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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 March 31, 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** **(Address of principal executive offices)**	**201210** **(Zip Code)**

+86 21 6163 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 ☒ No ☐

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

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

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

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

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

As of May 5, 2022, 979,087,430 ordinary shares of the registrant, par value $0.000006 per share, were outstanding, of which 729,604,650 ordinary shares were held in the form of American Depositary Shares.

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Zai Lab Limited
Quarterly Report on Form 10-Q

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 those discussed 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”) 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 (“HKSAR” or “Hong Kong”), Macau Special Administrative Region (“Macau SAR” or “Macau”) and Taiwan, collectively; and references in this Quarterly Report on Form 10-Q 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; Zai Lab (US) LLC, domiciled in the United States. Additionally, 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. 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, issue securities to foreign investors and transfer certain scientific data.

We are required to obtain certain permissions from Chinese authorities to operate, 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, the CSRC recently 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 and in this Quarterly Report on Form 10-Q.

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, or 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 the majority of our operations are in mainland China and our auditor has been located in mainland China, a jurisdiction where the U.S. Public Company Accounting Oversight Board ("PCAOB") is currently unable to conduct inspections without the approval of Chinese authorities, there have been concerns regarding oversight of the audits of our financial statements filed with the SEC. In March 2022, SEC staff conclusively identified us under the Holding Foreign Companies Accountable Act ("HFCAA") as an issuer that uses an auditor that the PCAOB is unable to inspect or investigate completely. Although in April 2022 our Audit Committee approved the engagement of KPMG LLP ("KPMG"), a U.S. auditor that is subject to inspection by the PCAOB, as our independent public accounting firm for the fiscal year ending December 31, 2022, KPMG is in the process of concluding its standard client evaluation procedures, including obtaining approval from the Hong Kong Stock Exchange to audit the Company's consolidated financial statements submitted to the Hong Kong Stock Exchange. If for any reason we continue to fail to meet the audit requirements of the HFCAA for three consecutive years, the HFCAA requires the SEC to prohibit the trading of our securities on a national securities exchange, including Nasdaq, or on over-the-counter markets in the United States. In addition, the U.S. Senate and U.S. House of Representatives have each passed bills, which, if enacted, would decrease the number of non-inspection years from three consecutive years to two, thus reducing the time period before our securities may be prohibited from trading on a U.S. securities exchange or delisted from Nasdaq. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including our independent registered public accounting firm, are required to be registered with the PCAOB and to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and applicable professional standards. Because our current auditor is located in mainland China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of Chinese authorities, our auditor is not currently inspected by the PCAOB.

PCAOB inspections of auditors located outside of mainland China and Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the PCAOB's inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in mainland China and Hong Kong prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections, which could result in limitations or restrictions on our access to the U.S. capital markets.

Furthermore, in recent years, the U.S. Congress and regulatory authorities have continued to express concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. As part of this continued focus on access to audit and other information currently protected by national law, in particular under Chinese law, the United States enacted the HFCAA in December 2020. 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"). 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. Our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years, and this ultimately could result in our ADSs being delisted.

Furthermore, in June 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act ("AHFCAA"), which, if enacted, would amend the HFCAA and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years (as opposed to the three years under the HFCAA). In February 2022, the U.S. House of Representatives passed the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (COMPETES) Act of 2022 (the "America COMPETES Act"), which similarly would amend the HFCAA to shorten the number of non-inspection years from three years to two years. The America COMPETES Act, however, includes a broader range of legislation than the AHFCA Act in response to the U.S. Innovation and Competition Act passed by the U.S. Senate in 2021. The U.S. House of Representatives and the U.S. Senate will need to agree on amendments to these respective bills to allow the legislature to pass their amended bills before the President can sign the bill into law. It is unclear if or when either of these bills will be signed into law.

In September 2021, the PCAOB adopted PCAOB Rule 6100, Board Determinations Under the Holding Foreign Companies Accountable Act, which provides a framework for the PCAOB to use when determining whether the PCAOB is unable to inspect or investigate completely a registered public accounting firm located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction for the purposes of the HFCAA. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. In November 2021, the SEC announced that it had approved Rule 6100.

In December 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCAA for Commission-Identified Issuers, which became effective on January 10, 2022. In addition, the PCAOB issued a Determination Report, pursuant to PCAOB Rule 6100, 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. The SEC began to identify Commission-Identified Issuers for fiscal years beginning after December 18, 2020. A Commission-Identified Issuer will be required to comply with the submission and disclosure requirements in the annual report for each year in which it was so identified. If an issuer is identified as a Commission-Identified Issuer based on its annual report for the fiscal year ended December 31, 2021, the issuer will be required to comply with the submission or disclosure requirements in its annual report for the fiscal year ended December 31, 2022.

In March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer. In April 2022 the Audit Committee of our Board of Directors approved the engagement of 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 for the annual consolidated financial statements of the Company filed with the SEC and the Company's internal controls over financial reporting in accordance with the Exchange Act. KPMG will also be engaged to audit the consolidated financial statements of the Company for the year ending December 31, 2022 submitted to the Hong Kong Stock Exchange in accordance with the Rules Governing the Listing of Securities of the Hong Kong Stock Exchange, subject to the Company's receipt of the approval from the Hong Kong Stock Exchange and the FRC. Even though such approval is expected to be administrative in nature, if such approval is rejected by the Hong Kong Stock Exchange or the FRC, or, for some reason, we are not able to enter into an engagement agreement with KPMG, the Company would need to engage another auditor that is inspected by the PCAOB in order to comply with the audit requirements of the HFCAA. Additionally, even if KPMG is approved as our auditor by the Hong Kong Stock Exchange and the FRC, there remains a risk that the CSRC or another Chinese governmental agency could limit or prohibit our ability to use KPMG as our auditor. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

While we understand that there appears to be ongoing, constructive dialogue among the CSRC, the SEC and the PCAOB regarding permitting the inspection of PCAOB-registered accounting firms in China, there can be no assurance that the U.S. and Chinese governments ultimately reach an agreement on these matters, or that we will be able to comply with requirements imposed by U.S. regulators, Nasdaq, the CSRC, or other Chinese regulators. If for any reason we continue to be identified as a Commission-Identified Issuer that uses an auditor not subject to PCAOB inspection for three consecutive years or, if the AHFCAA or the America COMPETES Act is passed, two consecutive years, our ADSs may be delisted from Nasdaq as a result. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Further, we may be prohibited from listing our ADSs on another U.S. securities exchange. The market price of our ordinary shares and/or ADSs 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	As of March 31, 2022 $	As of December 31, 2021 $
Assets			
Current assets:			
Cash and cash equivalents	3	846,957	964,100
Short-term investments		465,274	445,000
Accounts receivable (net of allowance for credit loss of $10 and $11 as of March 31, 2022 and December 31, 2021, respectively)		33,394	47,474
Notes receivable		10,848	7,335
Inventories	4	20,288	18,951
Prepayments and other current assets		16,490	18,021
Total current assets		1,393,251	1,500,881
Restricted cash, non-current		803	803
Long term investments (including the fair value measured investment of $8,444 and $15,383 as of March 31, 2022 and December 31, 2021, respectively)		8,444	15,605
Prepayments for equipment		4,978	989
Property and equipment, net	5	45,227	43,102
Operating lease right-of-use assets		16,986	14,189
Land use rights, net		7,774	7,811
Intangible assets, net		1,745	1,848
Long-term deposits		941	870
Value added tax recoverable		20,766	23,858
Total assets		**1,500,915**	**1,609,956**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		98,161	126,163
Current operating lease liabilities		6,795	5,927
Other current liabilities	8	49,956	60,811
Total current liabilities		154,912	192,901
Deferred income		26,896	27,486
Non-current operating lease liabilities		11,099	9,613
Total liabilities		**192,907**	**230,000**
Commitments and contingencies (Note 14)			
Shareholders' equity			
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 957,035,440 and 955,363,980 shares issued as of March 31, 2022 and December 31, 2021, respectively; 956,637,360 and 954,981,050 shares outstanding as of March 31, 2022 and December 31, 2021, respectively)		6	6
Additional paid-in capital		2,838,655	2,825,948
Accumulated deficit		(1,500,468)	(1,418,074)
Accumulated other comprehensive loss		(25,838)	(23,645)
Treasury Stock (at cost, 398,080 and 382,930 shares as of March 31, 2022 and December 31, 2021, respectively)		(4,347)	(4,279)
Total shareholders' equity		**1,308,008**	**1,379,956**
Total liabilities and shareholders' equity		**1,500,915**	**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 March 31, 2022 $	2021 $
Revenues:			
Product revenue, net	6	46,095	20,103
Collaboration revenue	6	629	—
Total revenues		46,724	20,103
Expenses:			
Cost of sales		(15,643)	(7,505)
Research and development		(53,854)	(203,852)
Selling, general and administrative		(56,991)	(35,838)
Loss from operations		(79,764)	(227,092)
Interest income		188	214
Other expenses, net		(2,597)	(6,227)
Loss before income tax and share of income (loss) from equity method investment		(82,173)	(233,105)
Income tax expense	7	—	—
Share of income (loss) from equity method investment		(221)	195
Net loss		(82,394)	(232,910)
Net loss attributable to ordinary shareholders		(82,394)	(232,910)
Loss per share - basic and diluted	9	(0.09)	(0.26)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		955,499,030	883,749,280
Loss per American Depositary Shares ("ADS")- basic and diluted		(0.86)	(2.64)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted		95,549,903	88,374,928

