
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38205

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

Cayman Islands
(State or other jurisdiction of
incorporation or organization)

98-1144595
(I.R.S. Employer
Identification No.)

4560 Jinke Road
Bldg. 1, Fourth Floor, Pudong
Shanghai
China

201210

314 Main Street
4th Floor, Suite 100
Cambridge, MA, USA
(Address of principal executive offices)

02142
(Zip Code)

+86 216163 2588
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 10 Ordinary Share, 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 x No o

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 x No o

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

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

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

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

As of August 3, 2022, 979,087,430 ordinary shares of the registrant, par value \$0.000006 per share, were outstanding, of which 743,559,650 ordinary shares were held in the form of American Depositary Shares.

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SPECIAL NOTES REGARDING THE COMPANY

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potentially,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the following:

- The effects of the COVID-19 pandemic, including any government actions and lockdown measures taken in response, particularly in mainland China where our operations are primarily located;
- Changes in United States and China trade policies and relations, as well as relations with other countries, and/or changes in regulations and/or sanctions that may adversely impact our business, operating results, ability to raise capital, and market price of our ordinary shares and/or our ADSs;
- Actions the Chinese government may take to intervene in or influence our operations, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs and ordinary shares, including potentially making those ADSs or ordinary shares worthless;
- Economic, political, and social conditions in mainland China, as well as governmental policies, that could affect the business environment and financial markets in mainland China and our ability to operate our business, liquidity, and access to capital;
- Uncertainties in the Chinese legal system that could materially and adversely affect us; including, particularly, China’s Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, and any other future laws and regulations, which may entail significant expenses for compliance and could materially affect our business;
- Any approval, filing, or procedural requirements by the CSRC or other Chinese regulatory authorities in connection with issuing securities to foreign investors under Chinese law, which could affect our ability to raise capital;
- Any violation or liability under the U.S. Foreign Corrupt Practices Act, or FCPA, or Chinese anti-corruption laws, which could have a material adverse effect on our business or reputation;
- Restrictions on currency exchange that could limit our ability to receive and use financing in foreign currencies effectively;
- Any limitation on the ability of our Chinese subsidiaries to make payments to us that could have a material and adverse effect on our ability to conduct our business or fund our cash and financing requirements;
- Chinese requirements on the ability of residents in mainland China to establish offshore special purpose companies by residents in mainland China, which may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries’ ability to increase their registered capital or distribute profits to us, or otherwise adversely affect us;
- Chinese regulations regarding acquisitions of mainland China based companies by foreign investors which could make it more difficult for us to pursue growth through acquisitions in mainland China;
- Any issues that our Chinese manufacturing facilities have with operating in conformity with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which could result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third-party contract manufacturers;
- Expiration of, or changes to, financial incentives or discretionary policies granted by local governments that could have an adverse effect on our results of operations;

- Any difficulty for overseas regulators to conduct investigations or collect evidence within mainland China that could adversely affect our business, compliance with regulatory requirements, ability to raise capital, and share price of our ordinary shares and ADSs;
- Any unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders if we were to be classified as a Chinese resident enterprise for Chinese income tax purposes;
- Any failure to comply with applicable Chinese, U.S., and Hong Kong regulations that could lead to government enforcement actions, subject us to fines and other legal or administrative sanctions, or otherwise adversely affect our business, financial condition, and results of operations;
- Any review by the Committee on Foreign Investment in the United States, or CFIUS, in our investments, which may delay or block a transaction from closing;
- Failure to renew our current leases or locate desirable alternatives for our leased properties which could materially and adversely affect our business;
- Our ability to generate revenues from our four approved products;
- Any inability of third parties on whom we rely to conduct our pre-clinical and clinical trials to successfully carry out their contractual duties or meet expected deadlines could adversely affect our ability to obtain regulatory approval for, or commercialize, our products or product candidates; and
- Any inability to obtain or maintain sufficient patent protection for our products and product candidates could adversely affect our business by allowing third parties to compete directly against us.

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, 2021 filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2022 (the “2021 Annual Report”), our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 10, 2022 (Q1 2022 Form 10-Q), and in this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Usage of Terms

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “Greater China” refer to mainland China, Hong Kong Special Administrative Region (“Hong Kong”), 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 are purchasing 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 Quarterly Report on Form 10-Q, Zai Anti Infectives (Hong Kong) Limited has non-substantial business operations.

Disclosures Relating to Our Chinese Operations

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

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

government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently, the value of our American Depositary Shares (“ADSs”) or ordinary shares may decline or become worthless.

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

There are significant legal and operational risks associated with conducting a substantial portion of our operations in mainland China, including that changes in the legal, political, and economic policies of the Chinese government, the relations between mainland China and the United States, or Chinese or U.S. regulations may materially and adversely affect our business, financial condition, results of operations, and the market price of our ADSs or ordinary shares. Any such changes could significantly limit or completely hinder our ability to offer or continue to offer our ADSs or ordinary shares to investors and could cause the value of our ADSs or ordinary shares to significantly decline or become worthless. For example, geopolitical events, such as the visit by the Speaker of the U.S. House of Representatives to Taiwan in August 2022, continue to cause heightened tensions between the United States and China, which could have potential adverse effects on our business, results of operations, ability to raise capital or raise capital on favorable terms, or the market price of our ordinary shares and/or ADSs. In addition, recent statements made and regulatory actions undertaken by the Chinese government, including the recent enactment of China’s Data Security Law, as well as our obligations to comply with China’s new Cybersecurity Review Measures (which became effective on February 15, 2022), regulations and guidelines relating to the multi-level protection scheme, Personal Information Protection Law, or PIPL, and any other future laws and regulations may require us to incur significant expenses and could materially affect our ability to conduct our business, accept foreign investments, or continue to be listed on a U.S. or foreign stock exchange.

For more information on these risks and other risks relating to our ADSs and ordinary shares, see “Item 1A. Risk Factors” in our 2021 Annual Report and in this Quarterly Report on Form 10-Q.

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

We are required to obtain certain permissions from Chinese authorities to operate in mainland China, issue securities to foreign investors, and transfer certain scientific data. The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to operate in mainland China may be undermined if our Chinese subsidiaries are not able to obtain or maintain approvals to operate in mainland China. The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could require additional expenditures and efforts on our part to comply with such regulations or interpretations.

As of the date of this Quarterly Report on Form 10-Q, we are not currently required to obtain approval or prior permission from the China Securities Regulatory Commission, or CSRC, or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, in January 2022, the CSRC released for public comment draft rules titled Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments), or the Draft Rules. If the Draft Rules are adopted in their current form, we would likely be required to submit filings to the CSRC in connection with the future issuance of our equity securities to foreign investors. As there are uncertainties with respect to the Chinese legal system and changes in laws, regulations, and policies, including how those laws, regulations, and policies will be interpreted or implemented, we could be subject to additional requirements, approvals, or permissions in the future. We are required to obtain certain approvals from Chinese authorities in order to operate our Chinese subsidiaries. We are also required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them.

If our Chinese subsidiaries do not receive or maintain approvals or inadvertently conclude that approvals needed for their business are not required, or if there are changes in applicable laws (including regulations) or interpretations of laws and our Chinese subsidiaries are required but unable to obtain approvals in the future, then such changes or need for approvals (if not obtained) could adversely affect the operations of our Chinese subsidiaries, including limiting or prohibiting the ability of our Chinese subsidiaries to operate, and the value of our ADSs or ordinary shares could significantly decline or become worthless.

For more information on these required permissions, see “Item 1A. Risk Factors” in our 2021 Annual Report.

To operate our general business activities currently conducted in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the State Administration for Market Regulation (“SAMR”).

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

Because our prior auditor, which filed an audit report with our last annual report, was located in mainland China, a jurisdiction where the U.S. Public Company Accounting Oversight Board (“PCAOB”) is unable to inspect or investigate completely because of restrictions imposed by Chinese authorities, SEC staff conclusively identified us under the Holding Foreign Companies Accountable Act (“HFCAA”) in March 2022. Because the Company subsequently engaged KPMG LLP (“KPMG”), a U.S. auditor that is subject to inspection and review by the PCAOB, to be our independent registered public accounting firm for the fiscal year ending December 31, 2022 and because the Company has a principal executive office, significant operations, and a majority of our Board members and executives in the United States, we believe we have mitigated our risk of delisting pursuant to the HFCAA. However, if we were to fail to meet the audit requirements of the HFCAA for three consecutive years (or two years, if bills passed by the U.S. Senate or House of Representatives are enacted), we may be prohibited from listing our securities on a national securities exchange or over-the-counter market in the United States and delisted from the Nasdaq Global Market (“Nasdaq”). The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

In recent years, the U.S. Congress and regulatory authorities have expressed concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in mainland China, and in December 2020, the United States enacted the HFCAA. The HFCAA requires the SEC to identify issuers that have filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor’s local jurisdiction (a “Commission-Identified Issuer”). The PCAOB has issued a Determination Report, which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by Chinese authorities in those jurisdictions, and in March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer because our prior auditor, which filed an audit report with our 2021 Annual Report, was located in mainland China.

Under the HFCAA, if the SEC conclusively identifies an issuer as a Commission-Identified Issuer for three consecutive years, the SEC is required to prohibit the trading of the issuer’s securities on a national securities exchange or through any other method that is within the jurisdiction of the SEC to regulate, including over-the-counter markets in the United States. If either the Accelerating Holding Foreign Companies Accountable Act passed by the U.S. Senate in June 2021 or the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (COMPETES) Act of 2022 passed by the U.S. House of Representatives in February 2022 are enacted, the number of non-inspection years would be reduced from three years to two years. It is unclear if or when either of these bills will be signed into law.

In May 2022 the Company engaged KPMG, an auditor located in the United States that is inspected by the PCAOB, as our independent registered public accounting firm for the fiscal year ending December 31, 2022. In addition, we have a principal executive office, significant operations, and a majority of our Board members and executive officers in the United States. As a result, we believe that we have mitigated our risk of delisting pursuant to the HFCAA. However, if we were to fail to meet the audit requirements of the HFCAA for three consecutive years (or two years if the number of non-inspection years is reduced by legislation), our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges, and this ultimately could result in our ADSs being delisted. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively. The market price of our ordinary shares and/or ADSs also could be adversely affected as a result of anticipated negative impacts of such legislative or executive actions upon, as well as negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States, regardless of whether such actions are implemented and regardless of our actual operating performance.

