# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2021**

**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**<br>(State or other jurisdiction of incorporation or organization) | **98-1144595**<br>(I.R.S. Employer Identification No.) |
|---|---|
| **4560 Jinke Road**<br>**Bldg. 1, Fourth Floor**<br>**Pudong**<br>**Shanghai, China**<br>(Address of principal executive offices) | **201210**<br>(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 1 Ordinary Share, par value $0.00006 per share** | **ZLAB** | **The Nasdaq Global Market** |
| **Ordinary Shares, par value $0.00006 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 October 31, 2021, 96,408,743 ordinary shares of the registrant, par value $0.00006 per share, were outstanding, of which 68,893,502 ordinary shares were held in the form of American Depositary Shares.

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**Zai Lab Limited**
**Quarterly Report on Form 10-Q**


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## SPECIAL NOTES REGARDING THE COMPANY

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potentially,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the risk factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020, and the additional risk factors discussed in the “Risk Factors” section in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and 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” refers to mainland China, Hong Kong, Macau, and Taiwan and “China” refers to mainland China 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. Our operating subsidiaries comprise 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 China; Zai Lab International Trading (Shanghai) Co., Ltd., domiciled in China; Zai Lab (Suzhou) Co., Ltd., domiciled in China; Zai Biopharmaceutical (Suzhou) Co., Ltd., domiciled in China; Zai Lab Trading (Suzhou) Co., Ltd., domiciled in China; Zai Lab (Taiwan) Limited, domiciled in Taiwan; Zai Lab (US) LLC, domiciled in the United States. Additionally, as of the date of this Quarterly Report on Form 10-Q, Zai Auto Immune (Hong Kong) Limited and Zai Anti Infectives (Hong Kong) Limited have non-substantial business operations.

Disclosures Relating to Our Chinese Operations

There are significant legal and operational risks associated with having the majority of our operations in China, including that changes in the legal, political and economic policies of the Chinese government, the relations between China and the United States, or Chinese or United States 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 China’s government, including the recent enactment of China’s new Data Security Law, as well as our obligations to comply with China’s Cybersecurity Review Measures (Revised Draft for Comment), regulations and guidelines relating to the multi-level protection scheme, Personal Information Protection Law 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 the risk factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020 and the risk factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020, and the additional risk factors discussed in the “Risk Factors” section in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and this Quarterly Report on Form 10-Q.

As of the date of this Quarterly Report on Form 10-Q, we are not required to obtain approval or prior permission from the China Securities Regulatory Commission or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such 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. For more information on these required permissions, see the "Recent Legal and Regulatory Developments" section below in Part I, Item 2 (Management's Discussion and Analysis of Financial Condition and Results of Operation), the risk factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, and the additional risk factors discussed in the "Risk Factors" section in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and this Quarterly Report on Form 10-Q.

*Business Licenses for Chinese Subsidiaries*

To operate our general business activities currently conducted in 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. 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: Drug Manufacturing Permits, Drug Distribution Permits and Medical Device Distribution Permits to manufacture and/or distribute drugs and applicable medical devices, and no application for any such material license or permit has been denied.

*Dividends and Other Distributions*

We are a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. If any of our Chinese subsidiaries incur debt on its own behalf in the future, the instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from our Chinese subsidiaries to our subsidiaries located in or outside of China. In addition, as of the date of this Quarterly Report on Form 10-Q, none of our subsidiaries have ever issued any dividends or distributions to us or their respective shareholders in or outside of China, and neither we nor any of our subsidiaries have ever directly or indirectly paid dividends or made distributions to U.S. investors. Zai Lab (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in China, received $266.5 million in capital contributions via twenty-two separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of China, from 2014 to 2021, to fund its business operations in China. Zai Lab International Trading (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in China, received RMB1.0 million in capital contributions via contributions from Zai Lab (Shanghai) Co., Ltd., its sole shareholder, in 2019 to fund its business operations in China. Zai Lab (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in China, received RMB166.5 million in capital contributions via ten separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of China, from 2015 to 2019 to fund its business operations in China. Zai Lab Trading (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in China, received RMB1.0 million in capital contributions via contributions from Zai Lab (Suzhou) Co., Ltd., its sole shareholder, in 2020 to fund its business operations in China. Zai Biopharmaceutical (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in China, received $15.0 million in capital contributions via four separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of China, from 2017 to 2018 to fund its business operations in China. In the future, cash proceeds raised from our overseas financing activities may be transferred by us to our Chinese subsidiaries via capital contribution or shareholder loans or intercompany loans, as the case may be.

According to the Foreign Investment Law of the People's Republic of China and its implementing rules, which jointly established the legal framework for the administration of foreign-invested companies, a foreign investor may, in accordance with other applicable laws, freely transfer into or out of China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of China in RMB or any foreign currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the People's Republic of China and other Chinese laws and regulations, our Chinese subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with Chinese accounting standards and regulations. In addition, each of our Chinese subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the Chinese subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our Chinese subsidiaries may allocate a portion of their after-tax profits based on Chinese accounting standards to a discretionary reserve fund.

Renminbi is not freely convertible into other currencies. As a result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use their potential future Renminbi revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our Chinese subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. Renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign debt (which may be denominated in foreign currency or Renminbi), including loans we may secure for our Chinese subsidiaries. Currently, our Chinese subsidiaries may purchase foreign currency for settlement of current account transactions, including payment of dividends to us, without the approval of the State Administration of Foreign Exchange of China (SAFE) by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. The Chinese government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi to fund our business activities outside of China or pay dividends in foreign currencies to holders of our securities. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries. See the risk factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, and the additional risk factors discussed in the "Risk Factors" section in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and this Quarterly Report on Form 10-Q for a detailed discussion of the Chinese legal restrictions on the payment of dividends and our ability to transfer cash within our group and the potential for our ADS holders and holders of our ordinary shares to be subject to Chinese taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes.

## 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 notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or SEC, on March 1, 2021.

**Item 1. Financial Statement**

**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 September 30, 2021 $ | As of December 31, 2020 $ |
|---|---|---|---|
| **Assets** | | | |
| **Current assets:** | | | |
| Cash and cash equivalents | 3 | 1,398,498 | 442,116 |
| Short-term investments | 5 | 170,000 | 744,676 |
| Accounts receivable (net of allowance for credit loss of $6 and $1 as of September 30, 2021 and December 31, 2020, respectively) | | 21,018 | 5,165 |
| Inventories | 6 | 12,494 | 13,144 |
| Prepayments and other current assets | | 17,077 | 10,935 |
| Total current assets | | 1,619,087 | 1,216,036 |
| Restricted cash, non-current | 4 | 743 | 743 |
| Long-term investments (including the fair value measured investment of $20,070 and nil as of September 30, 2021 and December 31, 2020, respectively) | 7 | 20,801 | 1,279 |
| Prepayments for equipment | | 1,129 | 274 |
| Property and equipment, net | 8 | 37,087 | 29,162 |
| Operating lease right-of-use assets | | 15,514 | 17,701 |
| Land use rights, net | | 7,749 | 7,908 |
| Intangible assets, net | | 1,678 | 1,532 |
| Long-term deposits | | 901 | 862 |
| Value added tax recoverable | | 23,390 | 22,141 |
| **Total assets** | | **1,728,079** | **1,297,638** |
| **Liabilities and shareholders' equity** | | | |
| **Current liabilities:** | | | |
| Accounts payable | | 51,406 | 62,641 |
| Current operating lease liabilities | | 6,312 | 5,206 |
| Other current liabilities | 11 | 54,292 | 30,196 |
| Total current liabilities | | 112,010 | 98,043 |
| Deferred income | | 17,487 | 16,858 |
| Non-current operating lease liabilities | | 10,652 | 13,392 |
| **Total liabilities** | | **140,149** | **128,293** |
| **Commitments and contingencies (Note 17)** | | | |
| **Shareholders' equity** | | | |
| Ordinary shares (par value of $0.00006 per share; 500,000,000 shares authorized, 95,273,589 and 87,811,026 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively) | | 6 | 5 |
| Additional paid-in capital | | 2,812,830 | 1,897,467 |
| Accumulated deficit | | (1,206,249) | (713,603) |
| Accumulated other comprehensive loss | | (15,124) | (14,524) |
| Treasury Stock (at cost, 27,722 and nil shares as of September 30, 2021 and December 31, 2020, respectively) | | (3,533) | — |
| **Total shareholders' equity** | | **1,587,930** | **1,169,345** |
| **Total liabilities and shareholders' equity** | | **1,728,079** | **1,297,638** |

*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|---|
| | | 2021 | 2020 | 2021 | 2020 |
| | | $ | $ | $ | $ |
| Revenue | 9 | 43,103 | 14,651 | 100,141 | 33,864 |
| Expenses: | | | | | |
| Cost of sales | | (12,162) | (4,934) | (30,535) | (9,914) |
| Research and development | | (55,144) | (58,100) | (401,220) | (160,149) |
| Selling, general and administrative | | (59,002) | (27,874) | (149,254) | (70,346) |
| Loss from operations | | (83,205) | (76,257) | (480,868) | (206,545) |
| Interest income | | 713 | 866 | 1,171 | 3,748 |
| Interest expenses | | — | (43) | — | (157) |
| Other (expenses) income, net | | (13,580) | 11,958 | (12,401) | 11,267 |
| Loss before income tax and share of loss from equity method investment | | (96,072) | (63,476) | (492,098) | (191,687) |
| Income tax expense | 10 | — | — | — | — |
| Share of loss from equity method investment | | (340) | (265) | (548) | (671) |
| Net loss | | (96,412) | (63,741) | (492,646) | (192,358) |
| Net loss attributable to ordinary shareholders | | (96,412) | (63,741) | (492,646) | (192,358) |
| Loss per share - basic and diluted | 12 | (1.01) | (0.84) | (5.34) | (2.59) |
| Weighted-average shares used in calculating net loss per ordinary share - basic and diluted | | 95,035,432 | 75,436,646 | 92,174,838 | 74,381,115 |

*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| Net loss | (96,412) | (63,741) | (492,646) | (192,358) |
| Other comprehensive income (loss), net of tax of nil: | | | | |
| Foreign currency translation adjustments | 1,741 | (9,901) | (600) | (7,535) |
| Comprehensive loss | (94,671) | (73,642) | (493,246) | (199,893) |