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)

	Three Months Ended March 31,	
	2022	2021
	$	$
Net loss	(82,394)	(232,910)
Other comprehensive (loss) income, net of tax of nil:		
Foreign currency translation adjustments	(2,193)	2,900
Comprehensive loss	(84,587)	(230,010)

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, 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 (Note 12)	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
Balance at December 31, 2021	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956
Issuance of ordinary shares upon vesting of restricted shares	514,800	0	0	—	—	—	—	—
Exercise of shares options	1,156,660	0	297	—	—	—	—	297
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(15,150)	(68)	(68)
Share-based compensation	—	—	12,410	—	—	—	—	12,410
Net loss	—	—	—	(82,394)	—	—	—	(82,394)
Foreign currency translation	—	—	—	—	(2,193)	—	—	(2,193)
Balance at March 31, 2022	957,035,440	6	2,838,655	(1,500,468)	(25,838)	(398,080)	(4,347)	1,308,008

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

Zai Lab Limited

Unaudited condensed consolidated statements of cash flows

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

	Three Months Ended March 31,	
	2022	2021
	$	$
Operating activities		
Net loss	(82,394)	(232,910)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss	(1)	1
Inventory write-down	138	14
Depreciation and amortization expenses	2,013	1,448
Amortization of deferred income	(708)	(78)
Share-based compensation	12,410	7,318
Noncash research and development expenses	—	62,250
Share of (income) loss from equity method investment	221	(195)
Loss from fair value changes of equity investment with readily determinable fair value	6,939	—
(Gain) loss on disposal of property and equipment	(11)	4
Noncash lease expenses	2,017	1,322
Changes in operating assets and liabilities:		
Accounts receivable	14,080	(3,651)
Notes receivable	(3,513)	—
Inventories	(1,475)	502
Prepayments and other current assets	1,531	(3,386)
Long-term deposits	(71)	(47)
Value added tax recoverable	3,092	(1,558)
Accounts payable	(28,002)	(21,226)
Other current liabilities	(11,122)	21,707
Operating lease liabilities	(2,389)	(893)
Deferred income	118	(122)
Net cash used in operating activities	(87,127)	(169,500)
Cash flows from investing activities:		
Purchases of short-term investments	(120,274)	—
Proceeds from maturity of short-term investment	100,000	743,902
Disposal of property and equipment	25	—
Purchase of property and equipment	(9,743)	(1,683)
Purchase of intangible assets	(152)	(214)
Net cash (used in) provided by investing activities	(30,144)	742,005
Cash flows from financing activities:		
Proceeds from exercises of stock options	297	702
Payment of public offering costs	—	(973)
Employee taxes paid related to net share settlement of equity awards	(39)	—
Net cash provided by (used in) financing activities	258	(271)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(130)	(930)
Net (decrease) increase in cash, cash equivalents and restricted cash	(117,143)	571,304
Cash, cash equivalents and restricted cash - beginning of period	964,903	442,859
Cash, cash equivalents and restricted cash - end of period	847,760	1,014,163
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	668	439
Payables for intangible assets	73	26
Payables for public offering costs	—	26
Payables for treasury stock	55	—
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	846,957	1,013,420
Restricted cash, non-current	803	743
Total cash and cash equivalents and restricted cash	847,760	1,014,163

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

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

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, in particular, oncology, autoimmune disorders, infectious diseases, and neuroscience.

The Company's principal operations and geographic markets are in mainland China, Hong Kong, Macau and Taiwan (hereinafter collectively referred to as "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 unaudited condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, shareholders' equity and cash flows in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's unaudited condensed consolidated financial statements for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2021 condensed consolidated balance sheet data were derived from audited financial statements, but do not include all disclosures required by U.S. GAAP. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. Interim results are not necessarily indicative of full year results and the unaudited condensed consolidated financial statements may not be indicative of the Company's future performance.

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 divided into 5,000,000,000 shares with a par value of US$0.000006 each. 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 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, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, accrual of rebate, 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 marketability discount of the ordinary shares issued in connection with collaboration and license arrangements (Note 12). Management bases the 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.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

(d) Fair value measurements

As of March 31, 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:

Description	Fair Value as of March 31, 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	8,444	8,444

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 does 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 March 31, 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 approximates 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.

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

3. Cash and cash equivalents

	As of	
	March 31, 2022	December 31, 2021
	$	$
Cash at bank and in hand	547,259	663,472
Cash equivalents (i)	299,698	300,628
	846,957	964,100
Denominated in:		
US$	782,295	932,888
RMB (ii)	58,569	23,791
Hong Kong dollar ("HK$")	5,551	6,674
Australian dollar ("A$")	495	475
Taiwan dollar ("TW$")	47	272
	846,957	964,100

Notes:

(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

The Company's inventory balance of $20,288 and $18,951 as of March 31, 2022 and December 31, 2021, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline ("GSK"), for distribution in Hong Kong, and 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.

	As of	
	March 31, 2022	December 31, 2021
	$	$
Finished goods	4,733	5,632
Raw materials	15,555	13,231
Work in Progress	—	88
Inventories	20,288	18,951

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 months ended March 31, 2022 and 2021, the Company recorded write-downs of $138 and $43, in cost of revenues, respectively.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

5. Property and equipment, net

Property and equipment, net consist of the following:

	As of	
	March 31, 2022	December 31, 2021
	$	$
Office equipment	838	836
Electronic equipment	5,932	5,036
Vehicle	222	220
Laboratory equipment	18,130	17,069
Manufacturing equipment	14,721	14,600
Leasehold improvements	10,506	10,432
Construction in progress	13,126	11,334
	63,475	59,527
Less: accumulated depreciation	(18,248)	(16,425)
Property and equipment, net	45,227	43,102

Depreciation expenses for the three months ended March 31, 2022 and 2021 were $1,869 and $1,340, respectively.

6. Revenue

Product revenue, net

The Company's product revenue is primarily derived from the sale 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 months ended March 31, 2022 and 2021.

	Three Months Ended March 31,	
	2022	2021
	$	$
Product revenue - gross	53,310	46,555
Less: Rebate and sales return	(7,215)	(26,452)
Product revenue - net	46,095	20,103

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.

Due to the inclusion of ZEJULA in the National Reimbursement Drug List ("NRDL") in December 2020 and December 2021 for certain therapies, the Company accrued sales rebates of $2,587 and $22,009 compensation to distributors for those products previously sold at the price prior to the NRDL implementation, for the three months ended March 31, 2022 and 2021, respectively.

The following table disaggregates net revenue by product for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
	$	$
ZEJULA	29,597	12,606
Optune	12,797	7,130
QINLOCK	2,959	367
NUZYRA	742	—
Product revenue - net	46,095	20,103

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

Collaboration revenue

The Company's collaboration revenue for the three months ended March 31, 2022 amounted to $629 was from the 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 all the periods presented.

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

8. Other current liabilities

Other current liabilities consist of the following:

	As of	
	March 31, 2022	December 31, 2021
	$	$
Payroll	16,318	25,685
Accrued professional service fee	5,170	4,319
Payables for purchase of property and equipment	668	2,568
Accrued rebate to distributors	14,625	15,001
Tax payables	9,931	8,817
Others (note (i))	3,244	4,421
Total	49,956	60,811

Note:

(i) Others are mainly payables to employees for exercising the share-based compensations, payables related to travel and business entertainment expenses.