PART I – FINANCIAL INFORMATION

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial information and the accompanying notes included in our 2021 Annual Report.

Item 1. Financial Statements.

Zai Lab Limited

Unaudited condensed consolidated balance sheets

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

	Notes	June 30, 2022	December 31, 2021
		\$	\$
Assets			
Current assets:			
Cash and cash equivalents	3	680,820	964,100
Short-term investments		575,274	445,000
Accounts receivable (net of allowance for credit loss of \$8 and \$11 as of June 30, 2022 and December 31, 2021, respectively)		27,054	47,474
Notes receivable		10,968	7,335
Inventories, net	4	23,339	18,951
Value added tax recoverable - current		219	—
Prepayments and other current assets		17,973	18,021
Total current assets		1,335,647	1,500,881
Restricted cash, non-current		803	803
Long term investments (including the fair value measured investment of \$2,827 and \$15,383 as of June 30, 2022 and December 31, 2021, respectively)		2,827	15,605
Prepayments for equipment		4,542	989
Property and equipment, net	5	46,419	43,102
Operating lease right-of-use assets		18,596	14,189
Land use rights, net		7,286	7,811
Intangible assets, net		1,673	1,848
Long-term deposits		947	870
Value added tax recoverable		37	23,858
Total assets		1,418,777	1,609,956
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		108,443	126,163
Current operating lease liabilities		6,824	5,927
Other current liabilities	8	53,610	60,811
Total current liabilities		168,877	192,901
Deferred income		24,775	27,486
Non-current operating lease liabilities		12,960	9,613
Total liabilities		206,612	230,000
Commitments and contingencies (Note 14)			
Shareholders' equity			
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 960,520,140 and 955,363,980 shares issued as of June 30, 2022 and December 31, 2021, respectively; 958,494,830 and 954,981,050 shares outstanding as of June 30, 2022 and December 31, 2021, respectively)		6	6
Additional paid-in capital		2,857,202	2,825,948
Accumulated deficit		(1,638,401)	(1,418,074)
Accumulated other comprehensive income (loss)		4,487	(23,645)
Treasury Stock (at cost, 2,025,310 and 382,930 shares as of June 30, 2022 and December 31, 2021, respectively)		(11,129)	(4,279)
Total shareholders' equity		1,212,165	1,379,956
Total liabilities and shareholders' equity		1,418,777	1,609,956

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

Zai Lab Limited

Unaudited condensed consolidated statements of operations

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

	Notes	Three Months Ended June 30,		Six Months Ended June 30,	
		2022	2021	2022	2021
		\$	\$	\$	\$
Revenues:					
Product revenue, net	6	47,575	36,935	93,670	57,038
Collaboration revenue	6	601	—	1,230	—
Total revenues		48,176	36,935	94,900	57,038
Expenses:					
Cost of sales		(17,407)	(10,868)	(33,051)	(18,373)
Research and development		(66,084)	(142,224)	(119,938)	(346,076)
Selling, general, and administrative		(63,401)	(54,414)	(120,392)	(90,252)
Loss from operations		(98,716)	(170,571)	(178,481)	(397,663)
Interest income		1,175	244	1,363	458
Other income (expenses), net		(40,392)	7,406	(42,988)	1,179
Loss before income tax and share of loss from equity method investment		(137,933)	(162,921)	(220,106)	(396,026)
Income tax expense	7	—	—	—	—
Share of loss from equity method investment		—	(403)	(221)	(208)
Net loss		(137,933)	(163,324)	(220,327)	(396,234)
Net loss attributable to ordinary shareholders		(137,933)	(163,324)	(220,327)	(396,234)
Loss per share - basic and diluted	9	(0.14)	(0.18)	(0.23)	(0.44)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		957,684,820	930,455,310	956,603,250	907,231,320
Loss per American Depositary Shares (“ADS”) - basic and diluted		(1.44)	(1.76)	(2.30)	(4.37)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted		95,768,482	93,045,531	95,660,325	90,723,132

Note: All the numbers of ordinary shares and per share data in these unaudited condensed consolidated financial statements have been retrospectively adjusted as a result of the Share Subdivision and the ADS Ratio Change that became effective on March 30, 2022. The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company. Refer to Note 2(a) for a detailed discussion.

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

Zai Lab Limited**Unaudited condensed consolidated statements of comprehensive loss****(In thousands of U.S. dollars (“\$”) except for number of shares and per share data)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
	\$	\$	\$	\$
Net loss	(137,933)	(163,324)	(220,327)	(396,234)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	30,325	(5,241)	28,132	(2,341)
Comprehensive loss	(107,608)	(168,565)	(192,195)	(398,575)

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

Zai Lab Limited

Unaudited condensed consolidated statements of shareholders' equity

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

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

	Ordinary Shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Treasury Stock		Total
	Number of Shares	Amount				Shares	Amount	
		\$	\$	\$	\$		\$	\$
Balance at December 31, 2020	878,110,260	5	1,897,467	(713,603)	(14,524)	—	—	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	816,000	0	0	—	—	—	—	—
Exercise of shares options	583,640	0	702	—	—	—	—	702
Issuance of ordinary shares in connection with collaboration and license arrangement	5,681,820	0	62,250	—	—	—	—	62,250
Issuance cost adjustment for secondary listing	—	—	65	—	—	—	—	65
Share-based compensation	—	—	7,318	—	—	—	—	7,318
Net loss	—	—	—	(232,910)	—	—	—	(232,910)
Foreign currency translation	—	—	—	—	2,900	—	—	2,900
Balance at March 31, 2021	885,191,720	5	1,967,802	(946,513)	(11,624)	—	—	1,009,670
Issuance of ordinary shares upon vesting of restricted shares	321,000	0	0	—	—	—	—	—
Exercise of shares option	4,905,170	0	3,289	—	—	—	—	3,289
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of \$879	57,164,000	1	817,995	—	—	—	—	817,996
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(60,860)	(924)	(924)
Share-based compensation	—	—	10,232	—	—	—	—	10,232
Net loss	—	—	—	(163,324)	—	—	—	(163,324)
Foreign currency translation	—	—	—	—	(5,241)	—	—	(5,241)
Balance at June 30, 2021	947,581,890	6	2,799,318	(1,109,837)	(16,865)	(60,860)	(924)	1,671,698

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

Zai Lab Limited
Unaudited condensed consolidated statements of cash flows
(In thousands of U.S. dollars (“\$”) except for number of shares and per share data)

	Six Months Ended June 30,	
	2022	2021
	\$	\$
Operating activities		
Net loss	(220,327)	(396,234)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss	(3)	4
Inventory write-down	193	290
Depreciation and amortization expenses	3,874	2,975
Amortization of deferred income	(1,386)	(156)
Share-based compensation	26,634	17,550
Noncash research and development expenses	—	62,250
Share of loss from equity method investment	221	208
Loss from fair value changes of equity investment with readily determinable fair value	12,556	—
(Gain) loss on disposal of property and equipment	(11)	4
Noncash lease expenses	3,825	2,779
Changes in operating assets and liabilities:		
Accounts receivable	20,422	(12,868)
Notes receivable	(3,633)	—
Inventories	(4,582)	1,740
Prepayments and other current assets	48	(1,953)
Long-term deposits	(78)	(29)
Value added tax recoverable	23,602	(1,682)
Accounts payable	(17,718)	62,980
Other current liabilities	29,510	28,078
Operating lease liabilities	(3,849)	(2,214)
Deferred income	(1,325)	930
Net cash used in operating activities	<u>(132,027)</u>	<u>(235,348)</u>
Cash flows from investing activities:		
Purchases of short-term investments	(260,274)	—
Proceeds from maturity of short-term investment	130,000	743,902
Purchase of property and equipment	(13,488)	(5,647)
Purchase of intangible assets	(107)	(427)
Net cash (used in) provided by investing activities	<u>(143,869)</u>	<u>737,828</u>
Cash flows from financing activities:		
Proceeds from exercises of stock options	4,619	3,992
Proceeds from issuance of ordinary shares upon public offerings	—	818,874
Payment of public offering costs	—	(1,323)
Employee taxes paid related to net share settlement of equity awards	(6,859)	(594)
Net cash (used in) provided by financing activities	<u>(2,240)</u>	<u>820,949</u>
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(5,144)	1,028
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(283,280)</u>	<u>1,324,457</u>
Cash, cash equivalents and restricted cash - beginning of period	964,903	442,859
Cash, cash equivalents and restricted cash - end of period	<u>681,623</u>	<u>1,767,316</u>
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	1,661	1,720
Payables for intangible assets	270	58
Payables for public offering costs	—	555
Payables for treasury stock	17	—
Receivables for stock option exercise under equity incentive plans	12	—
Right-of-use asset acquired under operating leases	8,451	—
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	680,820	1,766,573
Restricted cash, non-current	803	743
Total cash and cash equivalents and restricted cash	<u>681,623</u>	<u>1,767,316</u>

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

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

1. Organization and principal activities

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

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 generally accepted accounting principles in the United States (“U.S. GAAP”), and applicable rules and regulations of the U.S. Securities and Exchange Commission (the “SEC”), regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this Quarterly Report on Form 10-Q 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, 2021 filed with the SEC on March 1, 2022 (the “2021 Annual Report”). The December 31, 2021 condensed consolidated balance sheet data included in this Quarterly Report on Form 10-Q were derived from the audited financial statements included in the 2021 Annual Report.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year ending December 31, 2022.

