
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended: December 31, 2024

Or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from [] to []

Commission file number: 001-38205



ZAI LAB LIMITED

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands

(State or Other Jurisdiction of
Incorporation or Organization)

98-1144595

(I.R.S. Employer
Identification No.)

4560 Jinke Road
Bldg. 1, 4th Floor
Pudong
Shanghai, China

201210

314 Main Street
4th Floor, Suite 100
Cambridge, MA, USA

02142

(Address of Principal Executive Offices)

(Zip Code)

+86 21 6163 2588

+1 857 706 2604

(Registrant's Telephone Number, Including Area Code)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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 has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 June 30, 2024, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the ordinary shares, including in the form of American Depositary Shares (“ADSs”), each representing ten ordinary shares, held by non-affiliates of the registrant was approximately \$1.7 billion, based upon the closing price of the registrant’s ADSs on the Nasdaq Global Market of \$17.33 on June 30, 2024.

As of February 21, 2025, 1,080,759,280 ordinary shares, par value \$0.000006 per share, were outstanding, of which 847,651,100 ordinary shares were held in the form of ADSs.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2024. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Zai Lab Limited
2024 Annual Report on Form 10-K
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Forward-Looking Statements

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

- Our ability to successfully commercialize and generate revenue from our approved products;
- Our ability to obtain funding for our operations and business initiatives;
- The results of our clinical and pre-clinical development of our product candidates;
- The content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates;
- Changes in U.S. and China trade policies and relations, as well as relations with other countries, and/or changes in laws, regulations, and/or sanctions;
- Actions the Chinese government may take to intervene in or influence our operations;
- Economic, political, and social conditions in mainland China as well as governmental policies;
- Uncertainties in the Chinese legal system, including with respect to the anti-corruption enforcement efforts in mainland China and the Counter-Espionage Law, the Data Security Law, the Cyber Security Law, the Cybersecurity Review Measures, the Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, the Security Assessment Measures, and other future laws and regulations or amendments to such laws and regulations;
- Approval, filing, or procedural requirements imposed by the CSRC or other Chinese regulatory authorities in connection with issuing securities to foreign investors under Chinese law;
- Any violation or liability under the FCPA or Chinese anti-corruption, anti-bribery, and anti-fraud laws;
- Restrictions on currency exchange;
- Limitations on the ability of our Chinese subsidiaries to make payments to us;
- Chinese requirements on the ability of residents in mainland China to establish offshore special purpose companies;
- Chinese regulations regarding acquisitions of companies based in mainland China by foreign investors;
- Any issues that our Chinese manufacturing facilities may have with operating in conformity with established GMPs and international best practices, and with passing FDA, NMPA, and EMA inspections;
- Expiration of, or changes to, financial incentives or discretionary policies granted by local governments in mainland China;
- Restrictions or limitations on the ability of overseas regulators to conduct investigations or collect evidence within mainland China;

- Significant business disruptions caused by events or developments outside of our control, such as pandemics, international war or conflict, natural disasters or extreme weather events, and other geopolitical events;
- Unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders if we were to be classified as a Chinese resident enterprise for Chinese income tax purposes;
- Failure to comply with applicable Chinese, U.S., and Hong Kong regulations that could lead to government enforcement actions, fines, other legal or administrative sanctions, and/or harm to our business or reputation;
- Delays or obstacles for closing transactions, such as review by the CFIUS in our investments;
- Any inability to renew our current leases on desirable terms or otherwise locate desirable alternatives for our leased properties;
- Any inability of third parties on whom we rely, such as our licensors, CMOs, and others that supply certain of our products and product candidates; CROs that conduct or support some of our pre-clinical and clinical trials; and distributors that sell our commercial products, to successfully carry out their contractual duties or meet expected deadlines; and
- Any inability to obtain or maintain sufficient patent protection for our products and product candidates.

For more information on these factors and other risks and uncertainties that may affect our business, see *Risk Factors*. These factors should not be construed as exhaustive and should be read with the other cautionary statements and information in this report. Forward-looking statements are based on our management's beliefs and assumptions and information currently available to our management. These statements, like all statements in this report, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this report.

Usage of Terms

Throughout this report, we use certain acronyms and terms that are defined in the *Glossary*. Unless the context requires otherwise, references to “Zai Lab,” the “Company,” “we,” “us,” and “our” refer to Zai Lab Limited, a holding company, and its subsidiaries, on a consolidated basis; and references to “Zai Lab Limited” refer to Zai Lab Limited, a holding company. Zai Lab Limited is the entity in which investors hold their interest.

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

We own various trademarks, including various forms of the Zai Lab brand (in English and Chinese), as well as several domain names that incorporate such trademarks. Trademarks and trade names of other companies appearing in this report are the property of their respective holders. Solely for convenience, some of the trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of, any other company.

Disclosures Relating to Our Chinese Operations

Zai Lab Limited is an exempted company incorporated in the Cayman Islands with limited liability in March 2013. We have substantial operations in mainland China. Below is a summary of certain risks related to our Chinese operations. For more information on material risks that may affect our business and securities, see *Risk Factors*.