*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 | | | | | Treasury Stock | | |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | Additional paid in capital | Accumulated deficit | Accumulated other comprehensive (loss) income | Shares | Amount | Total |
| | | $ | $ | $ | $ | | $ | $ |
| Balance at December 31, 2020 | 87,811,026 | 5 | 1,897,467 | (713,603) | (14,524) | — | — | 1,169,345 |
| Issuance of ordinary shares upon vesting of restricted shares | 81,600 | 0 | 0 | — | — | — | — | — |
| Exercise of shares option | 58,364 | 0 | 702 | — | — | — | — | 702 |
| Issuance of ordinary shares in connection with collaboration and license arrangement (Note 15) | 568,182 | 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 | 88,519,172 | 5 | 1,967,802 | (946,513) | (11,624) | — | — | 1,009,670 |
| Issuance of ordinary shares upon vesting of restricted shares | 32,100 | 0 | 0 | — | — | — | — | 0 |
| Exercise of shares option | 490,517 | 0 | 3,289 | — | — | — | — | 3,289 |
| Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $879 | 5,716,400 | 1 | 817,995 | — | — | — | — | 817,996 |
| Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation | — | — | — | — | — | (6,086) | (924) | (924) |
| Share-based compensation | — | — | 10,232 | — | — | — | — | 10,232 |
| Net loss | — | — | — | (163,324) | — | — | — | (163,324) |
| Foreign currency translation | — | — | — | — | (5,241) | — | — | (5,241) |
| Balance at June 30, 2021 | 94,758,189 | 6 | 2,799,318 | (1,109,837) | (16,865) | (6,086) | (924) | 1,671,698 |
| Issuance of ordinary shares upon vesting of restricted shares | 54,050 | 0 | 0 | — | — | — | — | 0 |
| Exercise of shares option | 461,350 | 0 | 2,916 | — | — | — | — | 2,916 |
| Issuance cost adjustment for follow-on public offering | — | — | 40 | — | — | — | — | 40 |
| Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation | — | — | — | — | — | (21,636) | (2,609) | (2,609) |
| Share-based compensation | — | — | 10,556 | — | — | — | — | 10,556 |
| Net loss | — | — | — | (96,412) | — | — | — | (96,412) |
| Foreign currency translation | — | — | — | — | 1,741 | — | — | 1,741 |
| Balance at September 30, 2021 | 95,273,589 | 6 | 2,812,830 | (1,206,249) | (15,124) | (27,722) | (3,533) | 1,587,930 |
| Balance at December 31, 2019 | 68,237,247 | 4 | 734,734 | (444,698) | 4,620 | — | — | 294,660 |
| Issuance of ordinary shares upon vesting of restricted shares | 80,200 | 0 | 0 | — | — | — | — | — |
| Exercise of shares option | 49,278 | 0 | 346 | — | — | — | — | 346 |
| Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $740 | 6,300,000 | 0 | 280,568 | — | — | — | — | 280,568 |
| Share-based compensation | — | — | 6,463 | — | — | — | — | 6,463 |
| Net loss | — | — | — | (47,988) | — | — | — | (47,988) |
| Foreign currency translation | — | — | — | — | 3,539 | — | — | 3,539 |
| Balance at March 31, 2020 | 74,666,725 | 4 | 1,022,111 | (492,686) | 8,159 | — | — | 537,588 |
| Issuance of ordinary shares upon vesting of restricted shares | 36,000 | 0 | 0 | — | — | — | — | 0 |
| Exercise of shares option | 179,613 | 0 | 2,729 | — | — | — | — | 2,729 |
| Issuance cost adjustment for follow-on public offering | — | — | (13) | — | — | — | — | (13) |
| Share-based compensation | — | — | 6,964 | — | — | — | — | 6,964 |
| Net loss | — | — | — | (80,629) | — | — | — | (80,629) |
| Foreign currency translation | — | — | — | — | (1,173) | — | — | (1,173) |
| Balance at June 30, 2020 | 74,882,338 | 4 | 1,031,791 | (573,315) | 6,986 | — | — | 465,466 |
| Issuance of ordinary shares upon vesting of restricted shares | 90,468 | 0 | 0 | — | — | — | — | 0 |
| Exercise of shares option | 560,662 | 0 | 1,008 | — | — | — | — | 1,008 |
| Issuance of ordinary shares upon secondary listing, net of issuance cost of $5,634 | 10,564,050 | 1 | 739,232 | — | — | — | — | 739,233 |
| Issuance cost adjustment for follow-on public offering | — | — | (2) | — | — | — | — | (2) |
| Share-based compensation | — | — | 6,978 | — | — | — | — | 6,978 |
| Net loss | — | — | — | (63,741) | — | — | — | (63,741) |
| Foreign currency translation | — | — | — | — | (9,901) | — | — | (9,901) |
| Balance at September 30, 2020 | 86,097,518 | 5 | 1,779,007 | (637,056) | (2,915) | — | — | 1,139,041 |

*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)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| | $ | $ |
| **Operating activities** | | |
| Net loss | (492,646) | (192,358) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Allowance for doubtful accounts | 5 | 2 |
| Inventory write-down | 402 | — |
| Depreciation and amortization expenses | 4,612 | 3,253 |
| Amortization of deferred income | (234) | (234) |
| Share-based compensation | 28,106 | 20,405 |
| Noncash research and development expenses (Note 15) | 62,250 | — |
| Share of loss from equity method investment | 548 | 671 |
| Loss from fair value changes of equity investment with readily determinable fair value | 9,930 | — |
| Loss on disposal of property and equipment | 12 | 1 |
| Noncash lease expenses | 4,595 | 3,251 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (15,858) | (3,704) |
| Inventories | 248 | (3,631) |
| Prepayments and other current assets | (6,142) | (3,564) |
| Long-term deposits | (39) | (474) |
| Value added tax recoverable | (1,249) | (6,845) |
| Accounts payable | (11,235) | 5,217 |
| Other current liabilities | 23,429 | (4,981) |
| Operating lease liabilities | (3,834) | (2,335) |
| Deferred income | 863 | 13,606 |
| Net cash used in operating activities | (396,237) | (171,720) |
| **Cash flows from investing activities:** | | |
| Purchases of short-term investments | (170,000) | (749,676) |
| Proceeds from maturity of short-term investment | 743,902 | — |
| Payment for investment in equity investee | (30,000) | — |
| Disposal of property and equipment | 3 | — |
| Purchase of property and equipment | (11,920) | (4,835) |
| Purchase of intangible assets | (539) | (370) |
| Net cash provided by (used in) investing activities | 531,446 | (754,881) |
| **Cash flows from financing activities:** | | |
| Repayment of short-term borrowings | — | (4,292) |
| Proceeds from exercises of stock options | 6,907 | 4,083 |
| Proceeds from issuance of ordinary shares upon public offerings | 818,874 | 1,025,970 |
| Payment of public offering costs | (1,836) | (1,275) |
| Employee taxes paid related to net share settlement of equity awards | (3,467) | — |
| Net cash provided by financing activities | 820,478 | 1,024,486 |
| Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash | 695 | 2,062 |
| Net increase in cash, cash equivalents and restricted cash | 956,382 | 99,947 |
| Cash, cash equivalents and restricted cash - beginning of period | 442,859 | 76,442 |
| Cash, cash equivalents and restricted cash - end of period | 1,399,241 | 176,389 |
| **Supplemental disclosure on non-cash investing and financing activities:** | | |
| Payables for purchase of property and equipment | 1,797 | 2,334 |
| Payables for intangible assets | 24 | 21 |
| Payables for public offering costs | — | 4,909 |
| **Supplemental disclosure of cash flow information:** | | |
| Cash and cash equivalents | 1,398,498 | 175,879 |
| Restricted cash, non-current | 743 | 510 |
| Total cash and cash equivalents and restricted cash | 1,399,241 | 176,389 |
| Interest paid | — | 157 |

*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 (the "Company") 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. The Company and its subsidiaries (collectively referred to as the "Group") are focused on developing and commercializing therapies that address medical conditions with unmet medical needs including, in particular, oncology, autoimmune disorders and infectious diseases.

The Group's principal operations and geographic markets are in mainland China (hereinafter referred to as "China"), Hong Kong, Macau and Taiwan (hereinafter collectively referred to as "Greater China"). The Group 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, 2020 condensed consolidated balance sheets 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, 2020. Interim results are not necessarily indicative of full year results and the unaudited condensed consolidated financial statements may not be indicative of the Group's future performance.

### *(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 arrangement (Note 15). 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.

### *(d) Long-term investments*

Long-term investments represent equity-method investments and equity investments with readily determinable fair values.

The Group accounts for equity investment in entities with significant influence under equity-method accounting. Under this method, the Group's pro rata share of income (loss) from investment is recognized in the consolidated statements of comprehensive income. Dividends received reduce the carrying amount of the investment. When the Group's share of loss in an equity-method investee equals or exceeds its carrying value of the investment in that entity, the Group continues to report its share of equity method losses in the statements of comprehensive income to the extent and as an adjustment to the carrying amount of its other investments in the investee. Equity-method investment is reviewed for impairment by assessing if the decline in market value of the investment below the carrying value is other-than-temporary. In making this determination, factors are evaluated in determining whether a loss in value should be recognized. These include consideration of the intent and ability of the Group to hold investment and the ability of the investee to sustain an earnings capacity, justifying the carrying amount of the investment. Impairment losses are recognized in other expense when a decline in value is deemed to be other-than-temporary.

Investments in equity securities that have readily determinable fair values (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) are measured at fair value, with unrealized gains and losses from fair value changes recognized in other (expenses) income, net in the unaudited condensed consolidated statements of operations.

**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)**

***(e) Fair value measurements***

The Group applies ASC topic 820 (“ASC 820”), Fair Value Measurements and Disclosures, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 - Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

The Group did not have any assets or liabilities that were measured at fair value on a recurring basis prior to 2021. As of September 30, 2021, information about inputs into the fair value measurement of the Group’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 September 30, 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 | 20,070 | 20,070 |

Financial instruments of the Group primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, long-term investments, accounts payable and other current liabilities. As of September 30, 2021 and December 31, 2020, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, accounts payable and other payable 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.

**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)**

***(f) Recent accounting pronouncements***

**Adopted Accounting Standards**

In December 2019, the Financial Accounting Standard Board (“FASB”) issued ASU 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. This update simplifies the accounting for income taxes as part of the FASB’s overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group adopted this standard on January 1, 2021. There was no material impact to the Group’s financial position or results of operations upon adoption.

***(g) 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, 2020.

**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 | |
|---|---|---|
| | September 30, 2021 | December 31, 2020 |
| | $ | $ |
| Cash at bank and in hand | 1,097,430 | 441,283 |
| Cash equivalents (note (i)) | 301,068 | 833 |
| | 1,398,498 | 442,116 |
| Denominated in: | | |
| US$ | 762,209 | 297,813 |
| RMB (note (ii)) | 28,802 | 23,898 |
| Hong Kong dollar (“HK$”) | 607,323 | 119,695 |
| Australian dollar (“A$”) | 134 | 710 |
| Taiwan dollar (“TW$”) | 30 | — |
| | 1,398,498 | 442,116 |

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 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 government of the People’s Republic of China (“PRC”).

**4. Restricted cash, non-current**

The Group’s restricted cash balance of $743 and $743 as of September 30, 2021 and December 31, 2020, respectively, was long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Group.

**5. Short-term investments**

Short-term investments are primarily comprised of time deposits with original maturities between three months and one year.

The Group’s short-term investments consisted entirely of short-term held to maturity debt instruments with high credit ratings, which were determined to have remote risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of September 30, 2021 and December 31, 2020, 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)**

## 6. Inventories

The Group's inventory balance of $12,494 and $13,144 as of September 30, 2021 and December 31, 2020, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline (GSK), for distribution in Hong Kong, and from NovoCure Limited ("NovoCure") and Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong and China, as well as finished goods and certain raw materials for ZEJULA commercialization in China.

| | As of | |
|---|---|---|
| | September 30, 2021 | December 31, 2020 |
| | $ | $ |
| Finished goods | 5,298 | 3,041 |
| Raw materials | 7,196 | 10,103 |
| Inventories | 12,494 | 13,144 |

The Group writes down inventory for any excess or obsolete inventories or when the Group believes that the net realizable value of inventories is less than the carrying value. During the three and nine months ended September 30, 2021, the Group recorded write-downs of $112 and $402, in cost of revenues, respectively. During the three and nine months ended September 30, 2020, the Group recorded reverses and write-downs of $7 and nil, in cost of revenues, respectively.