Effective as of March 30, 2022, the Company subdivided each of its issued and unissued ordinary shares into ten ordinary shares (the “Share Subdivision”). Following the Share Subdivision, the Company’s authorized share capital became \$30,000 divided into 5,000,000,000 shares with a par value of US\$0.000006 per share. The numbers of issued and unissued ordinary shares and per share data as disclosed elsewhere in these unaudited condensed consolidated financial statements and notes thereto are presented on a basis after taking into account the effects of the Share Subdivision and have been retrospectively adjusted, where applicable. In connection with the Share Subdivision, the conversion ratio of our ADSs to ordinary shares changed from one ADS to one ordinary share to a new ratio of one ADS representing ten ordinary shares (the “ADS Ratio Change”). The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

(b) Principles of consolidation

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

(c) Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, and assessing the impairment of long-lived assets, discount rate of operating lease liabilities, accrual of rebates, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets, and a lack of

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

marketability discount of the ordinary shares issued in connection with collaboration and license arrangements (Note 12). Management bases its estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

(d) Fair value measurements

As of June 30, 2022 and December 31, 2021, information about inputs into the fair value measurement of the Company's assets that are measured at a fair value on a recurring basis in periods subsequent to their initial recognition is as follows (in thousands):

Description	Fair Value as of June 30, 2022 US\$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US\$
Equity Investments with Readily Determinable Fair Value	2,827	2,827

Description	Fair Value as of December 31, 2021 US\$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US\$
Equity Investments with Readily Determinable Fair Value	15,383	15,383

The Company did not have assets or liabilities measured at fair value on a nonrecurring basis during the periods presented.

Financial instruments of the Company primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities. As of June 30, 2022 and December 31, 2021, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximated its fair value based on the nature of the assessment of the ability to recover these amounts.

(e) Recent accounting pronouncements

Adopted accounting standards

In November 2021, the FASB issued ASU2021-10, Government Assistance (Topic 832) — Disclosures by Business Entities about Government Assistance. The amendments in this ASU require disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model to increase transparency about (1) the types of transactions, (2) the accounting for the transactions, and (3) the effect of the transactions on an entity's financial statements. The amendments in this ASU are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this standard as of January 1, 2022. There was no material impact to the Company's financial position or results of operations upon the adoption.

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Notes to the unaudited condensed consolidated financial statements

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the 2021 Annual Report.

3. Cash and cash equivalents

The following table presents the Company's cash and cash equivalents as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	\$	\$
Cash at bank and in hand	381,225	663,472
Cash equivalents (i)	299,595	300,628
	<u>680,820</u>	<u>964,100</u>
Denominated in:		
US\$	611,478	932,888
RMB (ii)	63,359	23,791
Hong Kong dollar ("HK\$")	5,138	6,674
Australian dollar ("A\$")	614	475
Taiwan dollar ("TW\$")	231	272
	<u>680,820</u>	<u>964,100</u>

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

4. Inventories, net

The Company's net inventory balance of \$23.3 million and \$19.0 million as of June 30, 2022 and December 31, 2021, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline ("GSK"), for distribution in Hong Kong, from NovoCure Limited ("NovoCure") for distribution in Hong Kong and mainland China, and from Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong, mainland China and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China. The following table presents the Company's inventories, net, as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	\$	\$
Finished goods	4,342	5,632
Raw materials	18,476	13,231
Work in Progress	521	88
Inventories, net	<u>23,339</u>	<u>18,951</u>

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. During the three and six months ended June 30, 2022, the Company recorded write-downs of \$0.1 million and \$0.2 million, respectively, in cost of sales. During the three and six months ended June 30, 2021, the Company recorded write-downs of \$0.3 million and \$0.3 million, respectively, in cost of sales.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

5. Property and equipment, net

The following table presents the Company's components of property and equipment, net as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	\$	\$
Office equipment	822	836
Electronic equipment	6,370	5,036
Vehicle	210	220
Laboratory equipment	18,593	17,069
Manufacturing equipment	13,984	14,600
Leasehold improvements	10,230	10,432
Construction in progress	15,343	11,334
	65,552	59,527
Less: accumulated depreciation	(19,133)	(16,425)
Property and equipment, net	46,419	43,102

Depreciation expense was \$1.7 million and \$3.6 million for the three and six months ended June 30, 2022, respectively, and \$1.4 million and \$2.7 million for the three and six months ended June 30, 2021, respectively.

6. Revenue

Product revenue, net

The Company's product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The table below presents the Company's net product sales for the three and six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Product revenue - gross	54,339	41,380	107,649	87,935
Less: Rebate and sales return	(6,764)	(4,445)	(13,979)	(30,897)
Product revenue - net	47,575	36,935	93,670	57,038

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

The Company lowered the selling price of ZEJULA due to its inclusion in the National Reimbursement Drug List ("NRDL") in December 2020 and December 2021 for certain therapies. Accordingly, the Company accrued \$0.3 million and \$2.9 million for sales rebates as compensation to distributors in mainland China for those products previously sold at the price prior to the NRDL implementation during the three and six months ended June 30, 2022, respectively, and nil and \$22.0 million during the three and six months ended June 30, 2021, respectively.

In June 2022, the Company lowered the selling price for QINLOCK and NUZYRA. Accordingly, the Company accrued \$2.9 million of sales rebates as compensation to distributors in mainland China for those products previously sold at the price prior to the reduction during the three months ended June 30, 2022.

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Notes to the unaudited condensed consolidated financial statements

The following table presents net revenue by product for the three and six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
ZEJULA	34,052	23,366	63,649	35,972
Optune	11,592	9,535	24,389	16,665
QINLOCK	623	4,034	3,582	4,401
NUZYRA	1,308	—	2,050	—
Product revenue - net	<u>47,575</u>	<u>36,935</u>	<u>93,670</u>	<u>57,038</u>

Collaboration revenue

The Company's collaboration revenue for the three and six months ended June 30, 2022 of \$0.6 million and \$1.2 million, respectively, was from its collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

7. Income Tax

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

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of June 30, 2022 and December 31, 2021. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

8. Other current liabilities

The following table presents the Company's other current liabilities as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30,	December 31,
	2022	2021
	\$	\$
Payroll	18,976	25,685
Accrued rebate to distributors	11,249	15,001
Tax payables	9,896	8,817
Accrued professional service fee	6,450	4,319
Other (i)	5,827	4,421
Payables for purchase of property and equipment	1,212	2,568
Total	<u>53,610</u>	<u>60,811</u>

- (i) Other primarily consists of tax withholding related to share-based compensation and accrued travel and business entertainment expenses.

9. Loss per share

The following table presents the computation of the basic and diluted net loss per share for the three and six months ended June 30, 2022 and 2021 (in thousands, except share and per share data):

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Numerator:				
Net loss attributable to ordinary shareholders	(137,933)	(163,324)	(220,327)	(396,234)
Denominator:				
Weighted average number of ordinary shares - basic and diluted	957,684,820	930,455,310	956,603,250	907,231,320
Net loss per share - basic and diluted	<u>(0.14)</u>	<u>(0.18)</u>	<u>(0.23)</u>	<u>(0.44)</u>

As a result of the Company's net loss for the three and six months ended June 30, 2022 and 2021, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	June 30, 2022	June 30, 2021
Share options	91,546,280	86,294,400
Non-vested restricted shares	34,356,250	6,325,350

10. Related party transactions

The Company incurred research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd ("MEDx"), over which an immediate family member of our Chief Executive Officer and Chairperson of the Board held significant influence. The Company incurred development expenses with MEDx of \$0.2 million and \$0.1 million during the three and six months ended June 30, 2022, respectively, and \$0.3 million and \$0.2 million, during the three and six months ended June 30, 2021, respectively.

11. Share-based compensation

In March 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan"), pursuant to which the Board of Directors could grant options to purchase ordinary shares to management including officers, directors, employees, and individual advisors who rendered services to the Company. In August 2017, in connection with the completion of the initial public offering (the "IPO") of the Company, the Board of Directors approved the 2017 Equity Incentive Plan (the "2017 Plan"). All equity-based awards subsequent to the IPO would be granted under the 2017 Plan. The 2017 Plan provided for an automatic annual increase to the number of ordinary shares reserved under the 2017 Plan on each January 1st between January 1, 2018 and January 1, 2027 equal to the lesser of 4% of the number of ordinary shares outstanding as of the close of business on the immediately prior December 31st or such number as approved by the Board on or prior to such date each year. The aggregate number of shares reserved and available for issuance under the 2017 Plan as of April 1, 2022 was 75,562,170.

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

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Notes to the unaudited condensed consolidated financial statements

For the six months ended June 30, 2022, the Company granted 17,885,480 share options and 27,360,150 share of non-vested restricted shares to certain management and employees of the Company under the 2017 Plan. The share options were granted at an exercise price ranging from \$2.95 to \$6.29 per share with a weighted-average grant-date fair value of \$2.84 per share.

The options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date. The non-vested restricted shares granted vest over a five- or four-year period, with 20% or 25% of the awards vesting beginning on the anniversary date one year after the grant date. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the award holders' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

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

Stock-based compensation expense has been reported in the Company's condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	\$	\$	\$	\$
Selling, general and administrative	8,931	5,962	15,923	10,432
Research and development	5,294	4,270	10,712	7,118
Total	14,225	10,232	26,635	17,550

As of June 30, 2022, there was unrecognized share-based compensation expense of \$121.2 million related to unvested share options which the Company expects to recognize over a weighted-average period of 3.58 years.

As of June 30, 2022, there was unrecognized share-based compensation expense of \$153.8 million related to unvested restricted shares which the Company expects to recognize over a weighted-average period of 3.91 years.

12. Licenses and collaborative arrangements pursuant to which milestone payments were made

The following is a description of the Company's significant ongoing collaboration agreements under which the Company has made milestone payments for the three and six months ended June 30, 2022.

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

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

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Company and argenx. As the upfront payment to argenx, the Company issued 5,681,820 ordinary shares of the Company with a par value of \$0.000006 per share to argenx on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares were subject to certain restrictions. The fair value of the shares on the closing date was determined to be \$62.3 million in the aggregate. In addition, the Company made a non-creditable, non-refundable development cost-sharing payment of \$75.0 million to argenx during the first quarter of 2021. In January

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

2022, the Company made a milestone payment of \$25.0 million to argenx due to the first regulatory approval by the U.S. Food and Drug Administration (“FDA”) in December 2021 for VYVGART (efgartigimod alfa-fcab). The Company recorded these payments in research and development expenses. Argenx is also eligible to receive tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed product in the territory.

