months ended September 30, 2024 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, immunology, neuroscience, and infectious disease. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. We currently have five commercial products – ZEJULA®, OPTUNE, QINLOCK®, NUZYRA®, and VYVGART® – that have received marketing approval and that we have commercially launched in one or more territories in Greater China. OPTUNE refers to Tumor Treating Fields devices marketed under various brand names, including OPTUNE GIO® for glioblastoma multiforme ("GBM"). We also have three products that have received marketing approval and are moving toward commercial launch for the approved indications – VYVGART Hytrulo (the subcutaneous formulation of efgartigimod), XACDURO® (SUL-DUR), and AUGTYRO® (repotrectinib) – as well as multiple 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. As discussed further below, we expect to continue to incur substantial costs related to our research and development and commercialization activities.

As we pursue our corporate strategic goals, 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 our product candidates 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 products or whether or when such products may become profitable.

Recent Developments

Commercial Products

Net product revenue was $101.8 million for the third quarter of 2024, an increase of 47% compared to the prior year period, primarily driven by increased sales for VYVGART since its launch in September 2023 and listing on China's National Reimbursement Drug List ("NRDL") in January 2024 for the treatment of adult patients with generalized myasthenia gravis ("gMG") who are anti-acetylcholine receptor ("AChR") antibody positive and increased sales for ZEJULA and NUZYRA. The NRDL listing for ZEJULA as a maintenance treatment was renewed in the first quarter of 2024, and ZEJULA continues to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China. Increased sales for NUZYRA were supported by the inclusion in the NRDL for its intravenous ("IV") formulation for the treatment of adult patients with community-acquired bacterial pneumonia ("CABP") and acute bacterial skin and skin structure infections ("ABSSSI") in the first quarter of 2023 and for its oral formulation for these indications in the first quarter of 2024.

Product Candidates

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

Oncology

- **Niraparib:** In July 2024, data from a Zai-supported study was published in *Cell* that provides new insights with potential to improve treatment of HRD-positive ovarian cancers, including through neoadjuvant monotherapy with niraparib and a combination of niraparib and ZL-1218, our investigational CCR8 antibody.

- **Early-Stage Global Pipeline:** In October 2024, we presented data from a Phase I study of ZL-1310, an investigational DLL3-antibody-drug conjugate, in second-line+ extensive stage small cell lung cancer. The data, from the ongoing Part Ia monotherapy dose-escalation portion of the study, included results from 25 patients across four dose cohorts (0.8 mg/kg, 1.6 mg/kg, 2.0 mg/kg, 2.4 mg/kg). Findings from this study suggest that ZL-1310 delivers anti-tumor activity across multiple dose levels with an overall response rate of 74%. It was well tolerated across all dose levels with the majority of treatment emergent adverse events being Grade 1 or 2.

Immunology, Neuroscience, and Infectious Disease

- **Efgartigimod:** In July 2024, the NMPA approved the Biologics License Application for efgartigimod alfa injection (subcutaneous injection), under the brand name VYVGART Hytrulo, as an add on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive. In November 2024, the NMPA approved the supplemental Biologics License Application for VYVGART Hytrulo for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy.

- **Xanomeline and Trospium Chloride (KarXT):**

    - **Schizophrenia:** In October 2024, we announced positive topline results from the Phase III bridging study evaluating the safety and efficacy of KarXT in schizophrenia in China. The study met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.2-point reduction in the Positive and Negative Syndrome Scale ("PANSS") total score compared to placebo at Week 5 (-16.9 KarXT vs. -7.7 placebo, p=0.0014). The study also met all secondary efficacy endpoints. We expect to submit a New Drug Application to the NMPA for KarXT for the treatment of patients with schizophrenia in early 2025.