## 7. Long-term investments

In June 2017, the Group entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group was RMB26,250 in cash, which was paid by the Group in 2017 and 2018, representing 20% and 18% of the equity interest of JING as of December 31, 2020 and September 30, 2021 respectively. The Group accounts for this investment using the equity method of accounting due to the fact that the Group can exercise significant influence on the investee. The Group recorded its gain on deemed disposal in this investee of nil and $463 for the three months and nine months ended September 30, 2021, and recorded loss of $340 and $1,011 for its portion of JING's net loss for the three months and nine months ended September 30, 2021, respectively. The Group recorded share of loss in this investee of $265 and $671 for the three and nine months ended September 30, 2020, respectively.

In July 2021, the Group made an equity investment in MacroGenics Inc. ("MacroGenics"), a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer, in a private placement with total contributions of $30,000 and obtained 958,467 newly issued common shares of MacroGenics at $31.30 per share (see Note 15). The Group recorded this investment at acquisition cost and subsequently measured at fair value, with the changes in fair value recognized in the statement of operations. The Group recognized its fair value loss of $9,930 and $9,930 for the three and nine months ended September 30, 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)**

**8. Property and equipment, net**

Property and equipment consist of the following:

| | As of | |
|---|---|---|
| | September 30, 2021 | December 31, 2020 |
| | $ | $ |
| Office equipment | 802 | 430 |
| Electronic equipment | 3,771 | 2,646 |
| Vehicle | 217 | 143 |
| Laboratory equipment | 15,274 | 11,933 |
| Manufacturing equipment | 13,313 | 12,198 |
| Leasehold improvements | 9,909 | 9,641 |
| Construction in progress | 8,306 | 2,423 |
| | 51,592 | 39,414 |
| Less: accumulated depreciation | (14,505) | (10,252) |
| Property and equipment, net | 37,087 | 29,162 |

Depreciation expenses for the three and nine months ended September 30, 2021 were $1,510 and $4,257, respectively. Depreciation expenses for the three and nine months ended September 30, 2020 were $1,061 and $3,035, respectively.

**9. Revenue**

The Group's revenue is primarily derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The table below presents the Group's net product sales for the three and nine months ended September 30, 2021 and 2020.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| Product revenue - gross | 47,555 | 17,152 | 135,490 | 37,567 |
| Less: Rebate and sales return | (4,452) | (2,501) | (35,349) | (3,703) |
| Product revenue - net | 43,103 | 14,651 | 100,141 | 33,864 |

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

The sales rebates included nil and $22,009 compensation to distributors for those products previously sold at the price prior to the National Reimbursement Drug List ("NRDL") implementation, due to the first-time inclusion of ZEJULA in the NRDL, for the three and nine months ended September 30, 2021. There was no such compensation for the three and nine months ended September 30, 2020.

The following table disaggregates net revenue by product for the three and nine months ended September 30, 2021 and 2020:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| ZEJULA | 28,162 | 8,503 | 64,134 | 22,294 |
| Optune | 10,653 | 5,950 | 27,318 | 11,372 |
| QINLOCK | 4,288 | 198 | 8,689 | 198 |
| Product revenue - net | 43,103 | 14,651 | 100,141 | 33,864 |

**10. 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 September 30, 2021 and December 31, 2020. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

**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)**

## 11. Other current liabilities

Other current liabilities consist of the following:

| | As of | |
|---|---|---|
| | September 30, 2021 | December 31, 2020 |
| | $ | $ |
| Payroll | 18,926 | 13,694 |
| Accrued professional service fee | 3,607 | 3,128 |
| Payables for purchase of property and equipment | 1,797 | 788 |
| Accrued rebate to distributors | 10,803 | 7,067 |
| Tax payable | 10,989 | 952 |
| Others (note (i)) | 8,170 | 4,567 |
| Total | 54,292 | 30,196 |

Note:

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

## 12. Loss per share

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| Numerator: | | | | |
| Net loss attributable to ordinary shareholders | (96,412) | (63,741) | (492,646) | (192,358) |
| Denominator: | | | | |
| Weighted average number of ordinary shares- basic and diluted | 95,035,432 | 75,436,646 | 92,174,838 | 74,381,115 |
| Net loss per share - basic and diluted | (1.01) | (0.84) | (5.34) | (2.59) |

As a result of the Group's net loss for the nine months ended September 30, 2021 and 2020, 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 | |
|---|---|---|
| | September 30, 2021 | September 30, 2020 |
| Share options | 8,180,157 | 9,093,582 |
| Non-vested restricted shares | 636,619 | 597,850 |

**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)**

## 13. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of September 30, 2021:

| Company Name | Relationship with the Group |
|---|---|
| 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 and nine months ended September 30, 2021, the Group incurred $96 and $303 in research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for product research and development services, respectively. The Group incurred $233 and $417 in research and development expense for the three and nine months ended September 30, 2020, respectively. All of the transactions are carried out with normal business terms and are on arms' length basis.

## 14. 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 Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool"). Subsequently, the Board of Directors approved the increase in the Option Pool to 7,369,767 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.

For the nine months ended September 30, 2020, the Group granted 1,059,431 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $44.94 to $82.50 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five- or three-year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

For the nine months ended September 30, 2021, the Group granted 553,198 share options to certain management and employees of the Group at the exercise price ranging from $130.96 to $180.00 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 nine months ended September 30, 2021 and 2020 were $82.21and $34.91 per share, respectively. The Group recorded compensation expense related to the options of $ 19,951 and $ 15,718 for the nine months ended September 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| Selling, general and administrative | 4,119 | 2,952 | 11,501 | 8,500 |
| Research and development | 3,056 | 2,411 | 8,450 | 7,218 |
| Total | 7,175 | 5,363 | 19,951 | 15,718 |

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

As of September 30, 2021, there was $ 93,248 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 1.39 years which is determined based on the number of shares and unrecognized years.

*Non-vested restricted shares*

For the nine months ended September 30, 2020, 50,000 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the nine months ended September 30, 2020, 71,250 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the nine months ended September 30, 2021, 19,260 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the nine months ended September 30, 2021, 271,509 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

The Group 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 September 30, 2021, there was $46,885 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of $8,155 and $4,687 for the nine months ended September 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | $ | $ | $ | $ |
| Selling, general and administrative | 2,028 | 1,065 | 5,078 | 3,179 |
| Research and development | 1,353 | 550 | 3,077 | 1,508 |
| Total | 3,381 | 1,615 | 8,155 | 4,687 |

**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)**

**15. Licenses and collaborative arrangement**

The following is a description of the Group’s significant ongoing collaboration agreements for the three and nine months ended September 30, 2021.

*License and collaboration agreement with GSK*

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, Inc, a company later acquired by GSK, pursuant to which it obtained an exclusive sublicense under certain patents and know-how of GSK (including such patents and know-how licensed from Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., and AstraZeneca UK Limited) to develop, manufacture and commercialize GSK’s proprietary PARP inhibitor, niraparib, in China, Hong Kong and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer). The Group also obtained the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of niraparib being developed by GSK in the licensed territory. Under the agreement, the Group agreed not to research, develop or commercialize certain competing products, and the Group also granted GSK the right of first refusal to license certain immuno-oncology assets developed by us. In February 2018, the Group entered into an amendment with GSK that eliminated GSK’s option to co-market niraparib in the licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $15,000 and one milestone payment of $1,000, and accrued one development milestone payment of $3,500 to GSK. On top of those, if the Group achieves other specified regulatory, development and commercialization milestones, the Group may be additionally required to pay further milestone payments up to $36,000 to GSK. In addition, if the Group successfully develops and commercializes the licensed products, the Group will pay GSK tiered royalties on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

*License and collaboration agreements with MacroGenics*

In November 2018, the Group entered into a collaboration agreement with MacroGenics, pursuant to which it obtained an exclusive license under certain patents and know-how of MacroGenics to develop and commercialize margetuximab, tebotelimab (MGD-013) and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, each as an active ingredient in all human fields of use, except to the extent limited by any applicable third party agreement of MacroGenics in Greater China.

Under the terms of the agreement, the Group paid an upfront license fee of $25,000 and two milestone payments in total of $4,000 to MacroGenics. The Group also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of $136,000, and tiered royalties at percentage rates for net sales of Margetuximab, tebotelimab and TRIDENT molecule in the territory.

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

In June 2021, the Group entered into a collaboration and license agreement with MacroGenics, pursuant to which the Group and MacroGenics made four collaboration programs involving up to four immuno-oncology molecules. The first collaboration program covers a lead research molecule that incorporates MacroGenics’ DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors. The second collaboration program will cover a target to be designated by MacroGenics. For both molecules, the Group received commercial rights in Greater China, Japan, and Korea and MacroGenics received commercial rights in all other territories. For the lead molecule, the Group receives an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share. The Group also obtained exclusive, global licenses from MacroGenics to develop, manufacture and commercialize two additional molecules. For these four programs, each company will contribute intellectual property to generate either CD3- or CD47-based bispecific antibodies.

Under the terms of the agreement, the Group paid an upfront payment of $25,000 to MacroGenics. In addition, MacroGenics is also eligible to receive up to $1,386,000 in potential development, regulatory and commercial milestone payments for the four programs. If products from the collaboration are commercialized, MacroGenics would also receive royalties on annual net sales in the Group’s territories.

**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)**

Pursuant to the collaboration and license agreement, the Group also made an equity investment of $30,000 in MacroGenics’ common stock at $31.30 per share in July 2021 (see Note 7).

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

**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 Deciphera*

In June 2019, the Group entered into a license agreement with Deciphera, pursuant to which it obtained an exclusive license under certain patents and know-how of Deciphera to develop and commercialize products containing ripretinib in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in Greater China.

Under the terms of the agreement, the Group paid Deciphera an upfront license fee of $20,000 and three milestone payments of $12,000. The Group also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $173,000, and certain tiered royalties (from low-to-high teens on a percentage basis and subject to certain reductions) based on the net sales of the licensed products in the territory.

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

*License agreements with Turning Point Therapeutics Inc ("Turning Point")*

In July 2020, the Group entered into an exclusive license agreement with Turning Point pursuant to which Turning Point exclusively licensed to the Group the rights to develop and commercialize products containing repotrectinib as an active ingredient in all human therapeutic indications, in Greater China.

Under the terms of the agreements, the Group paid an upfront payment of $25,000 and one milestone payment of $2,000, and accrued two milestone payments totaling $3,000 to Turning Point. Turning Point is also eligible to receive up to $146,000 in development, regulatory and sales milestones. Turning Point will also be eligible to receive certain tiered royalties (from mid-to-high teens on a percentage basis and subject to certain reductions) based on annual net sales of repotrectinib in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Turning Point.

In January 2021, the Group entered into a license agreement with Turning Point, which expanded their collaboration. Under the terms of the new agreement, the Group obtained exclusive rights to develop and commercialize TPX-0022, Turning Point's MET, SRC and CSF1R inhibitor, in Greater China.

The Group paid an upfront license fee in the amount of $25,000 to Turning Point. The Group also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $336,000. Turning Point will also be eligible to receive certain tiered royalties (from mid-teens to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of TPX-0022 in Greater China. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology product candidate discovered by the Group.