License and collaboration agreement with Paratek Bermuda Ltd. (“Paratek”)

In April 2017, the Company entered into a license and collaboration agreement with Paratek Bermuda Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., pursuant to which it obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, and commercialize products containing omadacycline (ZL-2401) as an active ingredient in Greater China in the field of all human therapeutic and preventative uses other than biodefense. Under certain circumstances, the exclusive sub-license to certain intellectual property Paratek licensed from Tufts University may be converted to a non-exclusive license if Paratek’s exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. The Company also obtained the right of first negotiation to be Paratek’s partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek retains the right to manufacture the licensed product in our licensed territory to support development and commercialization of the product outside of our licensed territory. The Company also granted to Paratek a non-exclusive license to certain of our intellectual property. Under the agreement, the Company agreed not to commercialize certain competing products in our licensed territory.

Under the terms of the agreement, the Company made an upfront payment of \$7.5 million to Paratek in 2017, a \$5.0 million milestone payment upon approval by the FDA of a New Drug Application (“NDA”) submission in 2018, and a \$3.0 million milestone payment upon submission of the first regulatory approval application for a licensed product in mainland China in 2020. In February 2022, The Company made another milestone payment of \$6.0 million upon regulatory approval of omadacycline for the treatment of adults with Acute Bacterial Skin and Skin Structure Infections and Community-Acquired Bacterial Pneumonia in mainland China in December 2021. The Company may be required to pay further commercial milestone payments of up to \$40.5 million to Paratek for the achievement of certain development and sales milestone events. In addition, the Company will pay Paratek tiered royalties on the net sales of licensed products, until the later of the abandonment, expiration, or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

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

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

Under the terms of the agreement, the Company paid an upfront payment of \$65.0 million to Mirati in 2021. During the three months ended June 30, 2022, the Company accrued a development milestone payment of \$5.0 million. Mirati is also eligible to receive up to \$268.0 million in-development, regulatory, and sales-based milestone payments. Mirati is also eligible to receive tiered royalties (from high-teens to low-twenties on a percentage basis) based on annual net sales of adagrasib in Greater China.

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

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

License agreement with Karuna Therapeutics, Inc. (“Karuna”)

In November 2021, the Company entered into a license agreement with Karuna for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including China, Hong Kong, Macau, and Taiwan.

Under the terms of the agreement, the Company paid an upfront payment of \$35.0 million to Karuna. During the three months ended June 30, 2022, the Company accrued a development milestone payment of \$5.0 million. Karuna is also eligible to receive up to \$147.0 million in development and regulatory, and sales-based milestone payments. Karuna is also eligible to receive tiered royalties based on annual net sales of commercialized products in Greater China.

The Company has the right to terminate this agreement by providing written notice of termination to Karuna.

Full details of the licenses and collaborative arrangements are included in the notes to the financial statements in our 2021 Annual Report. As noted above, the Company has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Company is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management’s evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Company up to approximately \$5,576.3 million in future contingent development and sales-based milestone payments. The development milestones, such as regulatory approval for the product candidates, may occur before the Company has commercialized the product or received any revenue from sales of such product candidate. These milestone payments are subject to uncertainties and contingencies and may not occur.

13. 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.

During the three and six months ended June 30, 2022 and 2021, no appropriation to statutory reserves was made 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 general reserve fund, the Company’s Chinese subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulation in mainland China may further restrict the Company’s Chinese subsidiaries from transferring funds to the Company in the form of dividends, loans, and advances. As of June 30, 2022 and December 31, 2021, amounts restricted are the paid-in capital of the Company’s Chinese subsidiaries, which both amounted to \$406.0 million.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

14. Commitments and Contingencies

(a) Purchase commitments

As of June 30, 2022, the Company's commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statement were \$19.5 million which is expected to be incurred within one year.

(b) Contingencies

The Company is a party to, or assignee of, license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 12).

15. Subsequent Event

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date financial statements were issued. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2021 Annual Report and our unaudited condensed consolidated financial statements and the accompanying notes included in “Item 1. Financial Statements” in this Quarterly Report on Form 10-Q.

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 discovering, developing, and commercializing innovative products that target medical conditions with unmet needs affecting patients in Greater China and worldwide, in the areas of oncology, autoimmune disorders, infectious diseases, and neurological disorders. As of August 3, 2022 we have four commercialized products that have received marketing approval in one or more territories in Greater China and twelve programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and to generate positive cash flow from operations over the next several years depends upon our ability to successfully market our four commercial products - ZEJULA, Optune, QINLOCK, and NUZYRA – and to successfully develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones as well as tiered royalties based on the net sales of the licensed products. These upfront and milestone payments are recorded in our research and development expense. During the six months ended June 30, 2022, we accrued \$10.4 million of research and development expense related to the achievement of certain developmental milestones by our partners during the second quarter of 2022. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

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

Recent Developments

Recent Product Developments

ZEJULA. In June 2022, we presented a new prespecified subgroup analysis from the Phase 3 PRIME study for ZEJULA in women in mainland China with ovarian cancer at the 2022 American Society of Clinical Oncology (“ASCO”) Annual Meeting. This analysis examined 384 newly diagnosed stage III or IV ovarian cancer patients enrolled in the PRIME study who experienced a complete response (“CR”) or partial response (“PR”) to first-line platinum-based chemotherapy. In the CR group, the median progression-free survival (“mPFS”) was 29.4 months for niraparib vs 8.3 months for placebo (HR=0.45; 95% CI, 0.32–0.61; P<0.001); in the PR group, the mPFS was 19.3 months for niraparib versus 8.3 months for placebo (HR=0.45; 95% CI, 0.23–0.86; P=0.014); and the safety profile of niraparib was consistent with previous clinical trials, with no new safety issues identified in this subgroup analysis.

Optune. In June 2022, the Company and Novocure announced the EF-31 phase 2 pilot study, evaluating the safety and efficacy of TTFIELDS together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric cancer, met its primary endpoint of objective response rate (“ORR”) with supportive signals across secondary endpoints. As of June 30, 2022, Optune has been listed in 50 regional customized commercial health insurance plans guided by provincial or municipal governments (or “supplemental insurance plans”).

QINLOCK. As of June 30, 2022, QINLOCK has been listed in 73 supplemental insurance plans since its commercial launch in mainland China in May 2021.

Adagrasib. At the ASCO Annual Meeting in June 2022, our partner Mirati Therapeutics, Inc. (“Mirati”) presented full results from the registration-enabling Phase 2 cohort of the KRYSTAL-1 study evaluating adagrasib in patients with previously treated non-small cell lung cancer (“NSCLC”) harboring a KRASG12C mutation; these results were concurrently published in the New England Journal of Medicine. This presentation included results from a retrospective subgroup analysis from the Phase 2 NSCLC cohort of the KRYSTAL-1 study evaluating adagrasib in patients with KRASG12C-mutated NSCLC and stable, previously treated central nervous system (“CNS”) metastases. The initial clinical results from the Phase 2 registration-enabling study (n=112) showed that the ORR was 43%, the disease control rate (“DCR”) was 80%, the median duration of response (“mDOR”) was 8.5 months (95% confidence interval (“CI”): 6.2 – 13.8), and the mPFS was 6.5 months (95% CI: 4.7 – 8.4). With a January 15, 2022 data cutoff, the median overall survival (“mOS”) was 12.6 months (95% CI: 9.2 – 19.2). With respect to CNS-specific activity in a subset analysis of stable, previously treated CNS metastases (n=33), results revealed an intracranial (“IC”) ORR of 33% (11/33). Mirati also reported updated findings from a pooled analysis from the KRYSTAL-1 study, including the registrational Phase 2 and Phase 1/1b NSCLC cohorts. The initial results of the pooled analysis of KRYSTAL-1 NSCLC cohorts (n=132) showed that the ORR was 44%, the DCR was 81%, the mDOR was 12.5 months, and the mPFS was 6.9 months. With a January 15, 2022 data cutoff, the mOS was 14.1 months.

In June 2022, Mirati also announced the results of a prospective analysis from the Phase 1b cohort of the KRYSTAL-1 study evaluating IC responses of adagrasib in patients with KRASG12C-mutated advanced NSCLC with active and untreated CNS metastases. The results of the CNS-specific activity in active and untreated CNS metastases (n=19) showed an IC ORR of 32% (6/19).

In addition, the Company treated the first patients in Greater China for the global Phase 3 KRYSTAL-10 study of the combination of adagrasib and cetuximab in patients with KRASG12C-mutated advanced colorectal cancer and for the global Phase 3 KRYSTAL-12 study of adagrasib in patients with KRASG12C-mutated advanced NSCLC in June 2022 and July 2022, respectively.

Bemarituzumab. Our partner Amgen initiated a Phase 1b/2 study (FORTITUDE-301), evaluating the safety and efficacy of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression. In addition, Amgen reported that the final analysis of the FIGHT study, a Phase 2 randomized, double-blind, controlled study evaluating bemarituzumab and modified FOLFOX6 (mFOLFOX6) in patients with previously untreated advanced gastric and gastroesophageal junction cancer was completed, with results continuing to demonstrate that bemarituzumab + mFOLFOX6 improves the clinical outcome of patients with FGFR2b expressing tumors with no new safety concerns and noting that a greater survival benefit was observed with increasing FGFR2b expression levels.

Repotrectinib. In May 2022, our partner Turning Point Therapeutics, Inc. (“Turning Point”) announced that the FDA granted an eighth regulatory designation, and third Breakthrough Therapy Designation (“BTD”), to repotrectinib, for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with one ROS1 TKI and who have not received prior platinum-based chemotherapy. In June 2022, the Center for Drug Evaluation (“CDE”) of the NMPA granted two Breakthrough Therapy Designations for investigational repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and one prior line of platinum-based chemotherapy and for those with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and no chemotherapy or immunotherapy. The Breakthrough Therapy Designations for repotrectinib were supported by the data from both global and Chinese TKI-pretreated ROS1-positive NSCLC patients enrolled in the Phase 1/2 TRIDENT-1 study.