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

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

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

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

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

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

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

Further, we are required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or controlled by those foreign parties. In addition, we may be subject to additional such requirements pursuant to the Security Assessment Measures, which may affect our Chinese subsidiaries or clinical trials. The Security Assessment Measures may require us to complete security assessments for certain cross-border data transfers, obtain prior approval from the CAC for transfers out of mainland China of certain important or personal data, or obtain prior clearance or approval from the HGRAC for certain transfers of data derived from human organs, tissues, or cells of Chinese individuals that contain human genetic materials. If we are not able to obtain or maintain

the necessary permissions or approvals, our ability to operate in mainland China may be restricted or prohibited, which may have a material adverse effect on our business prospects, financial condition, results of operations, and the price of our securities.

Although we are not currently required to obtain prior approval or permission from the CSRC or any other Chinese regulatory authority to issue our securities to foreign investors, the CSRC has promulgated the Trial Measures and five supporting guidelines, which require us to submit filings to the CSRC following the submission of future overseas listings and the completion of future offerings of our equity securities to foreign investors. For example, we were required to file with the CSRC with respect to the registered offering of our ADSs in November 2024. If we are not able to complete the necessary filings for future securities offerings, our ability to raise capital may be adversely affected.

PART I

Item 1. Business

Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are focused on discovering, developing, and commercializing products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies to generate a broad pipeline, including multiple commercial products and multiple programs in late-stage clinical development. We have also built an in-house R&D team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights.

Our Mission and Corporate Strategic Goals

Our mission is to be a leading global biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies that improve the lives of patients.

To execute on that mission, we have developed a corporate strategy with the following three pillars to help us drive innovation in China and beyond:

- **Accelerate Medicines to Patients:** We seek to advance our global and regional pipelines by continuing to invest in research and development activities;
- **Expand and Strengthen Our Pipeline:** We seek to continue to expand and strengthen our differentiated global and regional pipelines through our internal discovery efforts and synergistic collaborations and corporate development activities; and
- **Continue Our Commercial Excellence and Execution:** We seek to continue delivering strong financial performance, including by increasing access to our existing commercial products and driving further increases in our efficiency and productivity as we prepare to launch additional products or new indications for existing products, as we advance along our path to achieve profitability.

We also seek to build and maintain the trust of our stakeholders, including through our Trust for Life strategy, which includes three commitments: improve human health, create better outcomes, and act right now with ethical business practices and strong corporate governance. As part of our corporate strategy, and the actions taken in support of our corporate goals, we will continue to develop and integrate our Trust for Life strategy into our business and operations.

Our Commercial Products and Operations

We currently have seven commercial programs with products that have received marketing approval and that we have commercially launched in one or more territories in Greater China.

The following table provides an overview of our partners and the approved indications and current geographic markets for our commercial products:

Product	Our Approved Indications	Our Current Markets	Partner
	1L ovarian cancer maintenance treatment Platinum sensitive relapsed ovarian cancer maintenance treatment	Mainland China, Hong Kong, and Macau	
	gMG	Mainland China	
	gMG and CIDP		
	CABP and ABSSSI	Mainland China and Macau	
	Newly diagnosed and recurrent GBM	Greater China	
	4L GIST	Greater China	
	HABP and VABP caused by ABC	Mainland China	
	ROS1+ NSCLC	Mainland China	

We have established a strong commercial infrastructure to support the sales of our commercial products. Our sales and marketing teams cover major medical centers across Greater China, and our commercial team has capabilities that cover the product sales cycle, including medical affairs, marketing, market access, and distributor management. Our commercial team has a proven track record and experience from leading global pharmaceutical companies including AstraZeneca, Roche, Novartis, and BMS, and we tailor our commercialization strategies according to our individual products and their market potential. For example, we work to increase access for our commercial products through NRDL inclusion or supplemental insurance coverage and increase brand perception and adoption through education and outreach.

The following sections include more information on our commercial products. For additional information on the license agreements for our commercial products, see *Overview of Significant License and Collaboration Agreements*, and for more information on how we source and sell our commercial products, see *Our Customers and Manufacturing, Suppliers, and Quality Control*. We are also evaluating other potential indications for our commercial products, as discussed in *Our Oncology Pipeline* and *Our Immunology, Neuroscience, and Infectious Disease Pipeline*.

ZEJULA (Niraparib)

ZEJULA is an orally administered PARP 1/2 inhibitor. PARP is a protein that helps repair DNA damage in cells. PARP inhibitors block PARP from repairing DNA damage, such as may be caused by radiation and/or certain

chemotherapies, which may lead to cancer cell death and slow the return or progression of cancer. Tumors that are deficient in key DNA damage repair pathways, such as BRCA1 mutant tumors, are particularly sensitive to ZEJULA. As a maintenance therapy, ZEJULA is for women who have had prior chemotherapy treatment but are at high risk of cancer recurrence. ZEJULA is intended to avoid or slow recurrence of the cancer if it is in remission after prior treatment. In the maintenance setting, ZEJULA does not require the addition of radiation or chemotherapies to kill tumor cells. We have an exclusive license from Tesaro (now a subsidiary of GSK) to develop and commercialize ZEJULA in mainland China, Hong Kong, and Macau.