*License and collaboration agreement with Five Prime Therapeutics, Inc. ("Five Prime")*

In December 2017, the Group entered into a license and collaboration agreement with Five Prime (a company later acquired by Amgen Inc.), pursuant to which it obtained an exclusive license under certain patents and know-how of Five Prime to develop and commercialize products containing Five Prime's proprietary afucosylated FGFR2b antibody known as bemarituzumab (FPA144) as an active ingredient in the treatment or prevention of any disease or condition in humans in Greater China.

Under the terms of the agreement, the Group made an upfront payment of $5,000 and a milestone payment of $2,000 to Five Prime. Additionally, the Group also agreed to pay further development and regulatory milestone payments of up to an aggregate of $37,000 to Five Prime and certain tiered royalties (from high-teens to low-twenties on a percentage basis and subject to certain reductions) based on the number of patients the Group enrolls in the bemarituzumab study.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Five Prime.

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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)**

*License agreement with Cullinan Pearl Corp. ("Cullinan")*

In December 2020, the Group entered into a license agreement with Cullinan, a subsidiary of Cullinan Management, Inc., formerly Cullinan Oncology, LLC, pursuant to which it obtained an exclusive license under certain patents and know-how of Cullinan to develop, manufacture and commercialize products containing CLN-081 as an active ingredient in all uses in humans and animals in Greater China.

Under the terms of the agreement, the Group paid an upfront payment of $20,000 to Cullinan. Cullinan is also eligible to receive up to $211,000 in development, regulatory and sales-based milestone payments. Cullinan is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on annual net sales of CLN-081 in Greater China.

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

*License agreement with Takeda Pharmaceutical Company Limited ("Takeda")*

In December 2020, the Group entered into an exclusive license agreement with Takeda. Under the terms of the license agreement, Takeda exclusively licensed to the Group the right to exploit products in the licensed field during the term.

Under the terms of the agreement, the Group paid an upfront payment of $6,000 to Takeda. Takeda is also eligible to receive up to $481,500 in development, regulatory and sales-based milestone payments. Takeda is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on net sales of each product sold by selling party during each year of the applicable royalty term.

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

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

In January 2021, the Group entered into a collaboration and license agreement with argenx. The Group received an exclusive license to develop and commercialize products containing argenx's proprietary antibody fragment, known as efgartigimod, in Greater China. The Group 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 Group and argenx. As the upfront payment to argenx, the Group issued 568,182 ordinary shares of the Company to argenx with par value $0.00006 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. The Group recorded this upfront payment in research and development expenses.

In addition, the Group made a non-creditable, non-refundable development cost-sharing payment of $75,000 to argenx. Argenx is also eligible to receive a cash payment of $25,000 upon the first regulatory approval of a licensed product by the U.S. Food and Drug Administration for myasthenia gravis and 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.

*Collaboration and license agreement with Mirati Therapeutics, Inc. ("Mirati")*

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

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

Under the terms of the agreement, the Group paid an upfront payment of $65,000 to Mirati. Mirati is also eligible to receive up to $273,000 in development, regulatory and sales-based milestone payments. Mirati is also eligible to receive high-teen- to low-twenties-percent tiered royalties based on annual net sales of adagrasib in Greater China.

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

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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)**

*Collaboration and license agreement with Schrödinger, Inc. (“Schrödinger”)*

In July 2021, the Group entered into a global discovery, development and commercialization collaboration with Schrödinger, pursuant to which the parties will jointly conduct a research program focused on a novel DNA damage repair program in the area of oncology. Following the selection of a development candidate, the Group will assume primary responsibility for global development, manufacturing and commercialization of the program.

Full details of the licenses and collaborative arrangements are included in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 1, 2021 and this Quarterly Report on Form 10-Q. As noted above, the Group 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 Group 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 Group up to an aggregate of approximately $4,878,738 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 Group 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.

**16. Restricted net assets**

The Group’s ability to pay dividends may depend on the Group receiving distributions of funds from its Chinese subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Group’s PRC subsidiaries only out of its retained earnings, if any, as determined in accordance with PRC 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 Group’s PRC subsidiaries.

In accordance with the Company Law of the PRC, 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 PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise’s PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group’s Chinese subsidiaries were established as domestic invested enterprise and therefore are subject to the above-mentioned restrictions on distributable profits.

During the three and nine months ended September 30, 2021 and 2020, no appropriation to statutory reserves was made because the Chinese subsidiaries had substantial losses during such periods.

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

Foreign exchange and other regulation in China may further restrict the Group’s Chinese subsidiaries from transferring funds to the Group in the form of dividends, loans and advances. As of September 30, 2021 and December 31, 2020, amounts restricted are the paid-in capital of the Group’s Chinese subsidiaries, which amounted to $306,010 and $255,858, respectively.

**17. Commitments and Contingencies**

***(a) Purchase commitments***

As of September 30, 2021, the Group’s commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statement were $24,191 which is expected to be incurred within one year.

***(b) Contingencies***

The Group 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 15).

**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)**

**18. Subsequent Event**

In November 2021, the Group and Blueprint Medicines Corporation (“Blueprint”) entered into a license and collaboration agreement, pursuant to which the Group obtained from Blueprint an exclusive license to develop, perform medical affairs for, manufacture and commercialize BLU-701 and BLU-945 in Greater China. Pursuant to the terms of the agreement, the Group will pay to Blueprint an upfront fee of $25,000 plus milestone payments of up to an aggregate of $590,000 upon the achievement of specified clinical, regulatory and sales milestones. Blueprint will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to mid teens percent on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

In November 2021, the Group and Karuna Therapeutics, Inc (“Karuna”) entered into a license agreement, pursuant to which the Group obtained from Karuna an exclusive license to develop, manufacture and commercialize KarXT in Greater China. Pursuant to the terms of the agreement, the Group will pay to Karuna an upfront fee of $35,000 plus milestone payments of up to an aggregate of $152,000 upon the achievement of specified clinical, regulatory and sales milestones. Karuna will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to high teens percent on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

In October and November 2021, the Group granted 60,066 share options to certain management and employees of the Group at the exercise price from $102.75 to $104.42 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.

In November 2021, the Group granted 92,700 share options to certain management and employees of the Group at the exercise price of $104.42 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a four-year period, with 25% of the awards vesting beginning on the anniversary date one year after the grant date.

In October and November 2021, 41,415 ordinary shares were authorized for grant to certain management and employees of the Group. 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In November 2021, 36,640 ordinary shares were authorized for grant to certain management and employees of the Group. One-fourth 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 Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In October 2021, 7,345 ordinary shares were authorized for grant to independent directors of the Group. One-third 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 directors’ service with the Group for any reason, any shares that are outstanding and not yet vested 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 China and worldwide, particularly in the areas of oncology, autoimmune disorders, and infectious diseases. As of November 9, 2021, we have three commercialized products that have received marketing approval in one or more territories in Greater China and thirteen programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires 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 three commercial products – ZEJULA, Optune and QINLOCK – 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 and totaled $274.3 million for the nine months ended September 30, 2021. 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 August 25, 2021, we announced that the Hong Kong Department of Health has approved our post-approval variation for ZEJULA, an oral, once-daily poly ADP-ribose polymerase (PARP) 1/2 inhibitor, as a maintenance treatment for adult patients with high grade serous epithelial ovarian cancer who are in a complete response or partial response to first-line platinum-based chemotherapy. Unlike other PARP inhibitors approved in Hong Kong for this setting, ZEJULA does not require BRCA mutation or other biomarker testing prior to administration.

On September 1, 2021, we announced that the Taiwan Food and Drug Administration has approved our New Drug Application (NDA) for QINLOCK for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib. QINLOCK targets the broad spectrum of KIT and PDGFRα mutations known to drive GIST.

On September 9, 2021, our partner, Novocure, announced that the United States Food and Drug Administration (FDA) granted breakthrough designation to the NovoTTF-200T System, a Tumor Treating Fields delivery system, for use with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer.

On September 14, 2021, we announced that the Center for Drug Evaluation of the National Medical Products Administration granted Breakthrough Therapy Designation for bemarituzumab for first-line treatment for patients with FGFR2b- overexpressing and human epidermal growth factor receptor (HER2)-negative metastatic and locally advanced gastric and gastroesophageal junction (GEJ) cancers in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).

On September 19, 2021, our partner, Mirati, announced results from a cohort of the Phase 1/2 KRYSTAL-1 study evaluating adagrasib at the 600mg BID dose as both monotherapy and in combination with cetuximab in patients with heavily pretreated colorectal cancer harboring a KRAS G12C mutation. Results showed that adagrasib alone and with cetuximab demonstrated significant clinical activity and broad disease control in these patients.

On September 20, 2021, our partner, Mirati, announced positive topline results from the potentially registrational Phase 2 KRYSTAL-1 study, evaluating adagrasib in a patient cohort with advanced non-small cell lung cancer harboring the KRAS G12C mutation following prior systemic therapy.

On October 4, 2021, we announced in a joint press release with our partner, Novocure, that the final patient has been enrolled in the phase 2 pilot trial of Tumor Treating Fields in combination with chemotherapy as a first-line treatment in patients with gastric adenocarcinoma. Final data collection is expected in the first half of 2022.

On October 4, 2021, our partner, Turning Point, announced the FDA granted a Breakthrough Therapy Designation to repotrectinib for the treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK tyrosine kinase inhibitors, with or without prior chemotherapy, and have no satisfactory alternative treatments.

On October 5, 2021, we announced that the bridging study of margetuximab plus chemotherapy in advanced, previously treated HER2+ breast cancer met its primary endpoint, with acceptable safety and tolerability. The study showed that efficacy of this combination in Chinese patients was consistent with that seen in the global population in the SOPHIA trial conducted by Zai Lab's partner MacroGenics.

On October 19, 2021, we, together with our partner Entasis Therapeutics Holdings Inc., announced positive topline readout of the global registrational Phase 3 ATTACK clinical trial in Acinetobacter infections. NDA submission to the FDA is planned for mid-2022. Acinetobacter baumannii.

On October 20, 2021, we announced ZL-1102 achieved proof-of-concept in the Phase 1b psoriasis study. Topical therapy with ZL-1102 resulted in clinical improvement in local PASI score, erythema and scaling, target lesion size and responder rates in patients with mild-to-moderate chronic plaque psoriasis. Consistent improvement was seen over time.

On October 25, 2021, we announced first patient treated in the Greater China portion of the global, potentially pivotal Phase 2 program of odronextamab.

On November 5, 2021, Deciphera Pharmaceuticals, Inc., our partner, issued a press release announcing top-line results from the INTRIGUE Phase 3 clinical study of QINLOCK in patients with gastrointestinal stromal tumor (GIST) previously treated with imatinib. The INTRIGUE Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. The study did not meet the primary endpoint of improved progression-free survival (PFS) compared with the standard of care sunitinib. We do not anticipate that the INTRIGUE study results will have a material effect on the current operations of the Company.

On November 9, 2021, we announced that we entered into a license and collaboration agreement with Blueprint Medicines Corporation ("Blueprint"), pursuant to which we agreed to collaboratively develop BLU-701 and BLU-945 in China, Macau, Hong Kong, and Taiwan. Under the agreement, the Company obtained from Blueprint an exclusive license to develop, perform medical affairs for, manufacture and commercialize BLU-701 and BLU-945 in the licensed territory.