      In September 2024, our partner BMS announced that the FDA had approved KarXT, under the brand name COBENFY™, for the treatment of adult patients with schizophrenia. In October 2024, BMS announced new topline results from the Phase III EMERGENT-4 and EMERGENT-5 open-label trials evaluating the long-term efficacy, safety, and tolerability of KarXT in adults with schizophrenia over 52 weeks of treatment. In the analysis, KarXT was associated with continued improvements in symptoms of schizophrenia across all efficacy measures. KarXT continued to see a lack of weight gain, and it was not associated with movement disorders or metabolic changes.

    - **ADP:** In July 2024, we joined the global Phase III ADEPT-2 study evaluating the safety and efficacy of KarXT for the treatment of psychosis associated with Alzheimer's disease ("ADP") in Greater China.

- **Early-Stage Global Pipeline:** In September 2024, Zai Lab presented pre-clinical data of ZL-1503, an IL-13/ IL-31 bi-specific antibody, at the European Academy of Dermatology and Venerology Congress 2024. The presentation discussed the potential of ZL-1503 as a novel treatment for moderate-to-severe atopic dermatitis, as well as other diseases involving the IL-13 and IL-31 pathways.

Corporate Updates

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

- **Business Development:** In July 2024, we entered into a strategic partnership and global license agreement with MabCare Therapeutics Co., Ltd. Through this collaboration, we expanded our global oncology pipeline with a next generation antibody-drug conjugate targeting ROR1, ZL-6301. ZL-6301 has the potential to be used in the treatment of solid tumors where ROR1 is commonly expressed and in hematological malignancies where ROR1 is a validated target. ZL-6301 has demonstrated an encouraging pre-clinical profile, and it is currently in the IND-enabling stage. We plan to focus on advancing its global development.

- **Organizational Update:** In September 2024, the Company appointed Prista Charuworn, M.D., as our Vice President, Immunology, Global R&D. Dr. Charuworn is an accomplished gastroenterologist with extensive experience and leadership in clinical development in hepatology and immunology. She reports to Rafael Amado, M.D., our President, Head of Global R&D, and is responsible for leading and advancing the R&D strategy for our immunology therapeutic area as well as our neuroscience and infectious disease assets. She previously held key leadership roles in clinical development at Amgen, AstraZeneca, and Gilead.

Factors Affecting Our Results of Operations

Our Commercial Products

We generate product revenue through the sale of our commercial products in Greater China, net of any related sales returns and rebates to distributors. Our cost of product revenue mainly consists of the costs of manufacturing ZEJULA and NUZYRA, costs of purchasing OPTUNE, QINLOCK, and VYVGART from our collaboration partners, any royalty fees incurred as a result of sales of our commercial products under our license and collaboration agreements, and amortization of any sales-based milestone fees incurred under our license and collaboration agreements. We expect our product revenue to increase in coming years as we continue to focus on increasing patient access to our existing commercial products, such as through NRDL listing or increased supplemental insurance coverage in the private-pay market, and as we launch additional commercial products, if and when we obtain required regulatory approvals. We expect our cost of product revenue to increase as the volume of products sold increases.

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. We are committed to advancing and expanding our pipeline of potential best-in-class and first-in-class products, such as through clinical and pre-clinical trials and business development activities. As a result, we expect to continue making significant investments in research and development, including internal discovery activities.

Elements of research and development expenditures primarily include:

- payroll and other related costs of personnel engaged in research and development activities;
- fees for exclusive development rights of products granted to the Company;
- costs related to pre-clinical testing of the Company's technologies and clinical trials, such as payments to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), investigators, and clinical trial sites that conduct our clinical studies; and
- costs to produce the product candidates, including raw materials and supplies, product testing, depreciation, and facility-related expenses.

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, and 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 expect these costs to continue to be significant to support sales of our commercial products and preparation to launch and subsequent sales of additional product candidates if and when approved.

Our Ability to Commercialize Our Product Candidates

We have multiple 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, and significant marketing efforts before we generate any revenue from product sales.