CLN-081. In June 2022, our partner Cullinan Oncology presented updated data from the Phase 1/2a study in NSCLC patients with EGFR exon 20 insertion mutations at the 2022 ASCO Annual Meeting. Of the 39 patients in the 100 mg BID dose group: 16 (41%) had a confirmed PR; the estimated mDOR was greater than 21 months; mPFS was 12 months; and the safety profile of CLN-081 was amenable for long-term treatment.

BLU-945. In June 2022, we received a Clinical Trial Application (“CTA”) approval from the NMPA for the BLU-945 monotherapy cohort of the global Phase 1/2 SYMPHONY study in Greater China.

YVVGART. In June 2022, efgartigimod was introduced to the Hainan Bo’ao Lecheng International Medical Tourism Pilot Zone, and the first Chinese patient was treated with efgartigimod. In July 2022, the NMPA accepted the Biologics License Application for efgartigimod alfa injection for the treatment of adult patients with generalized myasthenia gravis (“gMG”) in mainland China.

KarXT. In August 2022, our partner Karuna announced positive topline results from its Phase 3 EMERGENT-2 trial evaluating the efficacy, safety, and tolerability of KarXT in adults with schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.6-point reduction in the Positive and Negative Syndrome Scale (“PANSS”) total score compared to placebo (-21.2 KarXT vs. -11.6 placebo, p<0.0001) at Week

5 (Cohen's d effect size of 0.61). KarXT also demonstrated an early and sustained statistically significant reduction of symptoms, as assessed by PANSS total score, starting at Week 2 and maintained such reduction through all timepoints in the trial. The trial also met its key secondary endpoints, demonstrating statistically significant reductions in positive and negative symptoms of schizophrenia, as measured by the PANSS positive, PANSS negative, and PANSS Marder negative subscales. KarXT was generally well tolerated, with a side effect profile substantially consistent with prior trials of KarXT in schizophrenia.

Simurosertib (CDC7 Inhibitor). Based on an extensive review of the data collected from previously completed studies, we have decided to terminate enrollment for the study of simurosertib.

ZL-1201 (CD47 Inhibitor). In July 2022, Zai Lab determined a recommended Phase 2 dose in the ongoing Phase 1 trial. Based on a review of the competitive landscape, Zai Lab has decided to deprioritize ZL-1201 for internal development but will pursue out-licensing opportunities.

Recent Business Developments

In May 2022, we completed our engagement of KPMG to be our independent registered public accounting firm for the fiscal year ending December 31, 2022. On May 25, 2022, the Company received the requisite approvals from the Hong Kong Stock Exchange and the Financial Reporting Council of Hong Kong, and on May 31, 2022, the Company and KPMG signed an engagement letter, and the appointment became effective on the same date.

We also completed our voluntary conversion from secondary listing status to primary listing on the Hong Kong Stock Exchange, effective June 27, 2022. The Company's ordinary shares and ADSs will continue to be traded on the Hong Kong Stock Exchange and Nasdaq, respectively, and remain mutually fungible. Because of our conversion to primary listing in Hong Kong, we are eligible for the Hong Kong Stock Exchange Stock Connect, a channel by which investors in mainland China can invest in stocks traded on the Hong Kong Stock Exchange. Our ordinary shares have been included in the Shenzhen-Hong Kong Stock Connect and Shanghai-Hong Kong Stock Connect programs since June 2022 and July 2022, respectively.

In July 2022, the Board further enhanced our corporate governance by appointing John Diekman to be lead independent director. The Board continues to believe that the Chief Executive Officer is best suited to serve as Chairperson of the Board at this time, including due to her extensive understanding of our business and industry and her ability to identify strategic opportunities, promote the effective execution of strategic initiatives, and facilitate the flow of information between management and the Board. While the roles of Chairperson of the Board and Chief Executive officer are combined, our lead independent director will, among other things, lead meetings of the Board when the Chairperson is not present, serve as liaison between the Chairperson and independent directors, have the authority to call meetings of the independent directors, and, if requested by major shareholders, be available for consultation and direct communication. As a result of Mr. Diekman's appointment as lead independent director, he stepped down as Chair of the Audit Committee, although he will continue to serve as a member of the Audit Committee. As a result, the Board appointed Scott Morrison to be Chair of the Audit Committee.

Josh Smiley, aged 53, joined the Company as Chief Operating Officer, effective August 1, 2022. Mr. Smiley brings over 26 years of experience working with the biopharmaceutical industry, including experience leading finance, corporate strategy, business development, venture capital, and global business services operations at Eli Lilly and Company. He will report directly to our Chief Executive Officer and will be a key member of our executive committee. He will oversee all aspects of our business, finance, and global operations.

Recent Legal and Regulatory Developments

Amendment to the Implementation Regulation of the PRC Drug Administration Law

On May 9, 2022, the NMPA published a comprehensive draft of Amendment to the Implementation Regulation of the PRC Drug Administration Law (the "Draft DAL Implementing Regulations") for public comments. The Draft Amendment introduced changes to the regulatory framework and aimed to codify certain regulatory initiatives implemented by the Chinese government since the promulgation of the current PRC Drug Administration Law in 2019 (the "DAL").

The Draft DAL Implementing Regulations propose to extend the reach of DAL to offshore development and manufacturing activities of pharmaceutical companies to the extent that the pharmaceutical companies would like to obtain marketing authorizations for their drug products in mainland China. All overseas R&D activities and production activities concerning a drug to be marketed in mainland China and/or already marketed in mainland China should be carried out in

compliance with the regulatory requirements specified in applicable Chinese laws, regulations, rules, standards, and specifications.

Patent linkage and regulatory data protection have been included in the Draft DAL Implementing Regulations. The Draft DAL Implementing Regulations propose to grant market exclusivity with a specified period to first-to-market generic drug contributing to the invalidity of relevant drug patent.

PRC Anti-Monopoly Law

On June 24, 2022, the Standing Committee of the National People's Congress published amendments to the PRC Anti-Monopoly Law (the "AML"), which came into effect on August 1, 2022. The amended AML formally implements China's latest anti-monopoly policies by, among other things, improving regulatory rules for anti-competitive agreements, expressly addressing monopoly issues in the platform economy, and substantially increasing the penalties for violating the law.

The improvements of the regulatory rules for anti-competitive agreements made by the amended AML mainly includes: (i) expressly stipulating that an agreement which fixes or limits resale prices, that is, a vertical anti-competitive agreement, is not prohibited if relevant business operators can prove that such agreement does not have the effect of eliminating or restricting competition; (ii) formally provides the "safe harbor" regime which stipulates that a vertical anti-competitive agreement is not prohibited, if the parties' market share in the relevant market is lower than the market share percentage set by the anti-monopoly enforcement agency and other conditions established by the anti-monopoly enforcement agency are met; (iii) codifies that business operators shall not organize other business operators to reach a monopoly agreement or provide substantial assistance for other business operators to reach a monopoly agreement.

The amended AML formally extends the anti-monopoly regulatory regime to the platform economy by outlining the general principal that business operators shall not engage in monopolistic activities, such as by taking advantage of data and algorithms, technology, capital advantage, and platform rules. The amended AML also specifically prohibits business operators from abusing market dominance, such as by using data and algorithms, technology, and platform rules.

Penalties for violation of the AML have been substantially increased by the amended AML. For example, according to the amended AML, if a company completes a concentration of business in violation of the AML that will have or is likely to have the effect of eliminating or restricting competition, in addition to other remedial measures, a fine of up to 10% of the last year's sales revenue may be imposed. If the concentration of business in violation of the AML completed by the company does not have the effect of eliminating or restricting competition, a fine of up to RMB 5 million may be imposed. In the case that the aforementioned violation has particularly serious circumstances, bad impact, or consequences, the fine imposed may be further increased to between two and five times the aforementioned fine amount.

Cross-Border Data Transfers

Measures on Security Assessment of Cross-Border Data Transfer

On July 7, 2022, the Cyberspace Administration of China ("CAC") issued Measures on Security Assessment of Cross-Border Data Transfer (the "Security Assessment Measures"), which sets out a security assessment framework for cross-border data transfers out of mainland China as well as ground rules for a security assessment filing for cross-border data transfers which was stipulated in the Cybersecurity Law ("CSL") and the Personal Information Protection Law ("PIPL").

A security assessment will be triggered if a cross-border data transfer out of mainland China falls into any of the following scenarios: (i) transfer of important data by data processors; (ii) transfer of personal information ("PI") by critical information infrastructure operators ("CIIOs") and data processors that process PI of more than one million individuals; (iii) transfer of PI by data processors that have transferred either PI of over 100,000 individuals or sensitive PI of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. According to statements by the CAC, a cross-border data transfer includes (i) an outbound transfer and overseas storage of data collected and generated during a data processor's operation in mainland China; and (ii) a remote access or use of data collected and generated by a data processor stored within mainland China by overseas institutions, organizations, and individuals.

Prior to applying for a security assessment with the CAC, data processors are required to carry out a self-risk assessment, which needs to be presented to the CAC along with an application filing and other required materials for a security assessment. During a security assessment, the CAC will primarily focus on risks to national security, public interests, and the legitimate rights and interests of individuals or organizations that such cross-border data transfer may

cause. A cross-border data transfer of relevant data will not be allowed if the CAC does not approve the security assessment filing. Once the CAC approves the security assessment filing, such approval will remain valid for two years and may be renewed. An application for security assessment needs to be re-submitted if there is a change in the cross-border data transfer that may affect the security of the exported data, such as changes in the purpose, method, scope, and type of the exported data and changes in the purpose and method of the processing of the exported data by overseas recipients.

The Security Assessment Measures have retroactive effect for cross-border data transfers out of mainland China of relevant data conducted prior to their effective date on September 1, 2022. If a Data Processor fails to complete its security assessment for any of its cross-border data transfers of relevant data out of mainland China prior to the effective date of the Security Assessment Measures, it needs to rectify the failure within six months after the effective date of the Security Assessment Measures.