On November 9, 2021, we also announced that we entered into a license agreement with Karuna Therapeutics, Inc. ("Karuna"), pursuant to which we agreed to collaboratively develop KarXT in China, Macau, Hong Kong, and Taiwan. Under the agreement, the Company obtained from Karuna an exclusive license to develop, manufacture and commercialize KarXT in the licensed territory.

*Recent Legal and Regulatory Developments*

Potential CSRC Approval Required

On July 6, 2021, the relevant Chinese government authorities published the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities and increased supervision of overseas listings by China-based companies, and propose to take effective measures, such as promoting the construction of relevant regulatory systems to regulate the risks and incidents faced by China-based overseas-listed companies. To date, no official guidance or related implementation rules have been issued in relation to these recently issued opinions and the interpretation and implementation of these opinions remain unclear at this stage. Based on existing Chinese laws and regulations, we are currently not required to obtain any pre-approval from the CSRC to issue our ADSs or ordinary shares to foreign investors, subject to interpretation of the existing Chinese laws and regulations by the Chinese government authorities. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future.

Proposed Cybersecurity Measures

On July 10, 2021, the Cyberspace Administration of China published the draft amendment to the Cybersecurity Review Measures (Revised Draft for Comment), which is expected to replace the current Cybersecurity Review Measures after it is adopted and becomes effective. The draft measures stipulate that, among other items, if an issuer is classified as a "critical information infrastructure operator" or a "data processing operator" as defined therein and such issuer possesses the personal information of more than one million users and intends to be listed on a securities exchange in a foreign country, it must complete a cybersecurity review. Alternatively, relevant governmental authorities in China may initiate a cybersecurity review if such governmental authorities determine an operator's cyber products or services, data processing or potential listing in a foreign country affect or may affect national security. The draft measures were released for public comment only, and the draft provisions and anticipated adoption or effective date are subject to changes and thus its interpretation and implementation remain substantially uncertain. We cannot predict the impact of the draft measures, if any, on the operations of our Company at this stage, and we will closely monitor and assess any development in the rule-making process.

The exact scope of "critical information infrastructure operators" and "data processing operators" under the draft measures and the current regulatory regime remains unclear, and the Chinese government authorities may have wide discretion in the interpretation and enforcement of these laws. Currently, the draft measures have not materially affected our business and operations. We maintain personally identifiable health information of patients in China in limited situations. As of the date of this Quarterly Report on Form 10-Q, we have not been informed by any relevant Chinese government authorities that we are identified as or considered a "critical information infrastructure operator" or "data processing operator." We are also not aware of any requirement that we should file for a cybersecurity review, nor have we received any inquiry, notice, warning, sanction in such respect or any regulatory objections. However, in anticipation of the strengthened implementation of cybersecurity laws and regulations, there can be no assurance that we will not be deemed as a critical information infrastructure operator or data processing operator under the Chinese cybersecurity laws and regulations in the future, or that the draft measures will not be further amended or other laws or regulations will not be promulgated to subject us to the cybersecurity review or other compliance requirements. In such case, we may face challenges in addressing such enhanced regulatory requirements.

Multi-Level Protection Scheme

The Cyber Security Law of China provides that China adopts a multi-level protection scheme (MLPS), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, an entity's operating information system must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network system belong—from the lowest Level 1 to the highest Level 5 pursuant to the Measures for the Graded Protection and the Guidelines for Grading of Classified Protection of Cyber Security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval. In August and September 2021, Zai Lab (Shanghai) Co., Ltd. received Level 2 registration certificates for its WeChat mini-program and e-order system from the Shanghai Municipal Public Security Bureau.

PRC Personal Information Protection Law

On August 20, 2021, the Standing Committee of the National People's Congress promulgated the PRC Personal Information Protection Law (PIPL), which became effective on November 1, 2021. The PIPL establishes a comprehensive framework of data privacy and protection requirements and obligations for the processing of personal information, which not only targets the processing of personal information within the territory of China, but also governs the exterritorial processing of Chinese personal information if such processing is for the purpose of providing products or services to persons in China, or to analyze or evaluate behaviors of persons in China. The PIPL provides that any entity that processes personal information shall take various measures to prevent the disclosure, modification or losing of the personal information processed by such entity, including, but not limited to, formulating a related internal management system and standard of operation, conducting classified management of personal information, taking safety technology measures to encrypt and de-identify the processed personal information, providing regular safety training and education for staff and formulating a personal information safety emergency accident plan. The PIPL, the Cyber Security Law, together with other industry-specific laws and regulations, require us to obtain consent from clinical trial subjects, customers, employees, and other individuals before collecting their personal information, including personal health information, take measures to keep such personal information secure and confidential, and promptly report security breaches involving personal information to the appropriate Chinese regulators. The PIPL further provides that a personal information processer shall conduct a prior evaluation of the impact of personal information protection before the occurrence of various situations, including, but not limited to, processing of sensitive personal information (personal information that, once leaked or illegally used, may lead to discrimination against an individual or serious harm to an individual's personal or property safety, including information on an individual's race, ethnicity, religious beliefs, personal biological characteristics, medical health information, financial accounts, or personal whereabouts), using personal information to make automated decisions and providing personal information to any overseas entity. Violations of the PIPL may trigger significant penalties, including but not limited to fines of up to RMB 50 million or 5% of the annual revenues of the prior year, and/or revocation of the entity's business license and/or relevant permits if the case is serious.

Measures on Security Assessment of Cross-Border Data Transfer (Draft for Comment)

On October 29, 2021, the Cyberspace Administration of China published the Measures on Security Assessment of Cross-border Data Transfer (Draft for Comment) (the "Draft Measures"). The Draft Measures are enacted in accordance with the Cyber Security Law, the Data Security Law and the PIPL. Under the Draft Measures, a data processor would be subject to mandatory security assessment for transfers of data out of China under any of the following circumstances: (i) the cross-border transfer is of personal information and important data collected and generated by critical information infrastructure operators; (ii) the cross-border transfer includes important data; (iii) the cross-border transfer includes personal information of more than one million individuals; and (iv) the cross-border transfer includes personal information of cumulatively more than 100,000 individuals or sensitive personal information of more than 10,000 individuals.

**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 September 30, 2021.

To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, a secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through September 30, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, our secondary listing and our follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $396.2 million and $171.7 million, for the nine months ended September 30, 2021 and September 30, 2020, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our thirteen late-stage clinical product candidates and continue research and development of 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 payments to 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 compensation charges, increased product distribution and promotion costs, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

**Our Ability to Commercialize Our Product Candidates**

As of September 30, 2021, twelve of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in 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 $274.3 million for the nine months ended September 30, 2021 and $5.1 million for the three months ended September 30, 2021. The upfront payments and milestone payments are recorded in research and development expense and was $77.6 million for the nine months ended September 30, 2020 and $25.9 million for the three months ended September 30, 2020.

**Key Components of Results of Operations**

**Taxation**

***Cayman Islands***

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see “Taxation-Material Cayman Islands Taxation” in our Annual Report on Form 10-K for the year ended December 31, 2020.

***People’s Republic of China***

Our subsidiaries incorporated in China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see “Taxation-Material People’s Republic of China Taxation” in our Annual Report on Form 10-K for the year ended December 31, 2020.

***Hong Kong***

Our subsidiaries incorporated in Hong Kong are subject to two-tiered tax rates for the nine months ended September 30, 2021 and 2020 on assessable profits earned in Hong Kong where the profits tax rate for the first HK$2 million of assessable profits is subject to profits tax rate of 8.25% and the assessable profits above HK$2 million is subject to profits tax rate of 16.5%. Our subsidiaries incorporated in Hong Kong did not have assessable profit for the nine months ended September 30, 2021 and 2020.

**Results of Operations**

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

| | Three months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| (in thousands, except share and per share data) | 2021 | 2020 | 2021 | 2020 |
| **Comprehensive Loss Data:** | | | | |
| Revenue | $ 43,103 | $ 14,651 | $ 100,141 | $ 33,864 |
| Expenses: | | | | |
| Cost of sales | (12,162) | (4,934) | (30,535) | (9,914) |
| Research and development | (55,144) | (58,100) | (401,220) | (160,149) |
| Selling, general and administrative | (59,002) | (27,874) | (149,254) | (70,346) |
| Loss from operations | $ (83,205) | $ (76,257) | $ (480,868) | $ (206,545) |
| Interest income | 713 | 866 | 1,171 | 3,748 |
| Interest expenses | — | (43) | — | (157) |
| Other (expenses) income, net | (13,580) | 11,958 | (12,401) | 11,267 |
| Loss before income tax and share of loss from equity method investment | $ (96,072) | $ (63,476) | $ (492,098) | $ (191,687) |
| Income tax expense | — | — | — | — |
| Share of loss from equity method investment | (340) | (265) | (548) | (671) |
| Net loss attributable to ordinary shareholders | $ (96,412) | $ (63,741) | $ (492,646) | $ (192,358) |
| Weighted-average shares used in calculating net loss per ordinary share, basic and diluted | 95,035,432 | 75,436,646 | 92,174,838 | 74,381,115 |
| Net loss per share, basic and diluted | $ (1.01) | $ (0.84) | $ (5.34) | $ (2.59) |

***Three Months Ended September 30, 2021 Compared to Three Months Ended September 30, 2020***

***Revenue***

Our revenue is primarily derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The following table disaggregates net revenue by product for the three months ended September 30, 2021 and 2020:

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| ZEJULA | $28,162 | 65.3% | $ 8,503 | 58.0% |
| Optune | 10,653 | 24.7% | 5,950 | 40.6% |
| QINLOCK | 4,288 | 10.0% | 198 | 1.4% |
| **Total product revenue—Net** | $43,103 | 100.0% | $14,651 | 100.0% |

***Research and Development Expenses***

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

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Research and Development Expenses:** | | | | |
| Personnel compensation and related costs | $20,564 | 37.3% | $12,204 | 21.0% |
| Licensing fees | 5,051 | 9.2% | 25,911 | 44.6% |
| Payment to CROs/CMOs/Investigators | 17,102 | 31.0% | 14,414 | 24.8% |
| Other costs | 12,427 | 22.5% | 5,571 | 9.6% |
| **Total** | $55,144 | 100.0% | $58,100 | 100.0% |

Research and development expenses decreased by $3.0 million to $55.1 million for the three months ended September 30, 2021 from $58.1 million for the three months ended September 30, 2020. The decrease in research and development expenses included the following:

- $20.9 million for decreased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees; and partially offset by,
- $8.4 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the three months ended September 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $2.7 million for increased payment to CROs, CMOs and investigators in the three months ended September 30, 2021 as we advanced our drug candidate pipeline; and
- $6.8 million for increased lab consumables and other costs in the three months ended September 30, 2021.