License and Collaboration Arrangements

Our results of operations have been, and will continue to be, affected by our license and collaboration agreements. In accordance with these agreements, we may be required to make upfront payments and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones for the relevant products as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. As of September 30, 2024, we may be required to pay development and regulatory milestone payments of up to an additional aggregate amount of $284.5 million for our current clinical programs and $613.0 million for other programs. Such development and regulatory milestone payments are contingent on the progress of our product candidates prior to commercialization, and we see these payments as favorable because they indicate that product candidates are advancing. As of September 30, 2024, we also may be required to pay sales-based milestone payments of up to an additional aggregate amount of $2,295.0 million as well as certain royalties at tiered percentage rates on annual net sales. Such sales-based milestone and royalty payments are contingent on the performance of our commercial products, and we see these payments as favorable because they signify that a product is achieving higher sales levels.

Results of Operations

In this section, we discuss our results of operations for the three and nine months ended September 30, 2024 compared to the same periods in 2023.

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	$	%	2024	2023	$	%
Revenues								
Product revenue, net	101,847	69,228	32,619	47 %	289,102	200,889	88,213	44 %
Collaboration revenue	418	—	418	NM	816	—	816	NM
Total revenues	102,265	69,228	33,037	48 %	289,918	200,889	89,029	44 %
Expenses								
Cost of product revenue	(36,569)	(25,479)	(11,090)	44 %	(105,336)	(70,579)	(34,757)	49 %
Cost of collaboration revenue	(348)	—	(348)	NM	(433)	—	(433)	NM
Research and development	(65,982)	(58,767)	(7,215)	12 %	(182,252)	(183,920)	1,668	(1)%
Selling, general, and administrative	(67,219)	(68,552)	1,333	(2)%	(216,123)	(198,982)	(17,141)	9 %
Gain on sale of intellectual property	—	—	—	NM	—	10,000	(10,000)	(100)%
Loss from operations	(67,853)	(83,570)	15,717	(19)%	(214,226)	(242,592)	28,366	(12)%
Interest income	9,029	9,172	(143)	(2)%	28,017	29,493	(1,476)	(5)%
Interest expense	(745)	—	(745)	NM	(1,350)	—	(1,350)	NM
Foreign currency gains (losses)	14,457	4,852	9,605	198 %	8,281	(26,315)	34,596	(131)%
Other income, net	3,441	394	3,047	773 %	3,859	223	3,636	1630 %
Loss before income tax	(41,671)	(69,152)	27,481	(40)%	(175,419)	(239,191)	63,772	(27)%
Income tax expense	—	—	—	— %	—	—	—	— %
Net loss	(41,671)	(69,152)	27,481	(40)%	(175,419)	(239,191)	63,772	(27)%

NM - Not Meaningful

Revenues

Product Revenue, Net

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	
	2024	2023	$	%	2024	2023	$	%
Product revenue - gross	107,678	74,018	33,660	45 %	307,401	220,240	87,161	40 %
Less: Rebates and sales returns	(5,831)	(4,790)	(1,041)	22 %	(18,299)	(19,351)	1,052	(5)%
Product revenue - net	101,847	69,228	32,619	47 %	289,102	200,889	88,213	44 %

Our product revenue is derived from the sales of our commercial products primarily in mainland China, net of sales returns and rebates to distributors with respect to the sales of these products.

Our net product revenue increased by $32.6 million and $88.2 million in the three and nine months ended September 30, 2024, respectively, primarily driven by increased sales for VYVGART since its launch in September 2023 and NRDL listing in January 2024 for the treatment of gMG. Net product revenue growth was also supported by increased sales volumes for ZEJULA and NUZYRA in the three and nine months ended September 30, 2024. ZEJULA sales remained strong as it continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China. The growth in NUZYRA sales was supported by the inclusion in the NRDL for its IV formulation for the treatment of CABP and ABSSSI in the first quarter of 2023 and for its oral formulation for these indications in the first quarter of 2024.