9. Loss per share

Basic and diluted net loss per share for each of the period presented are calculated as follows:

	Three Months Ended March 31,	
	2022	2021
	$	$
Numerator:		
Net loss attributable to ordinary shareholders	(82,394)	(232,910)
Denominator:		
Weighted average number of ordinary shares- basic and diluted	955,499,030	883,749,280
Net loss per share - basic and diluted	(0.09)	(0.26)

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars ("$") and Renminbi ("RMB") except for number of shares and per share data)

As a result of the Company's net loss for the three months ended March 31, 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.

	As of	
	March 31, 2022	March 31, 2021
Share options	80,514,330	86,932,740
Non-vested restricted shares	9,846,360	4,800,100

10. Related party transactions

The table below sets forth the major related party and the relationship with the Company as of March 31, 2021:

Company Name	Relationship with the Company
MEDx (Suzhou) Translational Medicine Co., Ltd.	Significant influence held by Samantha Du's (Director, Chairwoman and Chief Executive Officer of the Company) immediate family

For the three months ended March 31, 2022 and 2021, the Company incurred $74 and $103 research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd., respectively.

11. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Company to purchase an aggregate of no more than 41,409,450 ordinary shares of the Company ("Option Pool"). Subsequently, the Board of Directors approved the increase in the Option Pool to 73,697,670 ordinary shares.

In connection with the completion of the initial public offering (the "IPO"), the Board of Directors approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan. The 2017 Plan provides 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. Accordingly, on January 1, 2022, the number of shares reserved under the 2017 Plan increased by 38,563,500. The aggregate number of shares reserved and available for issuance under our 2017 Plan as of April 1, 2022 was 75,562,170.

On April 20, 2022, the Board of Directors of the Company approved the Zai Lab Limited 2022 Equity Incentive Plan (the "2022 Plan"), which is conditioned on and subject to the dual-primary listing of the Company on the Main Board of The Stock Exchange of Hong Kong Limited becoming effective and shareholder approval at the annual general meeting scheduled on June 22, 2022, and subject to the granting of the waiver on Note 1 to Rule 17.03(9) of the HK Listing Rules by The Stock Exchange of Hong Kong Limited. If approved and adopted, the aggregate number of shares that may be delivered in satisfaction of awards under the 2022 Plan is 97,908,743 ordinary shares. Once the 2022 Plan becomes effective, no new grants will be made under the 2015 Plan or the 2017 Plan.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

For the three months ended March 31, 2021, the Company granted 151,000 share options to certain management and employees of the Company at the exercise price $16.20 per share under the 2017 Plan. These 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.

For the three months ended March 31, 2022, the Company granted 984,310 share options to certain management and employees of the Company at the exercise price ranging from $5.26 to $6.29 per share under the 2017 Plan. These 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 weighted-average grant-date fair value of the options granted in the three months ended March 31, 2022 and 2021 were $3.24 and $9.88 per share, respectively. The Company recorded compensation expense related to the options of $7,207 and $5,549 for the three months ended March 31, 2022 and 2021, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2022	2021
	$	$
Selling, general and administrative	4,069	3,259
Research and development	3,138	2,290
Total	7,207	5,549

As of March 31, 2022, there was $89,126 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 2.79 years which is determined based on the number of unvested shares and unrecognized years.

Non-vested restricted shares

For the three months ended March 31, 2021, 192,600 ordinary shares were authorized for grant to the independent directors. 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 independent directors’ service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the three months ended March 31, 2021, 31,000 ordinary shares were authorized for grant to certain management. One-fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the three months ended March 31, 2022, 388,150 ordinary shares were authorized for grant to the independent directors. 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 independent directors’ service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

For the three months ended March 31, 2022, 477,150 ordinary shares were authorized for grant to certain management. One-fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

The Company measured the fair value of the non-vested restricted shares as of respective grant dates and recognized the amount as compensation expense over the deemed service period using a graded vesting attribution model on a straight-line basis.

As of March 31, 2022, there was $68,292 of total unrecognized compensation expense related to non-vested restricted shares. The Company recorded compensation expense related to the restricted shares of $5,203 and $1,769 for the three months ended March 31, 2022 and 2021, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2022	2021
	$	$
Selling, general and administrative	2,923	1,211
Research and development	2,280	558
Total	5,203	1,769

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 months ended March 31, 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 to argenx with par value $0.000006 per share 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 are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $62,250 in the aggregate. In addition, the Company made a non-creditable, non-refundable development cost-sharing payment of $75,000 to argenx during the first quarter in 2021 to argenx. During the three months ended March 31, 2022, the Company made a milestone payment of $25,000 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 expenses 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.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

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 same outside 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 $7,500 to Paratek in 2017, $5,000 upon approval by the FDA of a New Drug Application (“NDA”) submission in 2018, $3,000 upon submission of the first regulatory approval application for a licensed product in the People’s Republic of China in 2020. The Company made another milestone payment of $6,000 during the three months ended March 31, 2022 upon regulatory approval of omadacycline for the treatment of adults with Acute Bacterial Skin and Skin Structure Infections (“ABSSSI”) and Community-Acquired Bacterial Pneumonia (“CABP”) in the People’s Republic of China in December 2021.The Company may be required to pay further commercial milestone payments of up to an aggregate of $40,500 to Paratek for the achievement of certain development and sales milestone events. In addition, the Company will pay to 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.

Full details of the licenses and collaborative arrangements are included in the notes to financial statements in our Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 1, 2022. 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 an aggregate of approximately $5,589,801 in future contingent milestone payments dependent upon the achievement of contractually specified development milestones, such as regulatory approval for the product candidates, which may be 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.

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Notes to the unaudited condensed consolidated financial statements

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

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 months ended March 31, 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 March 31, 2022 and December 31, 2021, amounts restricted are the paid-in capital of the Company’s Chinese subsidiaries, which both amounted to $406,010.

14. Commitments and Contingencies

(a) Purchase commitments

As of March 31, 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 $22,294 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

From April 1, 2022 to May 5, 2022, the Company granted 16,614,930 shares of stock options to certain management and employees of the Company at exercise prices ranging from $3.96 to $4.55 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a 5-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date. During the same period, the Company also granted 5,173,390 restricted ordinary shares to certain management and employees of the Company. One-fifth of the restricted shares will vest on each yearly anniversary from the date of the agreement. Upon termination of the optionees’ service with the Company for any reason, any unvested shares will be immediately forfeited.

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

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, particularly in the areas of oncology, autoimmune disorders, infectious diseases and neuroscience. As of May 5, 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 our other product candidates that we are able to successfully commercialize. 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 payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our unaudited condensed consolidated financial statements. We did not accrue any such payments during the three months ended March 31, 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 Business Developments

On January 6, 2022, we announced that the NMPA accepted the new drug application (NDA) for margetuximab, an investigational, Fc-engineered monoclonal antibody that targets HER2. The margetuximab NDA is for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease, in combination with chemotherapy.

On January 12, 2022, we announced treatment of the first patient in Greater China in the PANOVA-3 trial, a Phase 3 pivotal trial of Tumor Treating Fields in patients with pancreatic cancer. PANOVA-3 is a global, open-label, randomized Phase III trial evaluating the efficacy of TTFields administered concomitantly with gemcitabine and nab-paclitaxel as front-line treatment for patients with unresectable, locally advanced pancreatic cancer. The primary endpoint is overall survival. Secondary endpoints include progression-free survival, local progression-free survival, objective response rate, one-year survival rate, quality of life, pain-free survival, resectability rate and toxicity.

In February 2022, the Center for Drug Evaluation (CDE) of the NMPA granted Breakthrough Therapy Designation for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI. The breakthrough therapy designation was supported by the initial data from both global and Chinese TKI-naïve ROS1-positive NSCLC patients enrolled in the Phase I/II TRIDENT-1 study. We plan to participate in all cohorts of the global TRIDENT-1 study.

In March 2022, we presented positive results from the Phase 3 PRIME study of ZEJULA (niraparib) as maintenance therapy at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting. ZEJULA demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) with a tolerable safety profile in Chinese patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status. In the PRIME study, median PFS was significantly longer for patients treated with niraparib compared to placebo: 24.8 months versus 8.3 months, hazard ratio (HR), 0.45; $p<0.001$.

We also continued to strengthen and expand our leadership team. On March 15, 2022, we announced the appointment of Joshua Smiley as our Chief Operating Officer, effective on 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. In addition, in April 2022, Jonathan Wang became our Chief Business Officer, taking on increased responsibilities after the departure of Tao Fu, our former Chief Strategy Officer.