The following table summarizes our research and development expenses by program for the three months ended September 30, 2021 and 2020, respectively:

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Research and Development Expenses:** | | | | |
| Clinical programs | $20,248 | 36.7% | $39,736 | 68.4% |
| Pre-clinical programs | 9,988 | 18.1% | 2,728 | 4.7% |
| Unallocated research and development expenses | 24,908 | 45.2% | 15,636 | 26.9% |
| **Total** | $55,144 | 100.0% | $58,100 | 100.0% |

During the three months ended September 30, 2021, 36.7% and 18.1% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the three months ended September 30, 2020, 68.4% and 4.7% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. 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 periods indicated.

| | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Selling, General and Administrative Expenses:** | | | | |
| Personnel compensation and related costs | $34,088 | 57.8% | $15,869 | 56.9% |
| Professional service fees | 6,194 | 10.5% | 2,258 | 8.1% |
| Other costs | 18,720 | 31.7% | 9,747 | 35.0% |
| **Total** | $59,002 | 100.0% | $27,874 | 100.0% |

Selling, general and administrative expenses increased by $31.1 million to $59.0 million for the three months ended September 30, 2021 from $27.9 million for the three months ended September 30, 2020. The increase in general and administrative expenses included the following:

- $18.2 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during the three months ended September 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $3.9 million for increased professional service fees, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company; and
- $9.0 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to commercial operations in Hong Kong and China.

***Interest Income***

Interest income decreased by $0.2 million, to $0.7 million for the three months ended September 30, 2021, from $0.9 million for the three months ended September 30, 2020, primarily due to the decrease in both short-term investment balances and interest rates.

***Interest Expenses***

Interest expenses are nil for the three months ended September 30, 2021, compared to $42.5 thousand for the three months ended September 30, 2020, as all the short-term borrowings were repaid in December 2020.

***Other (Expenses) Income, net***

Other expenses were $13.6 million for the three months ended September 30, 2021, as compared to other income of $12.0 million for the three months ended September 30, 2020, primarily as a result of the foreign exchange loss for the three months ended September 30, 2021, compared with foreign exchange gain for the three months ended September 30, 2020, and the fair value loss of $9.9 million for the equity investment in MacroGenics.

***Share of loss from equity method investment***

In June 2017, we entered into an agreement with three third-parties to launch JING, an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. We recorded a loss of $0.3 million and $0.3 million for our portion of this investee’s net loss for the three months ended September 30, 2021 and 2020, respectively.

***Net Loss Attributable to Ordinary Shareholders***

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $96.4 million for the three months ended September 30, 2021 compared to net loss attributable to ordinary shareholders of $63.7 million for the three months ended September 30, 2020.

***Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020***

***Revenue***

Our revenue is primarily derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The amount of revenue from ZEJULA for the nine months ended September 30, 2021 was adjusted in accordance with the normal process in 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 nine months ended September 30, 2021 and 2020:

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| **(in thousands)** | **2021** | **%** | **2020** | **%** |
| ZEJULA | $ 64,134 | 64.0% | $22,294 | 65.8% |
| Optune | 27,318 | 27.3% | 11,372 | 33.6% |
| QINLOCK | 8,689 | 8.7% | 198 | 0.6% |
| **Total product revenue—Net** | $100,141 | 100.0% | $33,864 | 100.0% |

***Research and Development Expenses***

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

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| **(in thousands)** | **2021** | **%** | **2020** | **%** |
| **Research and Development Expenses:** | | | | |
| Personnel compensation and related costs | $ 50,543 | 12.6% | $ 33,804 | 21.1% |
| Licensing fees | 274,299 | 68.4% | 77,631 | 48.5% |
| Payment to CROs/CMOs/Investigators | 52,246 | 13.0% | 34,226 | 21.4% |
| Other costs | 24,132 | 6.0% | 14,488 | 9.0% |
| **Total** | $401,220 | 100.0% | $160,149 | 100.0% |

Research and development expenses increased by $241.1 million to $401.2 million for the nine months ended September 30, 2021 from $160.1 million for the nine months ended September 30, 2020. The increase in research and development expenses included the following:

- $16.7 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the nine months ended September 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $196.7 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees;
- $18.0 million for increased payment to CROs, CMOs and investigators in the nine months ended September 30, 2021 as we advanced our drug candidate pipeline; and
- $9.7 million for increased lab consumables and other costs in the nine months ended September 30, 2021.

The following table summarizes our research and development expenses by program for the nine months ended September 30, 2021 and 2020, respectively:

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| **(in thousands)** | **2021** | **%** | **2020** | **%** |
| **Research and Development Expenses:** | | | | |
| Clinical programs | $299,937 | 74.8% | $112,071 | 70.0% |
| Pre-clinical programs | 41,033 | 10.2% | 5,643 | 3.5% |
| Unallocated research and development expenses | 60,250 | 15.0% | 42,435 | 26.5% |
| **Total** | $401,220 | 100.0% | $160,149 | 100.0% |

During the nine months ended September 30, 2021, 74.8% and 10.2% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the nine months ended September 30, 2020, 70.0% and 3.5% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. 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 periods indicated.

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| **(in thousands)** | **2021** | **%** | **2020** | **%** |
| **Selling, General and Administrative Expenses:** | | | | |
| Personnel compensation and related costs | $ 87,560 | 58.7% | $42,951 | 61.1% |
| Professional service fees | 14,583 | 9.8% | 6,828 | 9.7% |
| Other costs | 47,111 | 31.5% | 20,567 | 29.2% |
| **Total** | $149,254 | 100.0% | $70,346 | 100.0% |

Selling, general and administrative expenses increased by $78.9 million to $149.3 million for the nine months ended September 30, 2021 from $70.4 million for the nine months ended September 30, 2020. The increase in general and administrative expenses included the following:

- $44.6 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during the nine months ended September 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $7.8 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company; and
- $26.5 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and China.

***Interest Income***

Interest income decreased by $2.5 million to $1.2 million for the nine months ended September 30, 2021, from $3.7 million for the nine months ended September 30, 2020, primarily due to both the decrease in short-term investment balances and interest rates.

***Interest Expenses***

Interest expenses are nil for the nine months ended September 30, 2021, compared to $0.2 million for the nine months ended September 30, 2020, as all the short-term borrowings were repaid in December 2020.

***Other (Expenses) Income, net***

Other expenses were $12.4 million for the nine months ended September 30, 2021, as compared to other income of $11.3 million for the nine months ended September 30, 2020, primarily as a result of the foreign exchange loss for the nine months ended September 30, 2021, compared with the foreign exchange gain for the nine months ended September 30, 2020, and the fair value loss of $9.9 million for the equity investment in MacroGenics.

***Share of loss from equity method investment***

In June 2017, we entered into an agreement with three third-parties to launch an entity that will provide services for product discovery and development, consultation and transfer of pharmaceutical technology. We recorded the gain on deemed disposal in this investee of $0.5 million and share of loss of $1.0 million for the nine months ended September 30, 2021, and recorded our share of loss in this investee of $0.7 million for the nine months ended September 30, 2020.

***Net Loss Attributable to Ordinary Shareholders***

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $492.6 million for the nine months ended September 30, 2021 compared to net loss attributable to ordinary shareholders of $192.4 million for the nine months ended September 30, 2020.

**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 continually 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***

In 2018, we adopted ASC Topic 606 (“ASC 606”), *Revenue from Contracts with Customers*, in recognition of revenue. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Our revenue is primary from product sales. We recognize revenue from product sales when we have satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the customers. Cost of sales mainly consists of the acquisition cost of products and royalty fees.

We have applied the practical expedients under ASC 606 with regard to assessment of financing components and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less. We have generated product sales revenue since 2018. Our product revenues were primarily generated from the sale of ZEJULA, Optune and QINLOCK to customers.

In China, we sell the 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. 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.

In Hong Kong, we sell the products to customers, which are typically healthcare providers such as oncology centers. We utilize a third party for warehousing services. Based on the nature of the arrangement, we have determined that we are a principal in the transaction since we are primarily responsible for fulfilling the promise to provide the products to the customers, maintain inventory risk until delivery to the customers and have latitude in establishing the price. Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

We did not recognize any contract assets and contract liabilities as of September 30, 2021 and December 31, 2020.

***Share-Based Compensation***

We grant share options and non-vested restricted shares to eligible employees, management and directors and account for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation*. 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. We determined the fair value of the stock options granted to employees using the Black-Scholes option valuation model.

We also grant share options to eligible non-employees and account for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation*. Non-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. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determined the fair value of the stock options granted to non-employees using the Black-Scholes option valuation model.

***Fair Value Measurements***

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Include other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches, for example, to measuring the fair value of assets and liabilities: (1) market approach, (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

We did not have any assets or liabilities that were measured at fair value on a recurring basis prior to 2021. As of September 30, 2021, information about inputs into the fair value measurement of our assets that are measured at a fair value on a recurring basis in periods subsequent to their initial recognition is as follows:

| Description<br>(in thousands) | Fair Value as of September 30, 2021 | Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) |
|---|---|---|
| Equity Investments with Readily Determinable Fair Value | $ 20,070 | $ 20,070 |

Financial instruments of our company primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, long-term investments, accounts payable and other current liabilities. As of each reporting date, the carrying values of cash and cash equivalents, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, 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 and the assessment of the ability to recover these amounts.

***Income Taxes***

Current income taxes are provided on the basis of net income for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions. We follow the liability method of accounting for income taxes.

Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statements carrying amounts and tax bases of assets and liabilities by applying enacted statutory tax rates that will be in effect in the period in which the temporary differences are expected to reverse. We record a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in our consolidated financial statements in the period of change.

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.

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.

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 September 30, 2021 and December 31, 2020, we did not have any significant unrecognized uncertain tax positions.

**B. Liquidity and Capital Resources**

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering on the Nasdaq stock exchange, our September 2020 secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through September 30, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, subsequent follow-on offerings, and our secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $396.2 million and $171.7 million, for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, we had cash, cash equivalents, restricted cash and short-term investment of $1,569.2 million. Our expenditures, as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash and cash equivalents as of November 9, 2021, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the unaudited condensed financial statements included in this Quarterly Report are issued. 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 nine months ended September 30, 2021 and 2020:

| | Nine months ended September 30, | |
|---|---|---|
| **(in thousands)** | **2021** | **2020** |
| Net cash used in operating activities | $(396,237) | $ (171,720) |
| Net cash provided by (used in) investing activities | 531,446 | (754,881) |
| Net cash provided by financing activities | 820,478 | 1,024,486 |
| Effect of foreign exchange rate changes | 695 | 2,062 |
| Net increases in cash, cash equivalents and restricted cash | $ 956,382 | $ 99,947 |

***Net cash used in operating activities***

During the nine months ended September 30, 2021, our operating activities used $396.2 million of cash, which resulted principally from our net loss of $492.6 million, adjusted for non-cash charges of $110.2 million, and cash used in our operating assets and liabilities of $13.8 million. Our net non-cash charges during the nine months ended September 30, 2021 primarily consisted of $62.3 million non-cash research and development expenses, a $4.6 million depreciation and amortization expenses, a $28.1 million share-based compensation expense, a $9.9 million loss from fair value changes of equity investment with readily determinable fair value and a $4.6 million non-cash lease expense.

***Net cash provided by (used in) investing activities***

Net cash provided by investing activities was $531.4 million for the nine months ended September 30, 2021 compared to net cash used in investing activities of $754.9 million for the nine months ended September 30, 2020. The increase in cash provided by investing activities was primarily due to the proceeds from maturity of short-term investments.

***Net cash provided by financing activities***

Net cash provided by financing activities was $820.5 million for the nine months ended September 30, 2021 compared to $1,024.5 million for the nine months ended September 30, 2020. The decrease in cash provided by financing activities was primarily due to the reduced proceeds from the issuance of ADSs in our follow-on offering during the nine months ended September 30, 2021, compared with our secondary listing in September 2020.