Our primary market for ZEJULA is patients with ovarian cancer in mainland China. Ovarian cancer is one of the most common gynecological cancers in China, with over 61,100 newly diagnosed cases and 32,600 deaths in China annually. We launched ZEJULA in mainland China in 2020, and it has been included in the NRDL since 2021 as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer and for adult patients with advanced ovarian cancer who are in a complete or partial response to first-line platinum-based chemotherapy and since 2022 as a maintenance treatment for first-line ovarian cancer.

We also launched ZEJULA in Hong Kong in 2018 as a maintenance therapy for adult patients with platinum-sensitive, relapsed high-grade, serous epithelial ovarian cancer who are in a complete or partial response to platinum-based chemotherapy and in Hong Kong and Macau in 2021 as a maintenance therapy for adult patients with high-grade serous epithelial ovarian cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

VYVGART / VYVGART Hytrulo (Efgartigimod)

Efgartigimod is a human IgG1 antibody fragment that binds to FcRn. FcRn is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from lysosomal degradation. Blocking FcRn prevents FcRn from binding IgG antibodies and rescuing them from lysosomal degradation resulting in a reduction in circulating IgG antibodies which may include pathogenic IgG antibodies that contribute to certain autoimmune diseases such as gMG and CIDP. We have an exclusive license from argenx to develop and commercialize efgartigimod in Greater China.

Our primary market for efgartigimod is patients with gMG in mainland China. There are approximately 200,000 patients in China living with MG. Approximately 85% of people with MG progress to gMG within 2 years, and of those patients, 85% are estimated to have confirmed AChR antibodies. We launched the IV formulation of efgartigimod, under the brand name VYVGART, in mainland China in September 2023 as an add on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive, and in January 2024, this product was added to the NRDL for this indication. In July 2024, the NMPA approved the BLA for the subcutaneous formulation of efgartigimod, under the brand name VYVGART Hytrulo, as an add on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive, and we launched VYVGART Hytrulo for this indication in the fourth quarter of 2024.

In November 2024, the NMPA approved the sBLA for VYVGART Hytrulo for the treatment of adult patients with CIDP, and we launched VYVGART Hytrulo for this indication in the fourth quarter of 2024. There are approximately 50,000 patients diagnosed with CIDP in mainland China.

NUZYRA (Omadacycline)

NUZYRA, a novel tetracycline-class antibacterial with both oral and IV formulations, is a broad-spectrum antibiotic. We have an exclusive license from Paratek (subsequently acquired by Gurnet Point Capital and Novo Holdings) to develop, manufacture, and commercialize NUZYRA in Greater China.

Our primary market for NUZYRA is patients with CABP or ABSSSI in mainland China. CABP is the most common type of pneumonia that is acquired outside of the hospital. It is one of the most common infectious diseases and is a significant cause of mortality and morbidity worldwide. ABSSSI are bacterial infections of skin and associated soft tissues, such as loose connective tissue and mucous membranes. ABSSSI are common and encompass a variety of disease presentations and degrees of severity. The World Health Organization has identified the worldwide development of resistance to currently available antibacterial agents as one of the greatest threats to human health. In 2020, the estimated

incidence of CABP in mainland China was approximately 10 million patients, and in 2015, the estimated incidence of ABSSSI in mainland China was 2.8 million patients. We launched the oral and IV formulations of NUZYRA in mainland China in 2021 for the treatment of adults with CABP and/or ABSSSI. NUZYRA was included in the NRDL for the treatment of adult patients with CABP and/or ABSSSI in January 2023 for its IV formulation and in January 2024 for its oral formulation. The NRDL listing for the IV formulation of NUZYRA for the treatment of adult patients with CABP and/or ABSSSI was renewed in January 2025.

NUZYRA is locally manufactured by CMOs in mainland China. We have an exclusive promotion agreement with Huizheng, a subsidiary of Hanhui, one of the leading pharmaceutical companies for antibiotics in mainland China, which allows us to use Hanhui's existing infrastructure for sales of NUZYRA in mainland China.

OPTUNE (Tumor Treating Fields)

OPTUNE is a cancer therapy that uses electric fields tuned to specific frequencies to kill tumor cells via a variety of mechanisms. TTFields therapy is delivered through a portable medical device. The complete delivery system for OPTUNE includes a portable electric field generator, arrays, rechargeable batteries, and accessories. We have an exclusive license from NovoCure to develop and commercialize any TTFields products in Greater China in the field of oncology.

Our primary market for OPTUNE is patients in mainland China with GBM, the most aggressive form of brain tumor. We estimate that there are more than 45,000 patients with GBM in China each year. We launched OPTUNE GIO in mainland China in 2020 for the treatment of patients with newly diagnosed GBM in combination with TMZ and as a monotherapy for the treatment of patients with recurrent GBM. We have also launched OPTUNE GIO for these GBM indications in Hong Kong, Taiwan, and Macau. Since launch, we have helped improve patient access to OPTUNE GIO in mainland China through supplemental insurance coverage.