In March 2022, our shareholders approved a Share Subdivision whereby the Company subdivided each of its issued and unissued ordinary shares into ten ordinary shares, effective March 30, 2022. The one-to-ten Share Subdivision increased the number of our ordinary shares in issue and reduced the nominal value and trading price of each ordinary share. Our Board of Directors believes that the Share Subdivision will increase the trading liquidity of the ordinary shares, lower the investment barrier, and attract more investors to trade in the ordinary shares. In connection with the Share Subdivision, the Company also effected the ADS Ratio Change, whereby 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 Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

In March 2022, SEC staff conclusively identified us under the HFCAA as a “Commission-Identified Issuer” because Deloitte Touche Tohmatsu Certified Public Accountants LLP and Deloitte Touche Tohmatsu (together, “Deloitte”), our auditor for the financial statements included in our 2021 Annual Report, is located in a foreign jurisdiction and the PCAOB has determined that it is unable to inspect or investigate the auditor completely because of a restriction imposed by a non-U.S. authority in the auditor’s local jurisdiction. In April 2022, the Audit Committee of our Board of Directors approved the engagement of KPMG, an auditor located in the United States that is subject to PCAOB inspection, as our independent registered public accounting firm for the fiscal year ending December 31, 2022. KPMG will be engaged to audit our annual consolidated financial statements filed with the SEC and our internal controls over financial reporting in accordance with the Exchange Act. KPMG also will be engaged to audit our consolidated financial statements submitted to The Hong Kong Stock Exchange in accordance with the Rules Governing the Listing of Securities of the Hong Kong Stock Exchange, subject to our receipt of the requisite approvals from the Hong Kong Stock Exchange and the Financial Reporting Council of Hong Kong (“FRC”), which are expected to be administrative in nature. KPMG is in the process of concluding its standard client evaluation procedures, including obtaining approval from the Hong Kong Stock Exchange to be appointed as our auditor. Upon completion of these standard procedures, KPMG will be in a position to execute an engagement letter and formally commence the engagement. For more information on the HFCAA and risks related to audits of companies with significant operations in China, see “Item 1A. Risk Factors” in this Quarterly Report on Form 10-Q.

In April 2022, we presented new data from its internal oncology discovery portfolio at the American Association for Cancer Research (AACR) Annual Meeting 2022. Key early-stage discovery programs were featured in these presentations, including first preview of preclinical data on ZL-1218 (a novel anti-CCR8 antibody for solid tumors) in oral presentation, as well as poster presentations featured ZL-1201 (a CD47-targeting antibody for advanced hematologic malignancies and solid tumors), ZL-1211 (a Claudin18.2-specific antibody for gastric and pancreatic cancer) and ZL-2201 (a highly selective small-molecule DNA-PK inhibitor for anti-cancer therapy).

In April 2022, we announced topline data for repotrectinib within the China region from the previously disclosed Phase 1/2 TRIDENT-1 study dataset. We plan to discuss topline TKI-naïve data with Chinese health authority in the fourth quarter of 2022.

- In TKI-naïve patients (EXP-1), in 71 total patients, there was a confirmed objective response rate (cORR) of 79% across the global trial. Ten of 11 patients responded within China for a cORR of 91% (95% CI: 59,100) and DOR ranged from 3.6+ to 7.5+ months with a median duration of follow-up of 3.7 months.

- In patients previously treated with 1 TKI and platinum-based chemotherapy (EXP-2), in 26 total patients, there was a cORR of 42% across the global trial. Two of 3 patients responded within China for a cORR of 67% (95% CI:9,99) and DOR ranged from 3.6+ to 3.7+ months with a median duration of follow-up of 3.7 months.
- In patients previously treated with two TKIs without prior chemotherapy (EXP-3), in 18 total patients, there was a cORR of 28% across the global trial. Two of 4 patients responded within China for a cORR of 50% (95% CI: 7,93) and DOR ranged from 1.9+ to 3.4+ months with a median duration of follow-up of 2.6 months.
- In patients previously treated with 1 TKI without prior chemotherapy (EXP-4), in 56 total patients, there was a cORR of 36% across the global trial. Four of 11 patients responded within China for a cORR of 36% (95% CI: 11,69) and DOR ranged from 2.0+ to 3.7+ months with a median duration of follow-up of 3.1 months.

In April 2022, the Board of Directors of the Company authorized the Company's senior management to proceed with the relevant preparatory work and undertake necessary steps to pursue a voluntary conversion to dual-primary listing on the Hong Kong Stock Exchange. Following the voluntary conversion, the Company's ordinary shares and American Depositary Shares will continue to be traded on the Hong Kong Stock Exchange and the Nasdaq Global Market, respectively, and remain mutually fungible. Becoming a dual-primary listed company will enable the Company to be 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.

Recent Legal and Regulatory Developments

Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments)

On April 2, 2022, the CSRC published the revised Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Draft Archives Rules").

The Draft Archives Rules require that, in relation to the overseas securities offering and listing activities of Chinese domestic enterprises, such domestic enterprises, as well as securities companies and securities service institutions providing relevant securities services, are required to strictly comply with the relevant requirements on confidentiality and archives management, establish a sound confidentiality and archives system and take necessary measures to implement their confidentiality and archives management responsibilities.

According to the Draft Archives Rules, if during the course of an overseas offering and listing (whether listed directly or indirectly), if a Chinese domestic company needs to publicly disclose or provide, or publicly disclose or provide through its overseas listed entity, to relevant entities or individuals including securities companies, other securities service providers and overseas regulators, any documents and materials that contain relevant state secrets, government department work secrets or that have a sensitive impact (i.e., that are detrimental to national security or the public interest if divulged), the Chinese domestic company should complete the relevant approval/filing and other regulatory procedures stipulated by applicable national regulations.

In addition, the Draft Archives Rules explicitly include within the scope of its supervision overseas accounting firms that engage in auditing business related to overseas securities offering and listings of Chinese domestic enterprises. Overseas accounting firms that engage in auditing business related to overseas securities offering and listings of Chinese domestic enterprises are required to abide by corresponding procedures in accordance with relevant Chinese national regulations.

Amended China Civil Procedure Law

The Civil Procedure Law of the People's Republic of China, or the China Civil Procedure Law, which was adopted on April 9, 1991 and amended on October 28, 2007, August 31, 2012, June 27, 2017, and December 24, 2021, prescribes the conditions for instituting a civil action, the jurisdiction of the people's courts, the procedures for conducting a civil action and the procedures for enforcement of a civil judgment or ruling. The most recent amendments to the China Civil Procedure Law on December 24, 2021, which came into effect on January 1, 2022, include the following improvements to the civil procedure under China's current judicial system: (i) with the consent of the parties, civil litigation activities may be conducted online through the information network platform and such online litigation activities have the same legal effect as offline litigation activities; (ii) in addition to civil cases followed by summary procedure, civil cases followed by ordinary procedure and civil cases of second instance which meet certain criteria may also be tried by a single judge; (iii) the scope of the litigation documents which are allowed to be served by electronic means expands to include judgments, awards and mediation statements; (iv) the period of service which is effected by public announcement in cases where the location of the recipient of the service is unknown or the service cannot be served by other means specified in the China Civil Procedure Law is shortened from 60 days to 30 days; (v) with respect to small claims procedure, the amount of the subject matter applicable to small claims procedure is raised, the trial time for small claims procedure is limited to three months and certain types of cases, such as cases of personal relation, are excluded from application of small claims procedure; and (vi) the jurisdiction of judicial conformation of a mediation agreement is further clarified and the parties to a mediation agreement are given more options in terms of choosing the people's court for judicial conformation.

Collecting and Using China-Sourced Human Genetic Resources and Derived Data

On March 4, 2022, the Ministry of Science and Technology (MOST) issued Answers to Frequently Asked Questions Regarding Human Genetic Resources (HGRs) Administration, or the Q&A Series I. The Q&A Series I provides short answers to 30 frequently asked questions relating to the collection, preservation, utilization and external provision of China-sourced HGRs. For example, the Q&A Series I clarifies that a notification filing with the Human Genetic Resources Administration Office of China, or HGRAC, is required for purpose of transferring China-sourced HGRs to regulatory authorities in other jurisdictions.