Specification for Certification of Personal Information Cross-Border Processing Activities

On June 24, 2022, the National Information Security Standardization Technical Committee issued Guidance on Network Security Standardized Practice – Specification for Certification of Personal Information Cross-Border Processing Activities (the “Certification Specification”), which serves as an industry standard. The Certification Specification provides that PI processors may apply for a personal information protection certification (a “PIPC”) from certain qualified institutions, pursuant to which PI processors, provided that the requirements stipulated by PIPL are met, may rely on a PIPC to comply with cross-border PI transfer requirements when engaging in (i) intra-group cross-border transfers within a multinational company or subsidiaries or affiliated companies of an economic / business entity, or (ii) data processing activities conducted outside of mainland China involving PI of individuals located in mainland China subject to the extra-territorial jurisdiction of the PIPL.

The PI processors involved in PI cross-border activities shall carry out a prior self-risk assessment focusing on whether the cross-border PI transfer is legitimate, justifiable, and necessary and the security protection measures taken are effective and appropriate to the degree of risks. A self-risk assessment must include the following factors: (i) whether the cross-border PI transfer complies with applicable laws and administrative regulations; (ii) the impact on the rights and interests of PI subjects, particularly the impact of the legal environment and network security environment of the foreign countries and regions; and (iii) other matters necessary to safeguard the rights and interests in relation to PI.

The list of qualified institutions for PIPC has not been released to date, and therefore, it is not yet possible for companies to rely on a PIPC to legitimize their cross-border data transfers.

Standard Contract for Cross-Border PI Transfer and Accompanying Regulations

On June 30, 2022, the CAC issued for public consultation draft Regulations on the Standard Contract for Cross-Border Transfer of Personal Information, which introduced a draft standard contract for the cross-border transfer of PI outside of mainland China (the “PRC SC”). The PRC SC clarifies terms and conditions to be agreed on between PI processors as a data exporter and an overseas recipient as a data importer with respect to cross-border data transfers of PI out of mainland China. When finalized, the PRC SC can be used to comply with requirements under the PIPL for cross-border data transfers of PI out of mainland China that do not need to undergo a security assessment.

When finalized, a PI processor may enter into the PRC SC and provide it along with other required materials to relevant governmental authorities for filing to ensure the legality of a cross-border transfer out of mainland China if the following conditions are satisfied: the PI processor (i) is not a CIIO; (ii) processes PI of fewer than 1 million individuals; (iii) has provided PI of fewer than 100,000 individuals overseas in aggregate since January 1 of the preceding year; and (iv) has provided sensitive PI of fewer than 10,000 individuals overseas in aggregate since January 1 of the preceding year.

The PRC SC imposes certain obligations on the parties of such cross-border PI transfers to protect the interests of PI subjects, including, for example, (i) data exporters are required to use reasonable efforts to ensure data importers have adequate technical and organizational measures to ensure secure processing and have relevant capabilities to fulfill their obligations relating to the data transfer, and (ii) the parties of such cross-border transfer are required to ensure that the rights and interests of data subjects are well recognized in practice (and data subjects’ inquiries are promptly responded to), as such data subjects are considered third-party beneficiaries of the PRC SC.

Factors Affecting our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of product candidates has been advancing and expanding, with twelve late-stage clinical product candidates being investigated as of June 30, 2022.

We have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, multiple follow-on offerings, and a secondary listing on the Hong Kong Stock Exchange in September 2020. Through June 30, 2022, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, follow-on offerings, and secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$132.0 million and \$235.3 million for the six months ended June 30, 2022 and 2021, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our twelve late-stage clinical product candidates, research and develop our clinical- and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. We review such expenditures for prioritization and efficiency purposes. These expenditures include:

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

The Company is in the process of evaluating its development programs and is developing a series of recommendations for prioritizing these programs to concentrate our resources on programs that have the greatest potential to beneficially impact patients, strengthen our global competitiveness, and provide long-term sustainability.

Selling, General, and Administrative Expenses

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

Our Ability to Commercialize Our Product Candidates

As of June 30, 2022, twelve of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may never occur. Certain of our product candidates may require additional pre-clinical and/or clinical

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

Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones for the relevant products under these agreements as well as tiered royalties based on the net sales of the licensed products. These accruals for upfront and milestone payments are recorded in research and development expense and were \$10.4 million for the three and six months ended June 30, 2022 and \$98.0 million and \$269.2 million for the three and six months ended June 30, 2021, respectively.

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Revenues:								
Product revenue, net	47,575	36,935	10,640	29 %	93,670	57,038	36,632	64 %
Collaboration revenue	601	—	601	100 %	1,230	—	1,230	100 %
Total revenues	48,176	36,935	11,241	30 %	94,900	57,038	37,862	66 %
Expenses:								
Cost of sales	(17,407)	(10,868)	(6,539)	60 %	(33,051)	(18,373)	(14,678)	80 %
Research and development	(66,084)	(142,224)	76,140	(54)%	(119,938)	(346,076)	226,138	(65)%
Selling, general, and administrative	(63,401)	(54,414)	(8,987)	17 %	(120,392)	(90,252)	(30,140)	33 %
Loss from operations	(98,716)	(170,571)	71,855	(42)%	(178,481)	(397,663)	219,182	(55)%
Interest income	1,175	244	931	382 %	1,363	458	905	198 %
Other income (expenses), net	(40,392)	7,406	(47,798)	(645)%	(42,988)	1,179	(44,167)	(3746)%
Loss before income tax and share of loss from equity method investment	(137,933)	(162,921)	24,988	(15)%	(220,106)	(396,026)	175,920	(44)%
Income tax expense	—	—	—	— %	—	—	—	— %
Share of loss from equity method investment	—	(403)	403	(100)%	(221)	(208)	(13)	6 %
Net loss	(137,933)	(163,324)	25,391	(16)%	(220,327)	(396,234)	175,907	(44)%
Net loss attributable to ordinary shareholders	(137,933)	(163,324)	25,391	(16)%	(220,327)	(396,234)	175,907	(44)%

Revenues

Product Revenue, net

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. Sales rebates are offered to distributors in mainland China and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories.

The Company lowered the selling price of ZEJULA due to its inclusion in the NRDL in December 2020 and December 2021 for certain therapies. Accordingly, the Company accrued \$0.3 million and \$2.9 million of sales rebates as compensation to distributors for those products previously sold at the price prior to the NRDL implementation during the three and six months ended June 30, 2022, respectively, and nil and \$22.0 million during the three and six months ended June 30, 2021, respectively.

QINLOCK and NUZYRA are also scheduled to enter negotiations with the National Healthcare Security Administration regarding potential inclusion in the NRDL, and in June 2022, the Company lowered the selling price for

these products. Accordingly, the Company accrued \$2.7 million and \$0.2 million for sales rebates as compensation to distributors previously sold at the price prior to the reduction during the three months ended June 30, 2022 for QINLOCK and NUZYRA, respectively.

In addition, between March 2022 and May 2022, a number of government restrictions or lockdown measures were imposed in Greater China to help control the spread of COVID-19, including in some large cities like Shanghai. These government restrictions or lockdown measures caused some patients to have limited or no access to ZEJULA, Optune, QINLOCK, or NUZYRA, which had a negative impact on our revenue. Although the revenue impact was modest in the second quarter of 2022, we expect some residual revenue impacts in the second half of 2022. For more information on risks related to the COVID-19 pandemic, see “Item 1A. Risk Factors.”

The following table presents net revenue by product for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
ZEJULA	34,052	23,366	10,686	46 %	63,649	35,972	27,677	77 %
Optune	11,592	9,535	2,057	22 %	24,389	16,665	7,724	46 %
QINLOCK	623	4,034	(3,411)	(85)%	3,582	4,401	(819)	(19)%
NUZYRA	1,308	—	1,308	— %	2,050	—	2,050	— %
Total product revenue, net	47,575	36,935	10,640	29 %	93,670	57,038	36,632	64 %

Collaboration revenue

Collaboration revenue increased by \$0.6 million to \$0.6 million for the three months ended June 30, 2022 from nil for the three months ended June 30, 2021. Collaboration revenue increased by \$1.2 million for the six months ended June 30, 2022 from nil for the six months ended June 30, 2021. These increases were due to our collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

Cost of Sales

Cost of sales increased by \$6.5 million to \$17.4 million for the three months ended June 30, 2022 from \$10.9 million for the three months ended June 30, 2021, and increased by \$14.7 million to \$33.1 million for the six months ended June 30, 2022 from \$18.4 million for the six months ended June 30, 2021. These increases were primarily due to increasing sales volume, higher product costs, and higher royalties.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Research and development expenses:								
Personnel compensation and related costs	\$ 27,045	\$ 17,282	\$ 9,763	56 %	\$ 51,847	\$ 29,979	\$ 21,868	73 %
Licensing fees	10,436	97,966	(87,530)	(89)%	10,436	269,248	(258,812)	(96)%
CROs/CMOs/Investigators expenses	23,368	19,618	3,750	19 %	46,918	35,144	11,774	34 %
Other costs	5,235	7,358	(2,123)	(29)%	10,737	11,705	(968)	(8)%
Total	\$ 66,084	\$ 142,224	\$ (76,140)	(54)%	\$ 119,938	\$ 346,076	\$ (226,138)	(65)%

Research and development expenses decreased by \$76.1 million to \$66.1 million for the three months ended June 30, 2022 from \$142.2 million for the three months ended June 30, 2021 primarily due to:

- a decrease of \$87.5 million in licensing fees as we recorded no upfront payments for licensing agreements; partially offset by
- an increase of \$9.8 million in personnel compensation and related costs primarily attributable to increased employee compensation costs due to headcount growth and the grants of new share options and restricted shares and the continued vesting of those awards during the three months ended June 30, 2022;
- an increase of \$3.8 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials in the three months ended June 30, 2022.