QINLOCK (Ripretinib)

QINLOCK is an orally administered switch-control TKI that broadly inhibits KIT and PDGFR α tyrosine kinases, including wild-type and forms with multiple primary and secondary mutations. Switch-control tyrosine kinases KIT and PDGFR α regulate kinase activity through a main activation switch and an auxiliary inhibitory switch that control kinase conformation in either an "on" or "off" position. Oncogenic kinase mutations predominantly function by disrupting one or more regulatory switch mechanisms, leading to dysregulated function and loss of normal, physiologic conformational control. Blocking the switch pocket region and the activation switch region locks KIT and PDGFR α kinases in an inactive conformation by a dual mechanism of action that provides broad inhibition of KIT and PDGFR α kinase activity thereby preventing downstream signaling and cell proliferation. We have an exclusive license from Deciphera to develop and commercialize QINLOCK in Greater China.

Our primary market for QINLOCK is patients with GIST in mainland China, where we believe QINLOCK is the standard of care. GISTs are the most common mesenchymal tumors of the gastrointestinal tract, accounting for about 0.1-3% of gastrointestinal tumors, with an estimated annual incidence of around 30,000 newly diagnosed patients per year in mainland China. We launched QINLOCK in mainland China in 2021 for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, or 4L GIST. QINLOCK was first included in the NRDL for this indication in January 2023. The NRDL listing for this indication was renewed in January 2025. We have also launched QINLOCK for 4L GIST in Hong Kong, Taiwan, and Macau.

XACDURO (Sulbactam/Durlobactam or SUL-DUR)

XACDURO is a combination of a beta-lactam antibiotic (sulbactam) and a beta-lactamase inhibitor (durlobactam). We have an exclusive license from Entasis (now a wholly owned subsidiary of Innoviva) to develop and commercialize SUL-DUR in Asia Pacific.

Our primary market for XACDURO is patients with HABP and VABP caused by ABC in mainland China. *Acinetobacter* belongs to a group of bacteria commonly found in the environment, such as soil and water. *Acinetobacter baumannii* accounts for most *Acinetobacter* infections in humans; the organism can cause infections in all organs, but bloodstream infection and pneumonia are most dangerous and associated with high mortality. In recent years, *Acinetobacter baumannii* has become multi-drug resistant. For carbapenem-resistant *Acinetobacter baumannii* infections, treatment options are extremely limited because remaining antibiotics are either toxic or of limited efficacy. In mainland China, *Acinetobacter baumannii* infections are often seen in the hospital setting. Based on the 2022 Annual Report of CARSS (China Antimicrobial Resistance Surveillance System), there were around 300,000 *Acinetobacter* infections reported in mainland China in 2022. According to recent surveillance data from China, overall resistance of *Acinetobacter baumannii* to the carbapenem class of antibiotics is approximately 53%, with some provinces as high as 70%. We commercially launched XACDURO in mainland China in January 2025 for the treatment of adult patients with HABP and VABP caused by ABC.

In November 2024, we entered into a strategic collaboration with Pfizer that will allow us to leverage the industry-leading commercialization infrastructure of Pfizer's affiliated companies in the anti-infective therapeutic area to support the early launch of XACDURO in mainland China.

AUGTYRO (Repotrectinib)

AUGTYRO is a next-generation TKI that targets *ROS1* oncogenic fusions. We have an exclusive license from Turning Point (now a wholly owned subsidiary of BMS) to develop and commercialize repotrectinib in Greater China.

Our primary market for AUGTYRO is patients with *ROS1*+ NSCLC in mainland China. In China, there were approximately 1.1 million new cases of lung cancer in 2022. NSCLC accounts for approximately 85% of lung cancer, and approximately 70% of NSCLC is locally advanced or metastatic at initial diagnosis. *ROS1* rearrangements occur in approximately 2% of patients with advanced NSCLC. We launched AUGTYRO in mainland China in December 2024 for the treatment of adult patients with locally advanced or metastatic *ROS1*+ NSCLC, and AUGTYRO was included in the NRDL for this indication in January 2025.

Our Pipeline of Product Candidates and R&D Activities

We believe research and development is important to our future growth and ability to remain competitive, and we are dedicated to discovering or licensing, and then developing and commercializing, innovative products that address significant unmet medical needs in Greater China and worldwide. We have a deep and differentiated pipeline of potential first-in-class / best-in-class products across our therapeutic areas. Our pipeline includes certain additional indications for our commercial products as well as new products for which we may seek regulatory approval and commercialization. Our pipeline includes both in-licensed assets as well as assets that we have internally developed. Our product candidates are in various stages of development, including several assets in late-stage development and various others in clinical and pre-clinical development.