**C. Research and Development, Patents and Licenses, etc.**

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.

**E. Off-balance Sheet Arrangements**

We currently do not engage in trading activities involving non-exchange traded contracts or interest rate swap transactions or foreign currency forward contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

**F. Tabular Disclosure of Contractual Obligations**

The following table sets forth our contractual obligations as of September 30, 2021. Amounts we pay in future periods may vary from those reflected in the table.

| (in thousands) | Total | Less than 1 year | 1 to 3 years | 3 to 5 years | More than 5 years |
|---|---|---|---|---|---|
| Purchase Obligations | $24,191 | $24,191 | $ — | $ — | $ — |
| Operating Lease Obligations | 17,497 | 6,573 | 5,349 | 4,160 | 1,415 |

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones as well as tiered royalties on net sales. We have not included these commitments on our balance sheet or in the table above because the commitments are cancellable if the milestones are not complete and achievement and timing of these obligations are not fixed or determinable.

***Recently Issued Accounting Standards***

For more information regarding recently issued accounting standards, please see "Part II—Item 8—Financial Statements and Supplementary Data—Recent accounting pronouncements" in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

**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 our company included aggregated amounts of RMB 186.8 million and RMB 155.9 million, which were denominated in RMB, as of September 30, 2021 and December 31, 2020, respectively, representing 2% and 5% of the cash and cash equivalents as of September 30, 2021 and December 31, 2020, respectively.

Our business mainly operates in 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 any significant direct foreign exchange risk and have not used any 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 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, China 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 China's 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.

A significant portion of our cash is kept in Hong Kong dollars (HK dollars) as well as U.S. dollars. The value of our ADSs will, therefore, 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 group's 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 group's assets denominated in HK dollars will be adversely affected.

***Credit Risk***

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents and short-term investment. The carrying amounts of cash and cash equivalents and short-term investment represent the maximum amount of loss due to credit risk. As of September 30, 2021 and December 31, 2020, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in China and international financial institutions outside of China which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

***Inflation***

In recent years, 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 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, 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 September 30, 2021, 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 Securities Exchange Act of 1934, as amended). 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 September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

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

During the nine months ended September 30, 2021, 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 Securities Exchange Act of 1934, as amended) 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.**

There have been no material changes from the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021, except as set forth in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, and as set forth below:

***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 U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. We conduct preclinical and clinical activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ordinary shares and/or our ADSs or prevent us from selling our drug products in certain countries.

Furthermore, the SEC has issued statements primarily focused on companies with significant China-based operations, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with a Variable Interest Entity, or a VIE, structure. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations in China. Further, we believe that we have robust disclosures relating to our operations in China, including the relevant risks noted in Chairman Gensler's statement. However, the Company's periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

***The audit report included in our annual reports are prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or 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.***

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

Inspections of auditors conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China 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 and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on Our Exchanges Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges, such as the Nasdaq, of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted.

Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act (HFCA Act), which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction and to prohibit the securities of such issuers that have has three consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020.

Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and departments with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks.

On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act (AHFCA Act), which amends the requirements of the HFCA Act to require that the SEC identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by any non-U.S. authority and to prohibit the securities of such issuers that have had two consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq.

On September 22, 2021, the PCAOB adopted PCAOB Rule 6100, *Board Determinations Under the Holding Foreign Companies Accountable Act*, implementing the HFCA Act, which provides a framework for the PCAOB to determine that it is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. 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. Chairman Gensler emphasized, in his October 5, 2021 testimony before the House Committee on Financial Services, that the PCAOB's adoption of Rule 6100 was "an important step to meet its requirements under the [HFCA Act] to protect U.S. investors;" that "we remain on track to finalize its required rulemaking before the end of the year;" and that "it is critical that the [Securities and Exchange] Commission and the PCAOB work together to ensure that the audits of foreign companies accessing U.S. capital markets play by the same rules." On November 5, 2021, the SEC announced that it has approved Rule 6100.

Under the HFCA Act (and, if enacted into law, the AHFCA Act), 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 (or, if the AHFCA Act is passed, two consecutive years), and this ultimately could result in our ADSs being delisted, which would materially adversely affect the Company.

Additionally, in October 2021, Nasdaq adopted additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer, or a Restrictive Market. Under the new rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by the Nasdaq to be a Restrictive Market. And China will likely be determined to be a Restrictive Market and, as a result, the Nasdaq may impose on us additional listing criteria or deny continued listing of our securities on the Nasdaq.

There can be no assurance that we or our auditor will be able to comply with the requirements imposed by Nasdaq or the U.S. regulators. We are evaluating, designing, and implementing additional business processes and control changes to meet the requirements of the HFCA Act which we believe will enable us to engage an independent public accounting firm that satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements, subject to compliance with SEC and other requirements prior to the three-year (or two-year under the AHFCA Act) deadline of the HFCA Act. However, any business processes and control changes that we may implement may not be sufficient or may take time for us to implement and they ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act (or, if enacted into law, the AHFCA Act). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong or may incur increased costs or suffer losses in order to do so. The market price of our ADSs could be materially adversely affected as a result of anticipated negative impacts of these rules and executive, regulatory or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these rules and executive, regulatory or legislative actions are implemented and regardless of our actual operating performance. Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs and ordinary shares.

***Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate in Greater China and other Asian markets have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law of the People's Republic of China, or the Cyber Security Law, which became effective in June 2017, created China's first national-level data protection regime for "network operators," which may include all organizations in China that provide services over the internet or another information network.

We maintain personally identifiable health information of patients in China in limited situations. We also collect and maintain de-identified or psuedonymized health data for clinical trials in compliance with local regulations. This data could be deemed as personal data or important data. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or psuedonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, the Data Security Law (as defined below), the Personal Information Protection Law (as defined below), and various implementing regulations and standards.

Under the Cyber Security Law and the Measures on Standard, Safety and Service of the National Medical Care Big Data (Tentative), or the Measures on Health and Medical Big Data, the transmission of certain personal information, important data and health and medical care big data outside of China is only permitted upon the completion of a security assessment conducted by or as determined by the Chinese government. Certain draft regulations, including the Measures for Security Assessment for Cross-border Transfer of Personal Information and Important Data (Draft for Comment), published in 2017, and the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, have been proposed by the Chinese government that specify the procedures and stipulate more detailed compliance requirements relating to such assessment, and in certain circumstances, government approval, prior to the transmission of such information and data outside of China.

In addition, the Standing Committee of the National People's Congress of the People's Republic of China, or the SCNPC, promulgated the Data Security Law of the People's Republic of China, or the Data Security Law, on June 10, 2021, which became effective on September 1, 2021. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and introduces a data classification and hierarchical protection system. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the PIPL which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We will be obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not fully guard us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we face. Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of important data, and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in China with judicial and law enforcement authorities outside of China. If judicial and law enforcement authorities outside China require us to provide data stored in China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impact on our operations in and outside of China.

Furthermore, in July 2021, the Cybersecurity Administration of China, China's top cyberspace regulator, issued a proposed amendment to the Cybersecurity Review Measures, or the Cybersecurity Review Measures, which have been in effect since June 1, 2020. Under the proposed amendment, the scope of entities required to undergo cybersecurity review to assess national security risks that arise from data processing activities would be expanded to include all critical information infrastructure operators who purchase network products and services and all data processors carrying out data processing activities that affect or may affect national security. In addition, the draft amendment proposed that all such entities that maintain or store the personal information of more than 1 million users and undertake a public listing of securities in a foreign country would be required to pass cybersecurity review, which would focus on the potential risk of core data, important data, or a large amount of personal information being stolen, leaked, destroyed, illegally used or exported out of China, or critical information infrastructure being affected, controlled or maliciously used by foreign governments after such a listing.

On October 29, 2021, the Cyberspace Administration of China ("CAC") published the Measures on Security Assessment of Cross-border Data Transfers (Draft for Comment) (the "Draft Measures"). The Draft Measures are enacted in accordance with the Cyber Security Law, the Data Security Law and the PIPL. Under the Draft Measures, a data processor would be subject to mandatory security assessment for transfers of data out of China under any of the following circumstances: (i) the cross-border transfer is of personal information and important data collected and generated by critical information infrastructure operators; (ii) the cross-border transfer includes important data; (iii) the cross-border transfer includes personal information of more than one million individuals; and (iv) the cross-border transfer includes personal information of cumulatively more than 100,000 individuals or sensitive personal information of more than 10,000 individuals.

The national security legal regime imposes stricter data localization requirements on personal information and human health-related data and requires us to undergo cybersecurity or other security review, obtain government approval or certification, or put in place certain contractual protections before transferring personal information and human health-related data out of China. As a result, personal information, important data and health and medical data that we or our customers, vendors, clinical trial sites, pharmaceutical partners and other third parties collect, generate or process in China may be subject to such data localization requirements and heightened regulatory oversight and controls. To comply with these requirements, maintaining local data centers in China, conducting security assessments or obtaining the requisite approvals from the Chinese government for the transmission outside of China of such controlled information and data could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside China. We expect that the evolving regulatory interpretation and enforcement of the national security legal regime will lead to increased operational and compliance costs and will require us to continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss of use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of China, be unable to comply with our contractual requirements, suffer reputational harm or be subject to penalties, including administrative, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. If any of these were to occur, it could adversely affect our ability to operate our business and our financial results.

The General Office of the State Council passed the Scientific Data Administrative Measures in March 2018, which provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality and security of scientific data. Scientific data is defined as data generated from basic research, applied research, experiments and developments in the fields of natural sciences, engineering and technology. It also includes the original and derived data by means of surveillance, monitoring, field studies, examination and testing that are used in scientific research activities. All scientific data generated by research entities, including research institutions, higher education institutions and enterprises that is created or managed with government funds, or funded by any source that concerns state secrets, national security, or social and public interests, must be submitted to data centers designated by the Chinese government for consolidation. Disclosure of scientific data will be subject to regulatory scrutiny.

The definition of scientific data is quite broad, but the Chinese government has not issued further guidance to clarify if clinical study data would fall within the definition of scientific data. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data centers, or prevented the cross-border transmission and sharing of clinical study data. We plan to closely monitor legal and regulatory developments in this area to see how scientific data is interpreted, and we may be required to comply with additional regulatory requirements for sharing clinical study data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the Regulation on the Administration of Human Genetic Resources, or the HGR Regulation, promulgated by the State Council of the People's Republic of China, or the State Council, which became effective on July 1, 2019, applies to activities that involve collection; biobanking; use of HGR, which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substance and derived data in China, (collectively, the China-Sourced HGR), and provision of such items to foreign parties or entities established or actually controlled by them. The HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR out of China. Chinese parties are required to seek an advance approval for the collection and biobanking of all China-Sourced HGR. Approval for any export or cross-border transfer of China-Sourced HGR in the form of biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the Human Genetic Resources Administration of China ("HGRAC") for record and obtain a notification filing number in order to transfer. The HGR Regulation also requires that foreign parties or entities established or actually controlled by them ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

If the Chinese parties fail to comply with data privacy and cybersecurity laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, we may lose our confidential information and be subject to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGRAC has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any clinical trial applications until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multinational pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAC approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of 6 to 12 months, respectively.