On March 22, 2022, the Ministry of Science and Technology (MOST) issued the Draft Implementing Rules of the Regulation on the Administration of Human Genetic Resources (Draft for Comment), or the Draft Implementing Rules, which closely scrutinizes all HGRs-related activity from upstream collection of HGR materials to downstream exploitation and external provision of the HGR materials and data derived therefrom ("HGR data"). The Draft Implementing Rules are intended to provide operational details and clarify questions that have emerged in the past few years after the Regulation on the Administration of Human Genetic Resources became effective. Under the Draft Implementing Rules, clinical studies conducted for purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of HGR materials, will be eligible for a notification filing (as opposed to the advance approval) if the HGR materials are collected by sites, and processed by sites or an onshore third-party lab specified in the clinical trial protocol. The Draft Implementing Rules provide clearer guidance on how to allocate the intellectual property derived from a Sino-foreign cooperative research utilizing China-Sourced HGRs. The Draft Implementing Rules enumerate situations where a security review is required for external provision or utilization in an open manner of HGR data, such as external provision or utilization in an open manner of HGR data about important genetic pedigrees, HGR data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals.

On April 15, 2022, MOST issued Answers to Frequently Asked Questions Regarding Human Genetic Resources Administration (Q&A Series II), or the Q&A Series II. The Q&A Series II provide formal written reply to 5 frequently asked questions relating to the collection, preservation, utilization and external provision of China-Sourced HGRs. The Q&A Series II specifies that collection, external provision or utilization in an open manner of the data related to clinical practices, patient demographics, lab tests, medical images, etc. that do not carry genetic attributes will not be regulated as collection, external provision or utilization in an open manner of HGR data. The Q&A Series II stipulates that no advance approval for Sino-foreign cooperative research is required for a research utilizing China-Sourced HGRs, if the foreign entity who provides funding support will not substantially participate in the research and have any access to or ownership of the research data and research results.

Auxiliary Rules for the Regulations on Supervision and Administration of Medical Devices

On March 18, 2021, the State Council published new Regulations on Supervision and Administration of Medical Devices, or Order 739, which became effective on June 1, 2021. This top-level medical device administrative regulation contains a number of important changes, the practical effects of which will be implemented in corresponding auxiliary regulations and rules. Recently, a series of regulations have been amended accordingly to support the implementation of Order 739 in terms of the production, distribution and clinical trials of medical devices.

- *Measures for the Supervision and Administration of the Production of Medical Devices*

  On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Production of Medical Devices, or Order 53, promulgated by the State Administration for Market Regulation, or SAMR, became effective. All medical device manufacturing activities within China should comply with Order 53. Order 53 clarifies the responsibilities and obligations of medical device registrants/ record-filing applicants and their entrusted manufacturers where applicable. Order 53 also establishes a medical device reporting system with an aim to improve administration of medical device production. The reporting system consists of several types of report, including annual self-inspection report, production product variety report, production conditions change report, re-production report and recall and disposal report. The medical device registrants/ record-filing applicants and/or the medical device manufacturers need to submit corresponding reports to the local relevant Medical Product Administrations in accordance with Order 53.

- *Measures for the Supervision and Administration of the Distribution of Medical Devices*

  On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Distribution of Medical Devices, or Order 54, promulgated by SAMR came into effect. All medical device distribution activities within China should comply with Order 54. Under Order 54, explicit regulatory requirements were introduced to distributors of medical devices. For example, Order 54 requires medical device distributors to establish quality management system and adopt quality control measures covering the total process of distribution and submit annual self-inspection reports to local relevant Medical Product Administrations.

- *Good Practices for Medical Device Clinical Trials*

  On May 1, 2022, a revised version of the Good Practices for Medical Device Clinical Trials, or 2022 Medical Device GCP, jointly released by the NMPA and the National Health Commission, came into effect. Going forward, all medical device clinical trials that haven't passed ethical review by May 1, 2022 should be conducted in compliance with the 2022 Medical Device GCP, if they are conducted for purpose of applying for medical device registration. The 2022 Medical Device GCP specifies responsibilities of each party participating in a medical device clinical trial, in particular the responsibilities of the sponsor. The 2022 Medical Device GCP no longer requires clinical trials of medical devices to be conducted in two or more clinical trial institutions. This will make it easier for medical device companies to conduct medical device registration studies.

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 steadily advancing and expanding, with twelve late-stage clinical product candidates being investigated as of March 31, 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 March 31, 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 $87.1 million and $169.5 million, for the three months ended March 31, 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. 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.

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 to incur 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 March 31, 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 upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our unaudited condensed consolidated financial statements and totaled nil and $171.3 million for the three months ended March 31, 2022 and March 31, 2021, respectively.

Results of Operations

Three Months Ended March 31, 2022 Compared to Three Months Ended March 31, 2021

Revenues

Total revenues consist of the following:

	Three months ended March 31,			
(in thousands)	2022	%	2021	%
Revenues:				
Product revenue, net	$46,095	98.7	$20,103	100.0
Collaboration revenue	629	1.3	—	—
Total	$46,724	100.0	$20,103	100.0

Product Revenue, net

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The amount of revenue of ZEJULA for the three months ended March 31, 2022 and March 31, 2021, respectively, was adjusted by the normal process in mainland China to compensate distributors for products recently sold at prices prior to the NRDL implementation. The following table disaggregates net revenue by product for the three months ended March 31, 2022 and 2021, respectively:

	Three months ended March 31,			
(in thousands)	2022	%	2021	%
ZEJULA	$29,597	64.2	$12,606	62.7
Optune	12,797	27.8	7,130	35.5
QINLOCK	2,959	6.4	367	1.8
NUZYRA	742	1.6	—	—
Total product revenue, net	$46,095	100.0	$20,103	100.0

Collaboration revenue

Collaboration revenue increased by $0.6 million to $0.6 million for the three months ended March 31, 2022 from nil for the three months ended March 31, 2021 from the collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

Cost of Sales

Cost of sales increased by $8.1 million to $15.6 million for the three months ended March 31, 2022 from $7.5 million for the three months ended March 31, 2021 primarily due to increasing sales volume, product costs and higher royalties during the three months ended March 31, 2022.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the respective period indicated.

	Three months ended March 31,			
(in thousands)	2022	%	2021	%
Research and development expenses:				
Personnel compensation and related costs	$24,802	46.1	$ 12,697	6.2
Licensing fees	—	—	171,282	84.0
CROs/CMOs/Investigators expenses	23,550	43.7	15,526	7.6
Other costs	5,502	10.2	4,347	2.2
Total	$53,854	100.0	$203,852	100.0

Research and development expenses decreased by $150.0 million to $53.9 million for the three months ended March 31, 2022 from $203.9 million for the three months ended March 31, 2021 primarily due to:

- a decrease of $171.3 million in licensing fees in connection with the upfront and milestone fee paid for licensing agreement due to no new licensing for the three months ended March 31, 2022; offset by
- an increase of $12.1 million in personnel compensation and related costs primarily attributable to increased employee compensation costs due to headcount growth during the three months ended March 31, 2022 and the grants of new share options and vesting of restricted shares to certain employees, and
- an increase of $8.0 million in CROs/CMOs/Investigators expenses in the three months ended March 31, 2022 as we advanced our drug candidate pipeline.

The following table summarizes our research and development expenses by program for the three months ended March 31, 2022 and 2021, respectively:

	Three months ended March 31,			
(in thousands)	2022	%	2021	%
Research and development expenses:				
Clinical programs	$22,852	42.4	$186,256	91.4
Pre-clinical programs	2,565	4.8	2,500	1.2
Unallocated research and development expenses	28,437	52.8	15,096	7.4
Total	$53,854	100.0	$203,852	100.0

Research and development expenses attributable to clinical programs decreased by $163.4 million from $186.3 million during the three months ended March 31, 2021 (which included the licensing fees of $171.3 million) to $22.9 million during the three months ended March 31, 2022. Research and development expenses attributable to pre-clinical programs remained relatively consistent during the three months ended March 31, 2022 compared to the three months ended March 31, 2021. 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 sets forth the components of our selling, general and administrative expenses for the respective period indicated.

	Three months ended March 31,			
(in thousands)	**2022**	**%**	**2021**	**%**
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	$38,203	67.0	$23,412	65.3
Professional service fees	7,433	13.0	3,583	10.0
Other costs	11,355	20.0	8,843	24.7
Total	$56,991	100.0	$35,838	100.0

Selling, general and administrative expenses increased by $21.2 million to $57.0 million for the three months ended March 31, 2022 from $35.8 million for the three months ended March 31, 2021 primarily due to:

- an increase of $14.8 million in personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs due to headcount growth during the three months ended March 31, 2022 and the grants and vesting of share options and restricted shares to certain employees;
- an increase of $3.9 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; and
- an increase of $2.5 million in other costs mainly including selling, rental, and administrative expenses primarily attributable to the commercial operation in mainland China, Hong Kong, and Taiwan.