We have assembled an integrated drug discovery and development team with extensive experience in discovery, translational medicine, and pre-clinical and clinical development in China and the United States that has been directly involved in the discovery and development of several innovative product candidates with global rights. We also supplement our internal capabilities through collaborations with commercial partners and external research partners, such as leading CROs and academic institutions, for the execution of our pre-clinical and clinical trials.

We will continue to evaluate the developmental possibilities of the programs in our pipeline. For example, our programs may have significant potential beyond those indications we are currently evaluating. We may in the future expand our research and development efforts to evaluate additional indications to those discussed below. In addition, we or our partners may decide to discontinue development of certain products based on a review of the competitive landscape and market opportunity or otherwise. For example, in the fourth quarter of 2023, we decided to discontinue our development of margetuximab and odronextamab, and we provided notice to terminate our related license agreements

with MacroGenics and Regeneron in accordance with their terms, effective on May 14, 2024 and December 20, 2024, respectively.

Global Pipeline

We are continuing to focus on expanding and advancing our global pipeline of innovative products through our internal discovery efforts and business development activities. Our innovative global pipeline includes ZL-1310, a potential first-in-class and best-in-class DLL3-targeted ADC for SCLC and other neuroendocrine tumors, for which we are conducting a Phase I study in extensive stage SCLC and initiating a Phase I study in neuroendocrine tumors; ZL-1102, a fully human V_H fragment that binds to IL-17, for which we are conducting a global Phase II study in chronic plaque psoriasis; ZL-1503, our internally developed IL-13/IL-31R bispecific antibody for atopic dermatitis and other immunologic diseases, for which we are completing IND-enabling studies; and ZL-6201, a novel potential first-in-class ADC targeting LRRC15 for the treatment of certain solid tumors, for which we are completing IND-enabling studies. We also have multiple other undisclosed IND-enabling assets, and we are targeting at least 1 new IND per year.

Regional Pipeline

We will also continue to advance and expand our regional pipeline through synergistic opportunities that help us further address significant unmet patient needs. The following table provides an overview of our key regional product candidates, including key indications we are evaluating for those products, their clinical stage and related studies in which we are participating, and our partners and potential geographic markets:

Product	Description	Potential Indications and Clinical Stage (Studies)	Our Potential Markets	Partner
<i>Oncology Pipeline</i>				
Bemarituzumab	Anti-FGFR2b antibody	1L Gastric/GEJ Cancer – Phase III (FORTITUDE-101 and FORTITUDE-102)	Greater China	Five Prime (now owned by Amgen)
Tumor Treating Fields	Portable device for delivery of electric fields	2L+ NSCLC – Phase III (LUNAR) Pancreatic Cancer – Phase III (PANOVA-3)	Greater China	NovoCure
Tisotumab vedotin (TIVDAK)	Tissue Factor ADC	2L+ Cervical Cancer – Phase III (innovaTV 301) 1L r/m Cervical Cancer - Phase II (innovaTV 205)	Greater China	Seagen (now owned by Pfizer)
Repotrectinib (AUGTYRO)	TKI targeting ROS1 oncogenic fusions	<i>NTRK</i> + Solid Tumors – Phase I/II (TRIDENT-1)	Greater China	Turning Point (now owned by BMS)
<i>Immunology, Neuroscience, and Infectious Disease Pipeline</i>				
Efgartigimod (VYVGART, VYVGART Hytrulo, Pre-Filled Syringe)	FcRn blocker	TED – Phase III (UplighTED) Myositis - Phase III (ALKIVIA) sn-gMG - Phase III (ADAPT-SERON) Ocular MG - Phase III (ADAPT-OCULUS) LN - Phase II	Greater China	argenx
Xanomeline and Trospium Chloride (COBENFY, KarXT)	Combination of muscarinic receptor agonist and antimuscarinic agent	Schizophrenia – Phase III (EMERGENT) ADP – Phase III (ADEPT-2 and ADEPT-3)	Greater China	Karuna (now owned by BMS)

The following sections include more information on significant product candidates in our oncology and immunology, neuroscience, and infectious disease pipelines. For more information on license agreements for our significant product candidates, see *Overview of Significant License and Collaboration Agreements*; for more information on how we source our product candidates, see *Manufacturing, Suppliers, and Quality Control*; and for information on

risks related to our potential products and R&D activities, including clinical trials and reliance on third parties, see *Risk Factors*.

Our Oncology Pipeline

ZL-1310 (DLL3 ADC)

ZL-1310 is a potential first-in-class and best-in-class next generation ADC targeting DLL3, an antigen that is overexpressed in many neuroendocrine tumors and is a validated therapeutic target for SCLC. ZL-1310 comprises a humanized anti-DLL3 monoclonal antibody linked to a novel camptothecin derivative (a topoisomerase 1 inhibitor) as its payload. The compound was designed with a novel ADC technology platform called TMALIN[®], which leverages the tumor microenvironment to overcome challenges associated with first-generation ADC therapies, including off-target payload toxicity. We have an exclusive global license from MediLink to research, develop, manufacture, and commercialize ZL-1310.