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	$	%	2024	2023	$	%
ZEJULA	48,227	41,593	6,634	16 %	138,727	127,230	11,497	9 %
OPTUNE	7,715	11,562	(3,847)	(33)%	32,779	38,596	(5,817)	(15)%
QINLOCK	8,643	5,702	2,941	52 %	21,774	14,535	7,239	50 %
NUZYRA	9,997	5,483	4,514	82 %	32,205	15,588	16,617	107 %
VYVGART	27,265	4,888	22,377	458 %	63,617	4,940	58,677	1188 %
Total product revenue, net	101,847	69,228	32,619	47 %	289,102	200,889	88,213	44 %

Cost of Product Revenue

Cost of product revenue increased by $11.1 million and $34.8 million in the three and nine months ended September 30, 2024, respectively, primarily due to increasing sales volumes and shifts in product sales mix.

Collaboration Revenue and Cost of Collaboration Revenue

In the three and nine months ended September 30, 2024, collaboration revenue related to promotional activities in mainland China was $0.4 million and $0.8 million, respectively, and cost of collaboration revenue was $0.3 million and $0.4 million, respectively. We had no such collaboration revenue in the prior year periods.

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	
	2024	2023	$	%	2024	2023	$	%
Personnel compensation and related costs	23,405	27,933	(4,528)	(16)%	82,622	85,967	(3,345)	(4)%
Licensing fees	22,634	9	22,625	NM	22,634	19,291	3,343	17 %
CROs/CMOs/Investigators expenses	13,004	23,136	(10,132)	(44)%	57,213	59,201	(1,988)	(3)%
Other costs	6,939	7,689	(750)	(10)%	19,783	19,461	322	2 %
Total	65,982	58,767	7,215	12 %	182,252	183,920	(1,668)	(1)%

NM - Not Meaningful

Research and development expenses increased by $7.2 million in the three months ended September 30, 2024, primarily due to:

- an increase of $22.6 million in licensing fees in connection with increased upfront and milestone payments for our license and collaboration agreements; partially offset by
- a decrease of $10.9 million in CROs/CMOs/Investigators expenses and other costs related to ongoing clinical trials; and
- a decrease of $4.5 million in personnel compensation and related costs primarily driven by the Company’s ongoing resource prioritization and efficiency efforts.

Research and development expenses decreased by $1.7 million in the nine months ended September 30, 2024, primarily due to:

- a decrease of $3.3 million in personnel compensation and related costs primarily driven by the Company's ongoing resource prioritization and efficiency efforts; and
- a decrease of $1.7 million in CROs/CMOs/Investigators expenses and other costs related to ongoing clinical trials; partially offset by
- an increase of $3.3 million in licensing fees in connection with increased upfront and milestone payments for our license and collaboration agreements.

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	
	2024	2023	$	%	2024	2023	$	%
Clinical programs	23,060	23,243	(183)	(1)%	63,196	68,232	(5,036)	(7)%
Pre-clinical programs	14,461	2,013	12,448	618 %	19,649	15,252	4,397	29 %
Unallocated research and development expenses	28,461	33,511	(5,050)	(15)%	99,407	100,436	(1,029)	(1)%
Total	65,982	58,767	7,215	12 %	182,252	183,920	(1,668)	(1)%

Research and development expenses attributable to pre-clinical programs increased by $12.4 million in the three months ended September 30, 2024 primarily due to an increase in licensing fees.

Research and development expenses attributable to clinical programs decreased by $5.0 million in the nine months ended September 30, 2024 primarily driven by a decrease of $7.3 million in CROs/CMOs/Investigators expenses related to the progress of existing studies, offset by an increase of $2.3 million in licensing fees. Research and development expenses attributable to pre-clinical programs increased by $4.4 million in the nine months ended September 30, 2024 primarily due to an increase of $3.4 million in CROs/CMOs/Investigators expenses related to newly initiated studies and progress of existing studies and an increase of $1.0 million in licensing fees.

Although we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any given time.