Interest Income

Interest income were $0.2 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively.

Other Expenses, Net

Other expenses decreased by $3.6 million to $2.6 million for the three months ended March 31, 2022 from $6.2 million for the three months ended March 31, 2021, primarily as a result of an increase in foreign exchange gain and governmental subsidies net of equity investment loss in MacroGenics.

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 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.

Preclinical 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 preclinical and clinical trial activities on behalf of us in the ongoing development of our product candidates. Expenses related to preclinical 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

Employees' share-based awards 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) 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) expected dividend yield on our ADS, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in some comparable companies' stock prices 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 fair value of 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, the 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 March 31, 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 the Nasdaq stock exchange, various follow-on offerings and our September 2020 secondary listing on the Hong Kong Stock Exchange of our ordinary shares and/or ADSs. Through March 31, 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 $87.1 million and $169.5 million, for the three months ended March 31, 2022 and 2021, respectively. We have commitments for capital expenditure of $22.3 million as of March 31, 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 costs and revenues.

As of March 31, 2022, we had cash, cash equivalents, restricted cash and short-term investment of $1,313.0 million. Our expenditures are principally focused on research and development and are largely discretionary. As such, we believe that our current losses and cash used in operations do not present going concern issues. 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 three months ended March 31, 2022 and 2021:

	Three months ended March 31,	
(in thousands)	2022	2021
Net cash used in operating activities	$ (87,127)	$(169,500)
Net cash (used in) provided by investing activities	(30,144)	742,005
Net cash provided by (used in) financing activities	258	(271)
Effect of foreign exchange rate changes	(130)	(930)
Net (decreases) increases in cash, cash equivalents and restricted cash	$(117,143)	$ 571,304

Net cash used in operating activities

During the three months ended March 31, 2022, our operating activities used $87.1 million of cash, which resulted principally from our net loss of $82.4 million, adjusted for non-cash charges of $23.0 million, and cash used in our operating assets and liabilities of $27.7 million.

During the three months ended March 31, 2021, our operating activities used $169.5 million of cash, which resulted principally from our net loss of $232.9 million, adjusted for non-cash charges of $72.1 million, and cash used in our operating assets and liabilities of $8.7 million. The decrease in cash used in operating activities was primarily due to the decrease of license payments.

Net cash (used in) provided by investing activities

Net cash used in investing activities was $30.1 million for the three months ended March 31, 2022 compared to net cash provided by investing activities of $742.0 million for the three months ended March 31, 2021. The decrease in cash provided by investing activities was primarily due to the decrease of proceeds from maturity of short-term investments during the three months ended March 31, 2022 compared to the three months ended March 31, 2021.

Net cash provided by (used in) financing activities

Net cash provided by financing activities was $0.3 million for the three months ended March 31, 2022 compared to net cash used in financing activities of $0.3 million for the three months ended March 31, 2021. The increase in cash provided by financing activities was primarily due to the reduced payment of public offering costs during the three months ended March 31, 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 371.8 million and RMB 151.7 million, which were denominated in RMB, representing 7% and 2% of the cash and cash equivalents, as of March 31, 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 $847.0 million and $964.1 million and short-term investments of $465.3 million and $445.0 million, as of March 31, 2022 and December 31, 2021, respectively. As of March 31, 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 March 31, 2022, our two largest debtors accounted for approximately 39% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of March 31, 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 March 31, 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 March 31, 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 March 31, 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, which describes various material risks and uncertainties to which we are or may become subject. These risks and uncertainties could, directly or indirectly, adversely affect our business, results of operations, financial condition, liquidity, 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 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 are set forth below:

Because the majority of our operations are in mainland China and our auditor has been located in mainland China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of Chinese authorities, there have been concerns regarding oversight of the audits of our financial statements filed with the SEC. In March 2022, SEC staff conclusively identified us under the HFCAA as an issuer that uses an auditor that the PCAOB is unable to inspect or investigate completely. Although in April 2022 our Audit Committee approved the engagement of KPMG, a U.S. auditor that is subject to inspection by the PCAOB, as our independent public accounting firm for the fiscal year ending December 31, 2022, KPMG is in the process of concluding its standard client evaluation procedures, including obtaining approval from the Hong Kong Stock Exchange to audit the Company's consolidated financial statements submitted to the Hong Kong Stock Exchange. If for any reason we continue to fail to meet the audit requirements of the HFCAA for three consecutive years, the HFCAA requires the SEC to prohibit the trading of our securities on a national securities exchange, including Nasdaq, or on over-the-counter markets in the United States. In addition, the U.S. Senate and U.S. House of Representatives have each passed bills, which, if enacted, would decrease the number of non-inspection years from three consecutive years to two, thus reducing the time period before our securities may be prohibited from trading on a U.S. securities exchange or delisted from Nasdaq. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including our independent registered public accounting firm, are required to be registered with the PCAOB and to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and applicable professional standards. Because our current auditor is located in mainland China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of Chinese authorities, our auditor is not currently inspected by the PCAOB.

PCAOB inspections of auditors located outside of mainland China and Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the PCAOB's inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in mainland China and Hong Kong prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections, which could result in limitations or restrictions on our access to the U.S. capital markets.

Furthermore, in recent years, the U.S. Congress and regulatory authorities have continued to express concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. As part of this continued focus on access to audit and other information currently protected by national law, in particular under Chinese law, the United States enacted the HFCAA in December 2020. 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"). 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. Our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years, and this ultimately could result in our ADSs being delisted.

Furthermore, in June 2021, the U.S. Senate passed the AHFCAA, which, if enacted, would amend the HFCAA and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years (as opposed to the three years under the HFCAA). In February 2022, the U.S. House of Representatives passed the America COMPETES Act, which similarly would amend the HFCAA to shorten the number of non-inspection years from three years to two years. The America COMPETES Act, however, includes a broader range of legislation than the AHFCA Act in response to the U.S. Innovation and Competition Act passed by the U.S. Senate in 2021. The U.S. House of Representatives and the U.S. Senate will need to agree on amendments to these respective bills to allow the legislature to pass their amended bills before the President can sign the bill into law. It is unclear if or when either of these bills will be signed into law.

In September 2021, the PCAOB adopted PCAOB Rule 6100, Board Determinations Under the Holding Foreign Companies Accountable Act, which provides a framework for the PCAOB to use when determining whether the PCAOB is unable to inspect or investigate completely a registered public accounting firm located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction for the purposes of the HFCAA. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. In November 2021, the SEC announced that it had approved Rule 6100.

In December 2021, the SEC adopted amendments to finalize rules implementing the submission and disclosure requirements in the HFCAA for Commission-Identified Issuers, which became effective on January 10, 2022. In addition, the PCAOB issued a Determination Report, pursuant to PCAOB Rule 6100, 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. The SEC began to identify Commission-Identified Issuers for fiscal years beginning after December 18, 2020. A Commission-Identified Issuer will be required to comply with the submission and disclosure requirements in the annual report for each year in which it was so identified. If an issuer is identified as a Commission-Identified Issuer based on its annual report for the fiscal year ended December 31, 2021, the issuer will be required to comply with the submission or disclosure requirements in its annual report for the fiscal year ended December 31, 2022.

In March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer. In April 2022 the Audit Committee of our Board of Directors approved the engagement of 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 for the annual consolidated financial statements of the Company filed with the SEC and the Company's internal controls over financial reporting in accordance with the Exchange Act. KPMG will also be engaged to audit the consolidated financial statements of the Company for the year ending December 31, 2022 submitted to the Hong Kong Stock Exchange in accordance with the Rules Governing the Listing of Securities of the Hong Kong Stock Exchange, subject to the Company's receipt of the approval from the Hong Kong Stock Exchange and the FRC. Even though such approval is expected to be administrative in nature, if such approval is rejected by the Hong Kong Stock Exchange or the FRC, or, for some reason, we are not able to enter into an engagement agreement with KPMG, the Company would need to engage another auditor that is inspected by the PCAOB in order to comply with the audit requirements of the HFCAA. Additionally, even if KPMG is approved as our auditor by the Hong Kong Stock Exchange and the FRC, there remains a risk that the CSRC or another Chinese governmental agency could limit or prohibit our ability to use KPMG as our auditor. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

While we understand that there appears to be ongoing, constructive dialogue among the CSRC, the SEC and the PCAOB regarding permitting the inspection of PCAOB-registered accounting firms in China, there can be no assurance that the U.S. and Chinese governments ultimately reach an agreement on these matters, or that we will be able to comply with requirements imposed by U.S. regulators, Nasdaq, the CSRC, or other Chinese regulators. If for any reason we continue to be identified as a Commission-Identified Issuer that uses an auditor not subject to PCAOB inspection for three consecutive years or, if the AHFCAA or the America COMPETES Act is passed, two consecutive years, our ADSs may be delisted from Nasdaq as a result. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Further, we may be prohibited from listing our ADSs on another U.S. securities exchange. The market price of our ordinary shares and/or ADSs 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.