Research and development expenses decreased by \$226.1 million to \$119.9 million for the six months ended June 30, 2022 from \$346.1 million for the six months ended June 30, 2021 primarily due to:

- a decrease of \$258.8 million in licensing fees as we recorded no upfront payments for licensing agreements; partially offset by
- an increase of \$21.9 million in personnel compensation and related costs primarily attributable to increased employee compensation costs due to headcount growth and the grants of new share options and restricted shares and the continued vesting of those awards during the six months ended June 30, 2022;
- an increase of \$11.8 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials in the six months ended June 30, 2022.

The following table summarizes our research and development expenses by program for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Research and development expenses:								
Clinical programs	\$ 33,292	\$ 93,433	\$ (60,141)	(64)%	\$ 56,144	\$ 279,689	\$ (223,545)	(80)%
Pre-clinical programs	1,657	28,545	(26,888)	(94)%	4,222	31,045	(26,823)	(86)%
Unallocated research and development expenses	30,835	20,246	10,589	52 %	59,272	35,342	23,930	68 %
Total	\$ 65,784	\$ 142,224	\$ (76,440)	(54)%	\$ 119,638	\$ 346,076	\$ (226,438)	(65)%

Research and development expenses attributable to clinical programs decreased by \$60.1 million to \$33.3 million for the three months ended June 30, 2022 from \$93.4 million during the three months ended June 30, 2021. Research and development expenses attributable to pre-clinical programs decreased by \$26.9 million to \$1.7 million for the three months ended June 30, 2022 from \$28.5 million during the three months ended June 30, 2021. Those decreases were driven by decreased license fees.

Research and development expenses attributable to clinical programs decreased by \$223.5 million to \$56.1 million for the six months ended June 30, 2022 from \$279.7 million during the six months ended June 30, 2021. Research and development expenses attributable to pre-clinical programs decreased by \$26.8 million to \$4.2 million for the six months ended June 30, 2022 from \$31.0 million during the six months ended June 30, 2021. Those decreases were driven by decreased license fees.

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

Selling, General, and Administrative Expenses

The following table summarizes our selling, general and administrative expenses by program for the three and six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Selling, General and Administrative Expenses:								
Personnel compensation and related costs	\$ 41,320	\$ 30,060	\$ 11,260	37 %	\$ 79,523	\$ 53,472	\$ 26,051	49 %
Professional service fees	8,072	4,806	3,266	68 %	15,505	8,389	7,116	85 %
Other costs	14,009	19,548	(5,539)	(28)%	25,364	28,391	(3,027)	(11)%
Total	\$ 63,401	\$ 54,414	\$ 8,987	17 %	\$ 120,392	\$ 90,252	\$ 30,140	33 %

Selling, general, and administrative expenses increased by \$9.0 million to \$63.4 million for the three months ended June 30, 2022 from \$54.4 million for the three months ended June 30, 2021 primarily due to:

- an increase of \$11.3 million in personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs due to headcount growth and grants of new share options and restricted shares and the continued vesting of those awards during the three months ended June 30, 2022;
- an increase of \$3.3 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; those increases were partially offset by
- a decrease of \$5.5 million in other costs mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan.

Selling, general, and administrative expenses increased by \$30.1 million to \$120.4 million for the six months ended June 30, 2022 from \$90.3 million for the six months ended June 30, 2021 primarily due to:

- an increase of \$26.1 million in personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs due to headcount growth and grants of new share options and restricted shares and the continued vesting of those awards during the six months ended June 30, 2022;
- an increase of \$7.1 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; those increases were partially offset by
- a decrease of \$3.0 million in other costs mainly related to selling, rental, and administrative expenses primarily for the commercial operation in mainland China, Hong Kong, and Taiwan.

Interest Income

Interest income was \$1.2 million and \$0.2 million for the three months ended June 30, 2022 and 2021, respectively, and \$1.4 million and \$0.5 million for the six months ended June 30, 2022 and 2021, respectively.

Other Income (Expenses), Net

Other income (expenses), net decreased by \$47.8 million to \$40.4 million of net expense for the three months ended June 30, 2022 from \$7.4 million of net income for the three months ended June 30, 2021 primarily as a result of an increase in foreign exchange loss of \$42.2 million and an equity investment loss in MacroGenics of \$5.6 million.

Other income (expenses), net decreased by \$44.2 million to \$43.0 million of net expense for the six months ended June 30, 2022 from \$1.2 million of net income for the six months ended June 30, 2021 primarily as a result of an increase in foreign exchange loss of \$33.5 million and an equity investment loss in MacroGenics of \$12.6 million, partially offset by an increase in governmental subsidies of \$1.5 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue recognition

Description

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

Judgments and Uncertainties

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories. We regularly review the information related to these estimates and adjust the amount accordingly.

Sensitivity of Estimate to Change

Actual amounts of rebates ultimately paid or billed may differ from our estimates. We will reassess estimates for rebates periodically. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Research and Development Expenses

Description

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

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

Judgments and Uncertainties

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

Sensitivity of Estimate to Change

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Share-Based Compensation

Description

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

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

Judgments and Uncertainties

We determine the fair value of the stock options granted to employees using the Black-Scholes option valuation model. Using this model, fair value is calculated based on assumptions with respect to (i) the expected volatility of our ADS price, (ii) the periods of time over which grantees are expected to hold their options prior to exercise (expected lives), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the expected lives of the options. Expected volatility has been estimated based on actual movements in the stock prices of certain comparable companies over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previous option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Sensitivity of Estimate to Change

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

Income Taxes

Description

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

Judgments and Uncertainties

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

Sensitivity of Estimate to Change

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of June 30, 2022 and 2021, we did not have any significant unrecognized uncertain tax positions.

B. Liquidity and Capital Resources

We have financed our activities primarily through private placements, our September 2017 initial public offering on Nasdaq, various follow-on offerings and our September 2020 secondary listing on the Hong Kong Stock Exchange of our ordinary shares and/or ADSs. Through June 30, 2022, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, secondary listing and subsequent follow-on offerings.

Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$132.0 million and \$235.3 million for the six months ended June 30, 2022 and 2021, respectively. We have commitments for capital expenditure of \$19.5 million as of June 30, 2022, mainly for the purpose of plant construction and installation. We currently are not aware of any events that are reasonably likely to cause a material change in the relationship between our costs and revenues.

As of June 30, 2022, we had cash, cash equivalents, restricted cash and short-term investment of \$1,256.9 million. Our expenditures are principally focused on research and development and are largely discretionary. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash and short-term investments will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. However, in order to bring to

fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		Change
	2022	2021	\$
Net cash used in operating activities	\$ (132,027)	\$ (235,348)	\$ 103,321
Net cash (used in) provided by investing activities	(143,869)	737,828	(881,697)
Net cash (used in) provided by financing activities	(2,240)	820,949	(823,189)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(5,144)	1,028	(6,172)
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (283,280)</u>	<u>\$ 1,324,457</u>	<u>\$ (1,607,737)</u>

Net cash used in operating activities

During the six months ended June 30, 2022, our operating activities used \$132.0 million of cash, which resulted principally from our net loss of \$220.3 million, adjusted for non-cash charges of \$45.9 million, and cash used in our operating assets and liabilities of \$42.4 million.

During the six months ended June 30, 2021, our operating activities used \$235.3 million of cash, which resulted principally from our net loss of \$396.2 million, adjusted for non-cash charges of \$85.9 million, and cash provided in our operating assets and liabilities of \$75.0 million.

Net cash (used in) provided by investing activities

Net cash used in investing activities was \$143.9 million for the six months ended June 30, 2022 compared to net cash provided by investing activities of \$737.8 million for the six months ended June 30, 2021. The shift from cash provided by to cash used in investing activities was primarily due to a decrease of \$613.9 million in proceeds from the maturity of short-term investments, an increase of \$260.3 million in purchases of short-term investments, and an increase of \$7.8 million from purchases of property and equipment during the six months ended June 30, 2022 compared to the six months ended June 30, 2021.

Net cash (used in) provided by financing activities

Net cash used by financing activities was \$2.2 million for the six months ended June 30, 2022 compared to net cash provided by financing activities of \$820.9 million for the six months ended June 30, 2021. The shift from cash provided by to cash used in financing activities was primarily because we had proceeds of \$818.9 million from our issuance of ordinary shares upon public offerings during the six months ended June 30, 2021 while there were no such transactions during the six months ended June 30, 2022.

C. Research and Development Activities and Expenditures, Including Patents and Licenses

Full details of our research and development activities and expenditures are provided in the “Research and Development Expenses” and “Results of Operations” sections above.

D. Trend Information

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

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, please see “Item 8. Financial Statements and Supplementary Data-Recent accounting pronouncements” in our 2021 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts of RMB 425.2 million and RMB151.7 million, which were denominated in RMB, representing 9% and 2% of the cash and cash equivalents, as of June 30, 2022 and December 31, 2021, respectively.

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

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

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

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

Credit Risk

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of \$680.8 million and \$964.1 million and short-term investments of \$575.3 million and \$445.0 million as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, 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 we continually monitor the credit worthiness of these financial institutions.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangement. We manage credit risk of accounts receivable through ongoing monitoring of the outstanding balances and limit the amount of credit extended based upon payment history and the debtor's current credit worthiness. Historically, we have collected the receivables from customers within the credit terms with no significant credit losses incurred. As of June 30, 2022, our two largest debtors accounted for approximately 35% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of June 30, 2022, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

Inflation

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

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

As of June 30, 2022, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2022, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

This Quarterly Report on Form 10-Q should be read in conjunction with our 2021 Annual Report and Q1 2022 Form 10-Q, which describe various material risks and uncertainties to which we are or may become subject. These risks and uncertainties could, directly or indirectly, adversely affect our business, results of operations, financial condition, liquidity, or cash flows and could cause our actual results to differ materially from our past results or the results contemplated by any forward-looking statements we make. We believe the risks described in this section of our Quarterly Report on Form 10-Q and our 2021 Annual Report and Q1 2022 Form 10-Q are the most significant we face; however, these are not the only risks we face. We face additional risks and uncertainties not currently known to us or that we currently believe are not material.