We are evaluating ZL-1310 for the treatment of SCLC and other neuroendocrine tumors. ZL-1310 is currently in a Phase Ia/Ib global clinical trial for the treatment of patients with previously treated extensive stage SCLC after at least one prior platinum-based chemotherapy regime.

In January 2025, the FDA granted orphan drug designation to ZL-1310 as a treatment for patients with SCLC. As a result of this designation, certain forms of financial assistance for development of ZL-1310 are available, and there is the potential, upon product approval, for the FDA to grant market exclusivity for a 7-year period. SCLC is one of the most aggressive and lethal solid tumors, accounting for around 15% of the approximately 2.5 million patients diagnosed with lung cancer worldwide each year. Two-thirds of all SCLC patients are diagnosed at extensive stage. The current median survival of patients with ES-SCLC is approximately twelve months following initial therapy, and the overall five-year survival rate is 5-10%.

Bemarituzumab

Bemarituzumab is a humanized monoclonal antibody (IgG1 isotype) specific to FGFR2b that is in clinical development as a targeted therapy for gastric and GEJ cancer patients whose tumors overexpress FGFR2b. We have an exclusive license from Five Prime (a company later acquired by Amgen) to develop and commercialize bemarituzumab in Greater China.

We are evaluating bemarituzumab for the treatment of gastric and GEJ cancer. We are participating in the Greater China portion of the global Phase III FORTITUDE-101 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy, in 1L gastric or GEJ cancer with FGFR2b overexpression. In addition, we are participating in the Greater China portion of the global Phase III FORTITUDE-102 study of bemarituzumab in combination with nivolumab and chemotherapy versus placebo in combination with nivolumab and chemotherapy in 1L gastric or GEJ cancer with FGFR2b overexpression. We estimate an annual incidence of around 95,000 1L gastric cancer patients with FGFR2b overexpression in China.

TIVDAK (Tisotumab Vedotin)

TIVDAK is an ADC composed of Genmab's human monoclonal antibody directed against cell surface tissue factor and Seagen's ADC technology that utilizes a protease-cleavable linker that covalently attaches MMAE to the antibody. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death of actively dividing cells. In vitro, TIVDAK also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity. We have an exclusive license from Seagen (a company later acquired by Pfizer) to develop and commercialize tisotumab vedotin in Greater China.

We are evaluating TIVDAK for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. TIVDAK received full approval in the United States for this indication in April 2024 based on results from the global, randomized Phase III innovaTV 301 clinical trial, which met its primary endpoint of OS. The key

secondary endpoints of investigator-assessed progression-free survival and objective response rate also demonstrated statistical significance. The safety profile of TIVDAK in innovaTV 301 was consistent with the known safety profile of TIVDAK as presented in the U.S. prescribing information, and no new safety signals were observed. In January 2025, we announced positive topline results from the China subpopulation of the innovaTV 301 study, which were consistent with those in the global population, and we intend to submit an NDA to the NMPA in the first quarter of 2025. We estimate that there are around 150,000 new cases of cervical cancer each year in China.

Additional Indications for OPTUNE (TTFields)

As discussed in *Our Commercial Products and Operations*, we have an exclusive license from NovoCure to develop and commercialize any TTFields products in Greater China in the field of oncology, and we have commercially launched TTFields in Greater China for certain GBM indications. Significant additional indications for TTFields therapy that we are evaluating include solid tumor types in 2L+ NSCLC and 1L pancreatic cancer.

- **2L+ NSCLC:** We participated in the Greater China portion of the Phase III pivotal LUNAR trial, which was intended for patients who had recently been diagnosed with progression of NSCLC during or after platinum-based therapy. The Phase III LUNAR trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in OS for patients with metastatic NSCLC after platinum-based therapies, and a profound OS benefit from TTFields therapy was demonstrated in the ICI subgroup. TTFields therapy was well tolerated with no added systemic toxicities and few grade 3 (and no grade 4 or 5) device-related adverse events. Lung cancer has the highest total incidence of any cancer in mainland China. According to the World Health Organization, the incidence of lung cancer in mainland China in 2022 was around 1.1 million cases. Lung cancer consists of NSCLC in approximately 85% of cases and SCLC in approximately 15% of cases. In October 2024, NovoCure announced that the FDA had approved TTFields therapy, under the brand name OPTUNE LUA, for concurrent use with PD-1/PD-L1 inhibitors or docetaxel, for the treatment of adult patients with metastatic NSCLC who have progressed on or after a platinum-based regimen. We are preparing a similar submission for this indication, with a goal to submit an MAA to the NMPA in the first half of 2025.
- **1L Pancreatic Cancer:** We participated in the Greater China portion of the Phase III pivotal PANOVA-3 trial evaluating the efficacy of TTFields therapy administered concomitantly with gemcitabine and nab-paclitaxel as a 1L treatment for patients with unresectable, locally advanced pancreatic cancer. In December 2024, we and NovoCure announced that the PANOVA-3 trial met its primary endpoint, demonstrating a statistically significant improvement in mOS versus control group. According to the World Health Organization, pancreatic cancer was the eighth-leading cancer type in China in 2020. There are approximately 134,000 new cases of pancreatic cancer diagnosed each year in China. The current median survival of patients with metastatic pancreatic cancer is four to six months, and the five-year survival rate of pancreatic cancer is 7.2%. We expect to file for regulatory approval in China in the second half of 2025.