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

Pursuant to the Draft Archives Rules, released by the CSRC for public comment on April 2, 2022, where Chinese domestic companies (including Chinese domestic companies that are listed outside of 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 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 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 Archive 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 LLP may subject us and KPMG LLP to additional approval, filing, and compliance obligations in China under the Draft Archive Rules.

We face risks related to public health crises, including the current ongoing COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our global operations expose us to risks associated with public health crises, such as epidemics and pandemics, natural catastrophes, such as earthquakes, hurricanes, typhoons, or floods, or other disasters such as fires, explosions and terrorist activity or war that are outside of our control, including government reactions due to such events. Our business operations and those of our suppliers, CROs, CMOs and other contractors may potentially suffer interruptions caused by any of these events.

In December 2019, a respiratory illness caused by a novel strain of coronavirus, SARS-CoV2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders and business shutdowns.

Although the COVID-19 outbreak appeared to have been largely under control within Greater China since the second fiscal quarter of 2020, there have been continuous rebound cases in Greater China, especially in some large cities like Shanghai, Shenzhen and Hong Kong since February 2022 and uncertainties associated with the future developments of the pandemic still exist, which resulted in unpredictable regional quarantines, travel restrictions and shutdown of businesses, which has caused slower recovery of the Chinese economy. In January and February 2022, Shanghai, where our principal executive offices are located, experienced a wave of intermittent government shutdowns in connection with COVID-19 control measures. From late March 2022, COVID-19 lockdown restrictions were increased and most of the city is subject to a full lockdown. Other cities or regions in China are or may be subject to similar government restrictions. The effect of these restrictive quarantine measures imposed by the Chinese government, which may continue for some indeterminate amount of time, may have a material adverse effect on our business for the remainder of this fiscal year.

The continued COVID-19 pandemic and related government restrictions could adversely impact our operations and, given the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of us and our business partners and the ability to advance our research and development activities and pursue development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results.

For example, due to business 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 could have limited or even 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. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to the outbreak of COVID-19. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. Although so far none of our NDA submissions and acceptances, key clinical development milestones or CTA 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 which may be effective in the future—could 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 current COVID-related restrictions in Shanghai continue, such restrictions may impact the distribution and sale of our products within China. These and other government restrictions could limit our and our distributors' ability to successfully sell our commercial products in Greater China, even if we implement contingent plans. Any or all of these adverse effects arising from COVID-19 may adversely affect our operations this year and cause the value of the Company to decline, potentially limiting our ability to obtain additional financing on terms acceptable to the Company.

We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including limiting non-essential travel, preparing pandemic prevention materials in the office, permitting work from home as appropriate, and providing COVID-19 testing for our employees. Certain of these measures could negatively affect our business. For instance, if our employees are required to continue to work remotely as a result of local government mandates, company policy updates, or otherwise, absenteeism or employee turnover could increase, or we may experience disruptions to our operations 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 will depend on many factors beyond our control.

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, may be adversely affected by the geopolitical factors arising in connection with Russia's invasion of Ukraine, including particularly how countries like the United States and China choose to respond to this war. As a result, the value of our ordinary shares and ADSs may significantly decline.

Although we do not conduct business in Russia or Ukraine, 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, may be adversely affected by geopolitical factors arising in connection with Russia's invasion of Ukraine. For example, in connection with this war, the United States and other nations have raised the possibility of secondary sanctions on China, Chinese banks and Chinese businesses that do business with Russia or its allies, including Belarus. We do not conduct business in Russia or Belarus, or with Russian or Belarusian counterparties, but we may be impacted by sanctions if third parties with which we do business, such as customers, suppliers, intermediaries, services providers or banks, are subject to such sanctions or if broader sanctions are imposed. 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. If sanctions are imposed or if this war continues or expands, or leads to continued political or economic instability, terrorist activity, or further government actions or increased economic or political tensions between the United States and China, 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, may be adversely impacted and the value of our ADSs and ordinary shares may significantly decline.

We may not be able to access the capital and credit markets on terms that are favorable to us.

We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements and other business initiatives. The capital and credit markets are experiencing, and have in the past experienced, extreme volatility and disruption, which leads to uncertainty and liquidity issues for both borrowers and investors. That volatility and unpredictability in the financial markets is adversely affecting the access to capital and credit for many life sciences companies, but that risk is currently exacerbated for companies like ours with significant operations in China by factors such as the geopolitical tensions between the U.S. and China, the ongoing war between Russia and Ukraine, and the uncertainty about the duration, scope, and effect of the COVID-19 restrictions imposed by the Chinese government. In the event that these continued adverse market conditions may affect us, we may be unable to obtain adequate capital or credit market financing, obtain that capital or credit on favorable terms, or access such capital or credit in the market(s) or manner most favorable to the Company.

Other Risk Factors

The following is a summary of significant risk factors and uncertainties that may affect our business which are discussed in more detail above and in our 2021 Annual Report:

- The uncertainties in the Chinese legal system could materially and adversely affect us;
- Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares and/or our ADSs;
- The Chinese government may intervene in or influence our operations at any time, 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;
- The audit report included in our 2021 Annual Report was prepared by an auditor who is not inspected by the PCAOB and, as such, you are deprived of the benefits of such inspection, we may be subject to additional Nasdaq listing criteria or other penalties and our ADSs may be delisted from the U.S. stock market;
- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act;
- Compliance with 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 may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, materially and adversely impacting our operating results;
- The economic, political and social conditions in mainland China, as well as governmental policies, could affect the business environment and financial markets in mainland China, our ability to operate our business, our liquidity and our access to capital;
- If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our ADSs or ordinary shares may decline in value or become worthless;
- The approval of, filing or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.
- We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation;
- Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies effectively;
- We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business;
- Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China 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 may otherwise adversely affect us;
- Chinese regulations establish complex procedures for some 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;
- Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which may 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;
- Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations;

- It may be difficult for overseas regulators to conduct investigations or collect evidence within mainland China;
- If we are classified as a Chinese resident enterprise for Chinese income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders;
- We and our shareholders face uncertainties in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises;
- Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations;
- Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, or CFIUS, which may delay or block a transaction from closing;
- Changes in United States and international trade policies and relations, particularly with regard to mainland China, may adversely impact our business and operating results;
- It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts;
- Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business;
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. To date, we have not generated sufficient revenue from product sales to cover corresponding expenses, and we may never achieve or sustain profitability;
- We are invested in the commercial success of our four approved products and our ability to generate product revenues in the near future is highly dependent on the commercial success of each of those products;
- We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates and our business could be substantially harmed;
- If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us;
- If we fail to maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired; and
- Other risks and uncertainties, including those described in the 2021 Annual Report.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and information in our 2021 Annual Report and our other filings with the SEC.

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.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
4.2	Form of American Depositary Receipt (incorporated by reference to Form 424B3 (File No. 333-220256 filed with the SEC on March 30, 2022)
4.3	Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-8 (File No. 333-264800) filed with the SEC on May 9, 2022).
4.5*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act
31.1*	Certification of Chief Executive Officer Required by Rule 13a-14(a)
31.2*	Certification of Chief Financial Officer Required by Rule 13a-14(a)
32.1**	Certification of Chief Executive Officer Required by Rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code
32.2**	Certification of Chief Financial Officer Required by Rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code
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

SIGNATURES

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

ZAI LAB LIMITED

Dated: May 10, 2022

By: /s/ Samantha Du
Name: Samantha Du
Title: Chief Executive Officer

Exhibit 4.5

DESCRIPTION OF SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 31, 2022, the registrant had the following series of securities registered pursuant to Section 12 of the U.S. Securities Exchange Act of 1934, as amended:

Title of each class:		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.