Material changes from the risk factors set forth in our 2021 Annual Report and our Q1 2022 Form 10-Q are set forth below:

We face risks related to the ongoing effects of the COVID-19 pandemic, including government actions and quarantine measures taken in response, particularly in mainland China where our operations are primarily located. For example, the COVID-19 pandemic has adversely affected our sales, marketing, development activities of our proprietary products and our licensor's products, and our clinical trial operations, and it may continue to adversely affect our business and results of operations, perhaps significantly, depending on the nature, severity, and duration of the continuing effects of the pandemic.

Since December 2019, global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment and have significantly increased economic volatility and uncertainty. Government authorities worldwide, including in mainland China, have implemented numerous measures to try to contain the spread of the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. Our business operations and those of our suppliers, CROs, CMOs, and other contractors and third parties on which we rely – as well as the Chinese economy more broadly – have been, and may continue to be, adversely affected by the effects of the pandemic and such government measures taken in response.

In the first quarter of 2022, there were a number of COVID-19 cases in Greater China, especially in some large cities like Shanghai, where one of our principal executive offices is located, that experienced a wave of intermittent government shutdowns in connection with COVID-19 control measures, especially between March and May 2022 when COVID-19 lockdown restrictions increased and most of the city was subject to a full lockdown. Other cities or regions in Greater China are, have been, or may be subject to similar government restrictions or lockdowns as a result of continued uncertainties associated with, and future developments of, the pandemic. The effects of the COVID-19 pandemic and restrictive quarantine measures imposed by the Chinese government in response have adversely affected our business, and may continue to adversely affect our business, perhaps significantly, for the remainder of this fiscal year and beyond, depending on the nature, severity, and duration of the ongoing effects of the COVID-19 pandemic, particularly in mainland China where our operations are primarily located.

Specifically, the COVID-19 pandemic has adversely impacted our operations, business, and financial results, including our manufacturing and supply chain, our and our partners' sales, marketing, and clinical trial operations, and our ability to advance our research and development activities and pursue the development of our pipeline products. For example, due to service interruptions to hospitals and treatment centers in mainland China arising in connection with the outbreak of COVID-19, some patients have experienced difficulties in accessing hospital care and, as a result, they have had limited or no access to ZEJULA, Optune, QINLOCK, or NUZYRA. The ability to conduct in-person interactions between medical representatives and physicians has also been adversely affected. Decreased access to our products has an adverse effect on our revenue. We expect the majority of the impact on our revenue from the lockdown measures in mainland China from March 2022 to May 2022 to be reflected in our results for the second half of 2022. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to outbreaks of COVID-19 where we are conducting such trials. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to outbreaks of COVID-19 in their respective territories. Although so far none of our

NDA submissions and acceptances, key clinical development milestones, or clinical trial application approvals have been materially delayed, there is no guarantee this will continue to be the case.

Additionally, the COVID-19 government restrictions and shutdown orders – those currently in effect and those which may be imposed in the future – may cause us or our commercial partners, licensors, and CMOs to experience delays or interruptions in the ability to manufacture and supply the products we are selling commercially in Greater China. For example, if COVID-related restrictions in Shanghai resume or are enhanced, such restrictions may impact the distribution and sale of our products within Greater China. These and other government restrictions may limit our and our distributors' ability to successfully sell our commercial products in Greater China, even if we implement contingency plans. Any or all of these adverse effects arising from COVID-19 may adversely affect our business and results of operations this year, and perhaps beyond, or cause the value of the Company to decline, potentially limiting our ability to obtain additional financing on terms acceptable to the Company.

COVID-19 government restrictions and lockdown orders, including those requiring our employees to work from their homes or preventing our executives from traveling to or from mainland China, Hong Kong, and the United States, could also negatively affect our business, such as through absenteeism or employee turnover, other operational disruptions, or increased risk of a cybersecurity incident.

There are no comparable recent events that provide guidance as to the effect the COVID-19 outbreak as a global pandemic may have and, as a result, the ultimate impact of the pandemic is highly uncertain and subject to change, and the actual effects on our business and results of operations will depend on many factors beyond our control.

We may be subject to additional approval, filing, and compliance obligations with Chinese authorities in connection with our engagement of KPMG, a U.S. auditor that is subject to PCAOB inspection.

Pursuant to the revised Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments), released by the CSRC for public comment on April 2, 2022 (the "Draft Archives Rules"), where Chinese domestic companies (including Chinese domestic companies that are listed outside of mainland China through a overseas holding entity, such as Zai Lab Limited) seek to disclose or provide, or disclose or provide through its overseas holding entity, documents and materials that have a sensitive impact (i.e., be detrimental to national security or the public interest if divulged) or contain state secrets or government department work secrets to relevant entities or individuals including securities companies, other securities service providers and overseas regulators in connection with a securities offering outside of mainland China, such company will be required to complete the relevant approval, filing, and other regulatory procedures. Disclosure of such materials to auditors based outside of mainland China is explicitly included within the scope of the Draft Archives Rules, and any such auditors are required under Chinese law to abide by the corresponding approval, filing, and compliance procedures in accordance with relevant Chinese regulations. The Draft Archives Rules are still in draft form, and we do not yet know the scope of materials that have a sensitive impact or contain state secrets or government department work secrets, but if the Draft Archives Rules become effective and our auditor's work papers are determined to be materials that have a sensitive impact or contain state secrets or government department work secrets, our engagement of KPMG may subject us and KPMG to additional approval, filing, and compliance obligations in mainland China under the Draft Archives Rules.

Our business and financial results, including our clinical development, our ability to raise capital or raise capital on favorable terms, and the market price of our ordinary shares and/or our ADSs, may be adversely affected by Russia's invasion of Ukraine, such as due to delays in certain partnered studies or as a result of imposed or threatened sanctions on China, Chinese banks, or companies with operations in China or heightened tensions between the United States and China as a result of actions taking in response to this war.

Although our business and financial results have not yet been adversely affected by the war in Ukraine, and we do not conduct business in Russia or Ukraine, our business and financial results, including our development programs, our ability to raise capital or raise capital on favorable terms, and the market price of our ordinary shares and/or our ADSs, may be adversely affected by Russia's invasion of Ukraine. For example, there have been, and may continue to be, delays in certain partnered studies. In addition, the United States and other nations have raised the possibility of sanctions on China, Chinese banks, and companies with operations in China that do business with Russia or its allies, including Belarus. Although we do not conduct business in Russia or Belarus, or with Russian or Belarusian counterparties, we may be impacted by sanctions imposed on third parties with which we do business, such as customers, suppliers, intermediaries, services providers, or banks. Our business and operations may also be adversely impacted by any actions taken by China in response to the war or any related sanctions or threatened sanctions. Such actual or threatened sanctions and other geopolitical factors arising in connection with the war, such as continued political or economic instability or increased economic or political tensions between the United States and China, could also adversely affect our business and financial

results, including our ability to raise capital or raise capital on favorable terms and the market price of our ordinary shares and/or our ADSs.

Our results of operations may be adversely impacted in the event of a sustained period of increased inflation.

The global economy, including the U.S. economy, has experienced rising inflation in recent quarters. Increased inflation may have an adverse impact on our expenses and, as a result, our results of operations. We source key materials from third parties located in the United States, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers, as well as through our licensors. For example, we rely on Turning Point to manufacture and supply TPX-0022 and repotrectinib (TPX-0005), argenx to manufacture and supply efgartigimod, MacroGenics to manufacture and supply margetuximab, tebotelimab and a pre-clinical multi-specific TRIDENT molecule, Entasis to manufacture and supply SUL-DUR, Novocure to manufacture and supply Optune, Deciphera to manufacture and supply QINLOCK, Incyte to manufacture and supply retifanlimab (INCMGA0012 (PD-1)), Regeneron to manufacture and supply odronextamab, Mirati to manufacture and supply adagrasib, and Blueprint to manufacture and supply BLU-701 and BLU-945. Sustained or rising inflation may result in increased cost to us in obtaining supplies of our products and product candidates, or key materials relating thereto. As a result, our results of operations may be adversely impacted.

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.

On June 22, 2022, the Company filed a Current Report on Form 8-K (the “Form 8-K”) to report on the voting results of the Company’s 2022 annual general meeting held on June 22, 2022 (the “Annual General Meeting”), including, among other matters, the results of the advisory non-binding votes of its shareholders regarding whether shareholder votes to approve the compensation of its named executive officers required by Section 14A(a)(1) of the Exchange Act and Rule 14a-21(a) promulgated thereunder (the “Say-on-Pay Vote”) should be held every one, two, or three years (the “Say-on-Frequency Proposal”). As previously reported on the Form 8-K, in an advisory vote held at the Annual General Meeting on the Say-on-Frequency Proposal, the Company’s shareholders expressed their preference for a Say-on-Pay Vote to be conducted every year. On July 13, 2022, the Company’s Board of Directors considered the outcome of this advisory vote and determined that future Say-on-Pay Votes will be conducted every year. The Company’s Board of Directors will re-evaluate this determination after the next Say-on-Frequency Proposal, which will be held no later than the 2028 annual general meeting of shareholders.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
3.1	Sixth Amended and Restated Memorandum and Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 22, 2022)
10.1 [#]	Zai Lab Limited 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 22, 2022)
10.2 [#]	Second Amended and Restated Employment Agreement between Harald Reinhart and Zai Lab (Hong Kong) Limited dated December 28, 2018 (incorporated by reference to Exhibit 10.22 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
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)

* Filed herewith
** Furnished herewith
Management contract or compensatory plan

SIGNATURES

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

Dated: August 9, 2022

ZAI LAB LIMITED

By: /s/ Billy Cho

Name: Billy Cho

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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

I, Samantha (Ying) Du, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Zai Lab Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2022

/s/ Samantha (Ying) Du

Samantha (Ying) Du

Chief Executive Officer

(Principal Executive Officer)

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

I, Billy Cho, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Zai Lab Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2022

/s/ Billy Cho

Billy Cho

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Zai Lab Limited (the “Company”), as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Samantha (Ying) Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2022

/s/ Samantha (Ying) Du

Samantha (Ying) Du

Chief Executive Officer

(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 of Zai Lab Limited (the “Company”), as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2022

/s/ Billy Cho

Billy Cho

Chief Financial Officer

(Principal Financial and Accounting Officer)