To further tighten the control of China-Sourced HGR, the SCNPC issued the Eleventh Amendment to the Criminal Law of the People's Republic of China on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR and the illegal transfer of China-sourced biospecimens outside of China. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to seven years and/or a criminal fine. In October 2020, the SCNPC adopted the Biosecurity Law of the People's Republic of China, or the PRC Biosecurity Law, which became effective on April 15, 2021. The PRC Biosecurity Law will establish an integrated system to regulate biosecurity-related activities in China, including, among others, the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time expressly declares that China has sovereignty over its HGR, and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of China-Sourced HGR by foreign parties or entities established or actually controlled by them in China. Though the PRC Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulator of HGR, the Ministry of Science and Technology, or MOST, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In addition, in the United States, at both the federal and state levels, and in territories outside of China where we have rights to and plan to develop and commercialize our in-licensed product candidates, we are subject to laws and regulations that address privacy, personal information protection and data security. Numerous laws and regulations, including security breach notification laws, health information privacy laws and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

We expect that these data privacy and cybersecurity laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under data protection, privacy and security laws in Greater China, the United States and other countries where we plan or conduct business will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, result in the suspension of ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including without limitation the European Union General Data Protection Regulation, Cyber Security Law, Data Security Law and HGR Regulation. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business and results of operations.

***China's economic, political and social conditions, as well as governmental policies or regulatory actions, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.***

Our substantial operations (including our commercial operations) are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development, data protection and allocation of resources. Some of these measures may benefit the overall economy in China but may have a negative effect on us. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and/or changes in tax, cyber and data security, capital investments, cross-border transaction and other regulations that are currently or may in the future be applicable to us. Recently, Chinese regulators have announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that materially adversely affect the business environment and financial markets in China as they relate to us, our ability to operate our business, our liquidity and our access to capital.

***The uncertainties in the China legal system could materially and adversely affect us.***

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities markets and promote the high-quality development of the capital markets, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation-making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us.

It is especially difficult for us to accurately predict the potential impact on the Company of new legal requirements in China because the China legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, the China legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the China legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

***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 and ordinary shares may decline in value or become worthless.***

In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities, or VIEs. Currently, our corporate structure contains no variable interest entities and we are not in an industry that is subject to foreign ownership limitations in 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 and regulations 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 ADSs and ordinary shares may decline in value or become worthless.

***We are not currently required to obtain approval or prior permission from the China Securities Regulatory Commission or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future. We are required to obtain approvals and permissions from Chinese authorities in connection with our general business activities currently conducted in China.***

As of the date of this Quarterly Report on Form 10-Q, we are not required to obtain approval or prior permission from the China Securities Regulatory Commission or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future.

To operate our general business activities currently conducted in 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. 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.

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. For more information on these required permissions, see the “Recent Legal and Regulatory Developments” section above in Part I, Item 2 (Management’s Discussion and Analysis of Financial Condition and Results of Operation) and the risk factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020, and the additional risk factors discussed in the “Risk Factors” section in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and this Quarterly Report on Form 10-Q.

Other Risk Factors

The following is a summary of significant risk factors and uncertainties that may affect our business which are discussed in more details above and in our Annual Report on Form 10-K for the year ended December 31, 2020:

- our ability to successfully commercialize ZEJULA, Optune, QINLOCK and any other products and product candidates that we may obtain regulatory approval for;
- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration, and acquisition agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs;

compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;

- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- patent terms, patent term extensions, patent office actions and expected availability and any period of regulatory exclusivity;
- the timing, outcome and impact of administrative, regulatory, legal or other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of certain business development transactions;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals of our products, product candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- reputational or financial harm to our business arising from adverse safety events, including product liability claims or lawsuits affecting our or any of our licensors' marketed products, generic or biosimilar versions of our or any of our licensors' marketed products or any other products from the same class as one of our or any of our licensors' products;
- unexpected impacts on our business operations including sales, expenses, supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;
- the potential impact of measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities or activities in new or existing manufacturing facilities;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, regulatory requirements, judicial decisions and accounting standards;
- the disruption of our business relationships with our licensors;
- the direct and indirect impact of the COVID-19 pandemic on our business and operations, our and our partners' ability to effectively travel, as needed, during the COVID-19 pandemic, and the duration and impact of COVID-19 or any of its variants that may affect, precipitate or exacerbate one or more of any of the risks and uncertainties mentioned in this section;
- our ability to effectively manage our growth;

- the disruption in the capital or credit markets which may adversely impact our ability to obtain necessary capital or credit market financing;
- the geopolitical tensions that exist between China and the United States may adversely affect our business, our ability to grow, and our access to necessary capital or credit markets;
- our ability to retain key executives and to attract, retain and motivate personnel;
- 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;
- compliance with China's new Data Security Law, Cybersecurity Review Measures (Revised Draft for Comment), Personal Information Protection Law regulations and guidelines relating to the multi-level protection scheme and any other future laws and regulations may entail significant expenses and could materially affect our business;
- the audit report included in our annual reports are prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or 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;
- our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results;
- China's economic, political and social conditions, as well as governmental policies or regulatory actions, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital;
- the uncertainties in the China legal system could materially and adversely affect us;
- 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 and our ordinary shares may decline in value or become worthless;
- we are not currently required to obtain approval or prior permission from the China Securities Regulatory Commission or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, as there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented, there can be no assurance that we will not be subject to such requirements, approvals or permissions in the future. We are required to obtain approvals and permissions from Chinese authorities in connection with our general business activities currently conducted in China;
- 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;
- both recent and future economic, political and social conditions, as well as governmental policies and regulatory actions implemented in China, could affect our ability to operate our business. The Chinese government has provided new guidance on China-based companies raising capital outside of China. Due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business, results of operations and the market price of our ADSs;
- changes in the legal, political and economic policies of the Chinese government, the relations between China and the United States, or Chinese or United States regulations may materially and adversely affect our business, financial condition, results of operations and the market price of our ADSs, which could cause the value of our ADSs to significantly decline or to become worthless. Any such changes may take place quickly and with very little notice. Recent statements made and regulatory actions undertaken by China's government, including the recent enactment of China's new Data Security Law, as well as our obligations to comply with China's Cybersecurity Review Measures (Revised Draft for Comment), regulations and guidelines relating to the multi-level protection scheme, Personal Information Protection Law 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 list on a U.S. or foreign stock exchange; and
- other risks and uncertainties, including those listed under "Part I-Item 1A-Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and other information in our Annual Report on Form 10-K for the year ended December 31, 2020 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 |
|---|---|
| 3.1 | Fifth Amended and Restated Memorandum of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 3.2 | Fifth Amended and Restated Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 24, 2021) |
| 4.1 | Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 4.2 | Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 4.3 | Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed with the SEC on August 9, 2021). |
| 4.4 | Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 4.5 | Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act (incorporated by reference to Exhibit 4.5 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.1*# | Non-Employee Director Compensation Policy |
| 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
# Management contract or compensatory plan or arrangement
^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

## SIGNATURES

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

**ZAI LAB LIMITED**

Dated: November 9, 2021

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

**Exhibit 10.1**

**ZAI LAB LIMITED**
**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

As of October 17, 2021, each individual who provides services to Zai Lab Limited (the "Company") as a director, other than a director who is employed by the Company or an affiliate, (a "Non-Employee Director") shall be entitled to receive the following amounts of compensation:

| Type of Compensation | Amount and Form of Payment |
|---|---|
| Annual cash retainer | $50,000 (payable in cash on a quarterly basis) |
| Equity retainer | Commencing in calendar year 2022, each Non-Employee Director is eligible to receive, effective as of a date designated by the Board of Directors (the "Date of Grant"), an annual grant of a number of shares of Restricted Stock (as defined in the 2017 Equity Incentive Plan) equal to US$500,000 *divided* by the closing price of the Company's ADS on NASDAQ on the Date of Grant (or on the next succeeding business day if the NASDAQ stock market is not open for trading on the Date of Grant), rounded down to the nearest whole share. Such shares of Restricted Stock shall vest in full on the first anniversary of the Date of Grant, subject to continued service as a member of our board of directors through such date. |
| New Member Grant | Commencing in calendar year 2021, each Non-Employee Director newly elected to the Board of Directors is eligible to receive, effective as of the date of his or her election to the Board of Directors (the "Date of Election"), an initial grant of a number of shares of Restricted Stock (as defined in the 2017 Equity Incentive Plan) equal to US$750,000 *divided* by the closing price of the Company's ADS on NASDAQ on the Date of Election (or on the next succeeding business day if the NASDAQ stock market is not open for trading on the Date of Election), rounded down to the nearest whole share. Such shares of Restricted Stock shall vest with respect to one-third of the initial grant on each of the next three anniversaries of the Date of Election, subject to continued service as a member of our board of directors through such date.<br>In the event that a newly elected Non-Employee Director's Date of Election is less than 180 days prior to the Date of Grant of the next annual grant to Non-Employee Director, such newly elected Non-Employee Director shall not be eligible to participate in that particular annual grant, but shall participate in all subsequent annual grants. |
| Additional annual cash retainer for Audit Committee chair | $20,000 (payable in cash on a quarterly basis) |
| Additional annual cash retainer for Audit Committee member | $10,000 (payable in cash on a quarterly basis) |
| Additional annual cash retainer for Compensation Committee chair | $15,000 (payable in cash on a quarterly basis) |
| Additional annual cash retainer for Compensation Committee member | $7,500 (payable in cash on a quarterly basis) |

| | |
|---|---|
| Additional annual cash retainer for Nominating Committee chair | $10,000 (payable in cash on a quarterly basis) |
| Additional annual cash retainer for Nominating Committee member | $5,000 (payable in cash on a quarterly basis) |
| Annual Limit on Non-Employee Director Compensation | The total compensation of each individual Non-Employee Director (including cash retainers and equity grants) shall not exceed US$750,000 in any calendar year or US$1,000,000 in the initial calendar year of such Non-Employee Director's service, as the case may be. |

Cash retainers shall be pro-rated for service for periods of less than a full calendar quarter. In addition, Non-Employee Directors will be reimbursed by the Company for reasonable and customary expenses incurred in connection with attendance at board of director and committee meetings, in accordance with the Company's policies as in effect from time to time.

For the avoidance of doubt, directors who are (i) employees of the Company, (ii) employees of one of its affiliates or (iii) (a) are affiliated with a shareholder holding more than one percent (1%) of the ordinary shares or ordinary share equivalents of the Company or (b) individually (or through any trust or estate planning entity) hold more than one percent (1%) of the ordinary shares or ordinary share equivalents) of the Company will not receive compensation for their service as a director, other than reimbursement for reasonable and customary expenses incurred in connection with attendance at board of director and committee meetings, in accordance with the Company's policies as in effect from time to time.

**Exhibit 31.1**

**CERTIFICATIONS**

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: November 9, 2021

/s/ Samantha (Ying) Du

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

**Exhibit 31.2**

**CERTIFICATIONS**

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: November 9, 2021

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

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO SECTION 906**
**OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of Zai Lab Limited (the "Company"), for the three months ended September 30, 2021, 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: November 9, 2021

/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 PURSUANT TO 18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO SECTION 906**
**OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of Zai Lab Limited (the "Company"), for the three months ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 9, 2021

/s/ Billy Cho
Billy Cho
Chief Financial 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.