Selling, General, and Administrative Expenses

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	$	%	2024	2023	$	%
Personnel compensation and related costs	39,984	45,410	(5,426)	(12)%	134,157	129,198	4,959	4 %
Professional service fees	5,863	4,404	1,459	33 %	14,917	18,752	(3,835)	(20)%
Other costs	21,372	18,738	2,634	14 %	67,049	51,032	16,017	31 %
Total	67,219	68,552	(1,333)	(2)%	216,123	198,982	17,141	9 %

Selling, general, and administrative expenses decreased by $1.3 million the three months ended September 30, 2024, primarily due to:

- a decrease of $5.4 million in personnel compensation and related costs primarily driven by the Company's ongoing resource prioritization and efficiency efforts; partially offset by

- an increase of $2.6 million in other costs primarily related to higher general selling expenses for VYVGART which was launched in September 2023.

Selling, general, and administrative expenses increased by $17.1 million in the nine months ended September 30, 2024, primarily due to:

- an increase of $16.0 million in other costs primarily related to higher general selling expenses for VYVGART which was launched in September 2023; and
- an increase of $5.0 million in personnel compensation and related costs primarily driven by headcount growth related to support VYVGART; partially offset by
- a decrease of $3.8 million in professional service fees primarily related to decreased finance and human resources administrative expenses.

Gain on Sale of Intellectual Property

We had a gain on sale of intellectual property of $10.0 million in the second quarter of 2023 in connection with our sale of certain patent rights and related know-how to a third party. We had no such gain or loss in the current year periods.

Interest Income

Interest income decreased by $0.1 million and $1.5 million in the three and nine months ended September 30, 2024, respectively, primarily due to decreased cash and cash equivalents.

Interest Expense

Interest expense increased by $0.7 million and $1.4 million in the three and nine months ended September 30, 2024, respectively, primarily due to interest expense on short-term debt we entered into in 2024. We had no such interest expense in the prior year periods.

Foreign Currency Gains (Losses)

Foreign currency gain increased by $9.6 million in the three months ended September 30, 2024, primarily driven by increased remeasurement gain due to appreciation of the RMB against the U.S. dollar.

Foreign currency gain was $8.3 million in the nine months ended September 30, 2024, primarily driven by remeasurement gain due to appreciation of the RMB against the U.S. dollar, compared to foreign currency loss of $26.3 million in the nine months ended September 30, 2023, driven by remeasurement loss due to depreciation of the RMB against the U.S. dollar.

Other Income, Net

Other income, net increased by $3.0 million and $3.6 million in the three and nine months ended September 30, 2024, respectively, primarily due to an increase of $3.2 million and $6.4 million in government grants, respectively, and an increase of $0.1 million and $1.3 million in other miscellaneous gain primarily driven by an increase in sublease rental income, respectively, partially offset by an increase of $0.3 million and $4.1 million in loss of our equity investment in MacroGenics, Inc. as a result of changes in its stock price, respectively.

Income Tax Expense

Income tax expense was nil in both the three and nine months ended September 30, 2024 and 2023.

Net Loss

Net loss was $41.7 million in the three months ended September 30, 2024, or a loss per ordinary share attributable to common stockholders of $0.04 (or loss per ADS of $0.42), compared to a net loss of $69.2 million in the three months ended September 30, 2023, or a loss per ordinary share of $0.07 (or loss per ADS of $0.71).

Net loss was $175.4 million in the nine months ended September 30, 2024, or a loss per ordinary share attributable to common stockholders of $0.18 (or loss per ADS of $1.80), compared to a net loss of $239.2 million in the nine months ended September 30, 2023, or a loss per ordinary share of $0.25 (or loss per ADS of $2.48).

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our financial statements in conformity with U.S. GAAP, which requires management to make judgments, estimates, and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. Some of those judgments can be subjective and complex. Actual results could differ from our estimates.

Our most critical accounting policies and estimates, including those that require the most difficult, subjective, or complex judgments and are the most inherently uncertain, are described below.