Citibank, N.A. acts as the depositary bank for the American Depositary Shares pursuant to the Deposit Agreement, dated as of September 20, 2017. Citibank's depositary offices are located at 388 Greenwich Street New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank has appointed a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A.—Hong Kong, located at 9/F., Citi Tower, One Bay East, 83 Hoi Bun Road, Kwun Tong, Kowloon, Hong Kong.

As of May 10, 2022, our authorized share capital consists of $30,000.00 divided into 5,000,000,000 ordinary shares, with a par value of $0.000006 each.

Each American depositary share ("ADS") represents the right to receive, and to exercise the beneficial ownership interests in, ten ordinary shares that are on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADS-to-ordinary share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

An ADS holder will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents such ADSs. The deposit agreement and the ADR specify our rights and obligations as well as ADS holders' rights and obligations as owner of ADSs and those of the depositary bank. ADS holders appoint the depositary bank to act on their behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require ADS holders to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. ADS holders are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on ADS holders' behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

We will not treat ADS holders as our shareholders and ADS holders will not have direct shareholder rights. The depositary bank will hold on ADS holders' behalf the shareholder rights attached to the ordinary shares underlying the ADSs. ADS holders will be able to exercise the shareholders rights for the ordinary shares represented by the ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement, an ADS holder will, as an ADS owner, need to arrange for the cancellation of such ADSs and become a direct shareholder.

The manner in which ADS holders owns the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect the holders' rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to the holders. An ADS holder may hold the ADSs either by means of an ADR registered in such holder's name, through a brokerage or safekeeping account, or through an account established by the depositary bank in such holder's name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If an ADS holder decides to hold the ADSs through such holder's brokerage or safekeeping account, the holder must rely on the procedures of his/her broker or bank to assert his/her rights as an ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit an ADS holder's ability to exercise such holder's rights as an owner of ADSs. ADS holders should consult with their broker or bank if they have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes ADS holders have opted to own the ADSs directly by means of ADSs registered in such holders' name and, as such, we will refer to ADS holders as the "holders."

The registration of the ordinary shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Distributions

Holders of ADSs generally have the right to receive the distributions we make on the securities deposited with the custodian. ADS holders' receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to Cayman Islands laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Ordinary Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary share ratio, in which case each ADS holders hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary share ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). Holders may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of such rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary bank will not distribute the rights to holders if:

- We do not timely request that the rights be distributed to holders or we request that the rights not be distributed to holders; or
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to holders. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to holders only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable holders to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to holders, holders will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to holders. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to holders and if we provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will not distribute the property to holders and will sell the property if:

- We do not request that the property be distributed to holders or if we request that the property not be distributed to holders; or
- We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to holders is not reasonably practicable; or
- The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. Holders may have to pay fees, expenses, taxes and other governmental charges upon the redemption of the ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary bank may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for the ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, the ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to holders, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of holders' existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary bank may not lawfully distribute such property to holders, the depositary bank may sell such property and distribute the net proceeds to holders as in the case of a cash distribution.

Issuance of ADSs upon Deposit of Ordinary Shares

Our ordinary shares have been and will be deposited with the custodian. The depositary bank may create ADSs on a holder's behalf if such holder or such holder's broker deposits ordinary shares with the custodian. The depositary bank will deliver these ADSs to the person such holder indicates only after such holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Holders' ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When a holder makes a deposit of ordinary shares, such holder will be responsible for transferring good and valid title to the depositary bank. As such, the holder will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- The holder is duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at holders' cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, Combination and Split-up of ADRs

Holders will be entitled to transfer, combine or split up their ADRs and the ADSs evidenced thereby. For transfers of ADRs, a holder will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have the ADRs either combined or split up, a holder must surrender his/her ADRs in question to the depositary bank with such holder's request to have them combined or split up, and such holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal Of Ordinary Shares Upon Cancellation Of ADSs

Holders will be entitled to present their ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Holders' ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by the ADSs, holders will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. Holders assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If a holder holds ADSs registered in his/her name, the depositary bank may ask such holder to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel the ADSs. The withdrawal of the ordinary shares represented by the ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

Holders will have the right to withdraw the securities represented by the ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.
- Obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.
- The deposit agreement may not be modified to impair holders' right to withdraw the securities represented by the ADSs except to comply with mandatory provisions of law.

Voting Rights

Holders generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by ADSs.

At our request, the depositary bank will distribute to holders any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs.

If the depositary bank timely receives voting instructions from a holder, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions as follows:

- *In the event of voting by show of hands*, the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders who provide timely voting instructions.
- *In the event of voting by poll, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders.*

In the event of voting by poll, holders in respect of which no timely voting instructions have been received shall be deemed to have instructed the depositary bank to give a discretionary proxy to a person designated by us to vote the ordinary shares represented by such holders' ADSs; provided, that no such instructions shall be deemed given and no such discretionary proxy shall be given with respect to any matter as to which we inform the depositary bank that we do not wish such proxy to be given; provided, further, that no such discretionary proxy shall be given (x) with respect to any matter as to which we inform the depositary that (i) there exists substantial opposition, or (ii) the rights of holders or the shareholders of our company will be materially adversely affected, and (y) in the event that the vote is on a show of hands.

Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure that holders will receive voting materials in time to enable them to return voting instructions to the depositary bank in a timely manner.

Fees and Charges

Holders will be required to pay the following fees under the terms of the deposit agreement:

Service	**Fees**
• Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-ordinary share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. 5¢ per ADS issued
• Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to-share ratio, or for any other reason)	Up to U.S. 5¢ per ADS cancelled
• Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. 5¢ per ADS held
• ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank

Holders will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary bank in the conversion of foreign currency;
- the fees and expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to holders. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of an ADS offering. Note that the fees and charges holders may be required to pay may vary over time and may be changed by us and by the depositary bank. Holders will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Amendments and Termination

We may agree with the depositary bank to modify the deposit agreement at any time without holders' consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to holders' substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges holders are required to pay. In addition, we may not be able to provide holders with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders will be bound by the modifications to the deposit agreement if they continue to hold their ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent holders from withdrawing the ordinary shares represented by the ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to holders at least 30 days before termination. Until termination, holders' rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until holders request the cancellation of their ADSs) and may sell the securities held on deposit.

After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

Books of Depositary

The depositary bank will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary bank's obligations to holders. Please note the following:

- we and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- the depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- the depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to holders on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- we and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- we and the depositary bank disclaim any liability if we or the depositary bank, or our respective controlling persons or agents are prevented or forbidden from, or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- we and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles of association or in any provisions of or governing the securities on deposit.
- we and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- we and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to holders.
- we and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- we and the depositary bank also disclaim liability for any consequential, indirect or punitive damages for any breach of the terms of the deposit agreement, or otherwise.
- no disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and holders.
- nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

Pre-release Transactions

The depositary bank has informed us that it no longer engages in pre-release transactions, and has no intention to do so in the future. **Taxes**

Holders will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. Holders will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on holders' behalf. However, holders may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. Holders are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes arising out of any refund of taxes, reduced rate of withholding or of the tax benefit obtained for or by the holders.

Foreign Currency Conversion

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. Holder may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing law/waiver of Jury Trial

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of the Cayman Islands.

By holding an ADS or an interest therein, ADS holders irrevocably agree that any legal suit, action or proceeding against or involving us or the Depositary, arising out of or based upon the deposit agreement, ADSs or ADRs, may only be instituted in a state or federal court in New York, New York, and ADS holders irrevocably waive any objection to the laying of venue and irrevocably submit to the exclusive jurisdiction of such courts with respect to any such suit, action or proceeding.

AS A PARTY TO THE DEPOSIT AGREEMENT, ADS HOLDERS IRREVOCABLY WAIVE THE RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT, THE ADRs AND ANY TRANSACTIONS CONTEMPLATED THEREIN (WHETHER BASED ON CONTRACT, TORT, COMMON LAW OR OTHERWISE) AGAINST US AND/OR THE DEPOSITARY BANK.

Exhibit 31.1

Certification by the Principal Executive Officer
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 of Zai Lab Limited;

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 31.2

Certification by the Principal Financial Officer
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 of Zai Lab Limited;

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2022

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

Exhibit 32.1

Certification by the Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report on Form 10-Q of Zai Lab Limited (the "Company") for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha (Ying) Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: May 10, 2022

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

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Zai Lab Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report on Form 10-Q of Zai Lab Limited (the "Company") for the quarter ended March 31, 2022 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.
Chief Financial Officer

Date: May 10, 2022

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

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Zai Lab Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.