Additional Indication for AUGTYRO (Repotrectinib)

As discussed in *Our Commercial Products and Operations*, we have an exclusive license from Turning Point (now a wholly owned subsidiary of BMS) to develop and commercialize repotrectinib in Greater China, and we have launched AUGTYRO in mainland China for *ROS1*+ NSCLC.

We are evaluating repotrectinib for the treatment of *NTRK*+ solid tumors and are participating in the Greater China portion of the global Phase I/II TRIDENT-I study for the treatment of TKI-naïve and TKI-pretreated patients with *NTRK*-positive advanced solid tumors. In August 2023, the NMPA granted BTB for repotrectinib for the treatment of patients with advanced solid tumors that have a *NTRK* gene fusion who have progressed following treatment with TRK TKIs. *NTRK*+ is estimated to be an oncogenic driver in approximately 0.5% of patients with a variety of advanced solid tumors.

In June 2024, BMS announced that, based on the results of the TRIDENT-1 trial, the FDA granted accelerated approval of AUGTYRO for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a *NTRK* gene fusion, are locally advanced or metastatic, or where surgical resection is likely to result in severe

morbidity. This indication was approved under accelerated approval based on overall response rate and duration of response, and continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial. We plan to submit an sNDA to the NMPA for *NTRK*+ solid tumors in the first half of 2025.

Our Immunology, Neuroscience, and Infectious Disease Pipeline

Additional Opportunities for Efgartigimod

As discussed in *Our Commercial Products and Operations*, we have an exclusive license from argenx to develop and commercialize efgartigimod in Greater China, and in mainland China, we have launched VYVGART for the treatment of adult patients with gMG and VYVGART Hytrulo for gMG and CIDP. We are evaluating significant additional indications for efgartigimod SC and the pre-filled syringe, including for the treatment of thyroid eye disease, myositis, seronegative gMG, ocular MG, and lupus nephritis.

- **TED:** We are participating in the Greater China portion of the global registrational Phase III UplighTED study of efgartigimod for the treatment of TED. We estimate that there are around 1 million patients with moderate to severe TED in China.
- **Myositis:** We are participating in the Greater China portion of the global registrational Phase II/III ALKIVIA study of efgartigimod for the treatment of idiopathic inflammatory myopathies, or myositis. We estimate that there are around 170,000 myositis patients diagnosed in China.
- **sn-gMG:** We are currently supporting enrollment in Greater China for the global registrational Phase III ADAPT-SERON study of efgartigimod for the treatment of sn-gMG. We estimate that there are around 25,000 patients diagnosed with sn-gMG in China.
- **Ocular MG:** We are currently supporting enrollment in Greater China for the global registrational Phase III ADAPT-OCULUS study of efgartigimod for the treatment of ocular MG. We estimate that there are around 44,000 patients diagnosed with ocular MG in China.
- **LN:** We are currently conducting a Phase II POC study of efgartigimod for the treatment of LN in China. We estimate that there are around 320,000 patients diagnosed with LN in China.

KarXT (Xanomeline and Trospium Chloride)

KarXT is a combination of an oral M1/M4-preferring muscarinic acetylcholine receptor agonist and a peripheral acting antimuscarinic agent, which is in development for the treatment of psychiatric and neurological conditions, including schizophrenia and psychosis associated with Alzheimer's Disease. KarXT preferentially stimulates muscarinic receptors implicated in these conditions, as opposed to current antipsychotic medicines, which mostly target dopamine or serotonin receptors. KarXT has the potential to represent a new class of treatment for schizophrenia and ADP based on its differentiated mechanism of action. We have an exclusive license from Karuna (a company later acquired by BMS) to develop, manufacture, and commercialize xanomeline and trospium chloride in Greater China.

We are evaluating KarXT for the treatment of schizophrenia and ADP.

- **Schizophrenia:** In January 2025, the NMPA accepted the NDA for KarXT for the treatment of schizophrenia. The NDA submission was supported by data from the Phase I PK study, Phase III China study, the global Phase III EMERGENT-2 and EMERGENT-3 clinical trials, and long-term follow-up results. This follows FDA approval of KarXT, under the brand name COBENFY, for the treatment of schizophrenia in adults in September 2024. COBENFY does not have atypical antipsychotic class warnings and precautions and does not have a boxed warning. We estimate that there are more than 8 million people living with schizophrenia in China.

- **ADP:** We are participating in the China portion of the global Phase III ADEPT-2 and ADEPT-3 trials in ADP. We estimate that around 8 million people are affected by Alzheimer’s disease in China and around 45% of these patients display psychotic symptoms.