Revenue Recognition

We sell our products to distributors (our customers), who ultimately sell the products to healthcare providers, primarily in mainland China. We recognize revenue when the performance obligations are satisfied upon the product's delivery to distributors.

We offer rebates to our distributors to compensate the distributors consistent with pharmaceutical industry practices. We are required to establish a provision for rebates in the same period the related product sales are recognized. The estimated amount of rebates, if any, is recorded as a reduction of revenue.

Significant judgments are required in making these estimates. In determining the appropriate accrual amount, we consider our contracted rates, sales volumes, levels of distributor inventories, and historical experiences and trends. If actual results vary from our estimates or our expectations change, we will 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

We have a significant amount of research and development expenses, including with respect to pre-clinical and clinical trials for our product candidates. Such costs are expensed as incurred when they have no alternative future uses.

We contract with third parties to 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 trial activities are accrued based on the Company's estimates of the actual services performed by the third parties, such as CROs and CMOs.

Significant judgments are required in estimating the actual services performed by the third parties for the respective period and the related expense accruals. In determining the appropriate accrual, we consider a variety of factors, including contractual requirements with respect to services to be provided, related rates, and our assessment of services performed during the period and progress with respect to any contractual milestones when we have not yet been invoiced or otherwise notified by third parties of actual costs. If the actual status and timing of services performed vary from our estimates, our reported expenses and earnings for the corresponding period may be affected.

Share-Based Compensation

We grant share-based awards, including share options and restricted shares, to eligible employees, non-employees, and directors. Such share-based awards are measured at grant date fair value.

Significant assumptions are required in determining the fair value of share options, which we estimate using the Black-Scholes option valuation model. These assumptions include: (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 term), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates. Since we do not have sufficient trading history since our September 2017 initial public offering on Nasdaq to cover the expected term of our share options, we estimate expected volatility based on movements in the share price of certain companies we consider comparable over the most recent equivalent historical period. Since we do not have sufficient historical information to develop reasonable expectations

about future exercise patterns and post-vesting employment termination behavior, the expected term 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, and risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the expected term. If actual results vary from our estimates or our expectations change, our reported expenses and earnings for the corresponding period may be affected.

Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial statement and income tax bases of assets and liabilities, which are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some or all of a deferred tax asset will not be realized. Significant judgements are required when evaluating tax positions in accordance with 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 the expiration of the applicable statute of limitations. The ultimate outcome for a particular tax position may not be determined with certainty prior to the conclusion of a tax audit and, in some cases, appeal or litigation process.

We consider positive and negative evidence when determining whether some or all of our deferred tax assets will not be realized. This assessment considers various factors, including 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. Our estimates 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. If actual benefits vary from our estimates or our expectations change, we will adjust the recognition and measurement estimates accordingly, which would affect reported expenses and earnings in the corresponding period.

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. In addition, 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 $159.1 million and $183.3 million in the nine months ended 2024 and 2023, respectively. For information on our research and development activities and related expenditures see the Research and Development Expenses, Selling, General, and Administrative Expenses, License and Collaboration Arrangements, and Results of Operations sections above. In addition, as of September 30, 2024, we had commitments for capital expenditures of $8.6 million mainly for the purpose of commercial manufacturing development, plant construction, and installation.

As of September 30, 2024, we had cash and cash equivalents, current restricted cash, and short-term investments of $716.1 million, which we expect will enable us to meet our cash requirements including the funding of operating expenses, capital expenditures, and debt obligations for at least the next 12 months.

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may, from time to time, identify opportunities to access capital through debt arrangements on favorable commercial terms. In the nine months ended September 30, 2024, we entered into four such debt arrangements with Chinese financial

institutions that allow certain of our subsidiaries to borrow up to approximately $198.9 million (or RMB1,421.7 million) to support our working capital needs in mainland China. As of September 30, 2024, we had short-term debt of approximately $113.0 million (or RMB791.8 million) pursuant to these debt arrangements. These debt arrangements will provide us with additional capital capacity that gives us enhanced flexibility to execute on our corporate strategic goals. For more information, see *Note 10*.

We may consider, or we may ultimately need, additional funding sources to bring to fruition our strategic objectives, 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
	2024	2023	$
Net cash used in operating activities	(159,100)	(183,261)	24,161
Net cash used in investing activities	(27,439)	(25,233)	(2,206)
Net cash provided by (used in) financing activities	112,077	(6,826)	118,903
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	402	(3,355)	3,757
Net decrease in cash, cash equivalents and restricted cash	(74,060)	(218,675)	144,615

Net Cash Used in Operating Activities

Net cash used in operating activities decreased by $24.2 million in the nine months ended September 30, 2024, primarily due to a decrease of $63.8 million in net loss, partially offset by a decrease of $23.0 million in adjustments to reconcile net loss to net cash used in operating activities and a decrease of $16.6 million in net changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities increased by $2.2 million in the nine months ended September 30, 2024, primarily due to a decrease of $86.1 million in proceeds from the maturity of short-term investments, an increase of $40.1 million from acquisition of intangible assets due to payments for milestone fees, a decrease of $10.0 million in proceeds from sale of intellectual property, and a decrease of $3.9 million in proceeds from land use right, partially offset by a decrease of $134.0 million in purchases of short-term investments, and a decrease of $3.9 million in purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $112.1 million in the nine months ended September 30, 2024, compared to net cash used in financing activities of $6.8 million in the nine months ended September 30, 2023. This shift was primarily due to $111.0 million in short-term debt proceeds net of related issuance costs as we entered into certain debt arrangements in the nine months ended September 30, 2024, and a decrease of $8.7 million in taxes paid related to settlement of equity awards, partially offset by a decrease of $0.6 million in proceeds from exercises of stock options and an increase of $0.3 million in repayment of short-term debt.

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 2023 Annual Report. The Company has not adopted any new accounting standards in the nine months ended September 30, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk including foreign exchange risk and credit 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 $40.1 million and $25.1 million, which were denominated in RMB, representing 7% and 3% of the cash and cash equivalents as of September 30, 2024 and December 31, 2023, 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 risk 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.

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 losses due to credit risk. As of September 30, 2024 and December 31, 2023, we had cash and cash equivalents of $616.1 million and $790.2 million, respectively, and short-term investments of nil and $16.3 million, respectively. As of September 30, 2024 and December 31, 2023, 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 revenue 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, 2024, our two largest customers accounted for approximately 22% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of September 30, 2024, 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.

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, 2024, 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, 2024 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 2023 Annual Report.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

During the period covered by this report, none of the Company's directors or executive officers 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).

On November 11, 2024, Professor Kai-Xian Chen informed the Company that he has decided to retire and plans to resign from the Board of Directors, effective December 31, 2024. There are no disagreements between Professor Chen and the Company relating to the Company's operations, policies, or practices that resulted in his decision to retire.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
10.1+	Unofficial English Translation of Maximum-Amount Irrevocable Letter of Guarantee, dated as of July 5, 2024, issued by Zai Lab Limited to China Merchants Bank Co., Ltd., Shanghai Branch (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed on July 9, 2024)
10.2+	Unofficial English Translation of Credit Agreement, dated as of July 5, 2024, by and between Zai Lab (Shanghai) Co., Ltd. and China Merchants Bank Co., Ltd., Shanghai Branch (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (File No. 001-38205) filed on July 9, 2024)
31.1	Certification of Chief Executive Officer Required by Exchange Act Rule 13a-14(a)
31.2	Certification of Chief Financial Officer Required by Exchange Act Rule 13a-14(a)
32.1	Certification of Chief Executive Officer Required by 18 U.S.C. Section 1350
32.2	Certification of Chief Financial Officer Required by 18 U.S.C. Section 1350
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

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

ZAI LAB LIMITED

Dated: November 12, 2024

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