Overview of Significant License and Collaboration Agreements

We have entered into various license and collaboration agreements with third parties, such as biopharmaceutical companies with innovative products in our therapeutic areas and external research parties, for the development and commercialization of our products and product candidates. We are generally required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones for the licensed products under these agreements as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. For a discussion of aggregate potential payments under our license and collaboration arrangements, see *Note 16* and *MD&A – License and Collaboration Arrangements*.

These agreements may include intellectual property rights associated with the products or product candidates, including the responsibility for obtaining and maintaining patents as well as enforcement of those patents.

These agreements generally remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The royalty terms generally continue until the latest of: (i) the expiration of the last-to-expire valid claim with respect to licensed patent rights; (ii) the expiration of market or regulatory exclusivity; or (iii) a specified period of time, generally around ten years, after the date of the first commercial sale of the licensed product. These agreements also contain customary provisions for termination by either party, including in the event of a material breach by the other party that remains uncured; by us for convenience upon a specified notice period; for certain bankruptcy, insolvency, or other similar events; and by our partners upon challenge of their licensed patent rights.

The following sections provide additional information on the license and collaboration arrangements for our commercial products and significant product candidates, such as the scope of the licensed products and licensed territories and any related supply arrangements. We have also entered into other license and collaboration arrangements that are not considered significant to our business at this time, such as because they relate to earlier stage assets. Such other license agreements may become material to our business in the future.

GSK (Niraparib)

In September 2016, we entered into a collaboration, development, and license agreement with Tesaro, a company later acquired by GSK, pursuant to which we 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 (ZEJULA), for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer) in mainland China, Hong Kong, and Macau. We 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, we agreed not to research, develop, or commercialize certain competing products, and we also granted GSK the right of first refusal to license certain immuno-oncology assets developed by us. In February 2018, we entered into an amendment with GSK that eliminated GSK’s option to co-market niraparib in the licensed territory. We will purchase ZEJULA from GSK for commercial use in Hong Kong. We are not otherwise obligated to purchase ZEJULA or other licensed products from GSK.

argenx (Efgartigimod)

In January 2021, we entered into a collaboration and license agreement with argenx, pursuant to which we obtained an exclusive license under certain patents and know-how of argenx to develop and commercialize products containing efgartigimod (including VYVGART and VYVGART Hytrulo) as an active ingredient in all human and animal uses for

any preventative or therapeutic indications in Greater China. Under the terms of the agreement, we are responsible for recruiting patients in Greater China to argenx's global registrational trials for the development of efgartigimod. We will purchase the licensed products exclusively from argenx.

Novo Holdings (Omadacycline)

In April 2017, we entered into a license and collaboration agreement with Paratek (which was subsequently acquired by Gurnet Point Capital and Novo Holdings A/S), pursuant to which we obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, and commercialize products containing omadacycline (NUZYRA) as an active ingredient in the field of all human therapeutic and preventative uses other than biodefense in Greater China. Under certain circumstances, our exclusive sub-license to certain intellectual property Paratek licensed from Tufts University may be converted to a non-exclusive license if Paratek's exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. We also obtained the right of first negotiation to be Paratek's partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek retains the right to manufacture the licensed products in our licensed territory to support development and commercialization of the same outside of our licensed territory. We also granted Paratek a non-exclusive license to certain of our intellectual property. Under the agreement, we agreed not to commercialize certain competing products in our licensed territory.

NovoCure (Tumor Treating Fields)

In September 2018, we entered into a license and collaboration agreement with NovoCure, pursuant to which we obtained an exclusive license under certain patents and know-how of NovoCure to develop and commercialize any Tumor Treating Fields (OPTUNE) products in all human therapeutic and preventative uses in the field of oncology in Greater China. We will purchase the licensed products exclusively from NovoCure.

Deciphera (Ripretinib)

In June 2019, we entered into a license agreement with Deciphera, pursuant to which we obtained an exclusive license under certain patents and know-how of Deciphera to develop and commercialize products containing ripretinib (QINLOCK) in the field of prevention, prophylaxis, treatment, cure, or amelioration of any disease or medical condition in humans in Greater China. We will purchase the licensed products exclusively from Deciphera.

Innoviva (Sulbactam-Durlobactam)

In April 2018, we entered into a license and collaboration agreement with Entasis (now a wholly owned subsidiary of Innoviva), pursuant to which we obtained an exclusive license under certain patents and know-how of Entasis to develop and commercialize Entasis's proprietary compounds, durlobactam with sulbactam (the combination, SUL-DUR also known as XACDURO) with the possibility of developing and commercializing a combination of such compounds with imipenem in all human diagnostic, prophylactic and therapeutic uses in Greater China, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand, and Japan. We will purchase the licensed products exclusively from Innoviva.

Pursuant to the terms of the agreement, we are responsible for (i) developing and commercializing the licensed products in the territory under a mutually agreed development plan; and (ii) providing Entasis (or its CRO) with clinical and financial support in the territory for the global pivotal Phase III ATTACK clinical trial of SUL-DUR as set forth in mutually agreed development plans. We are also responsible for a portion of the costs of the global pivotal Phase III ATTACK clinical trial of SUL-DUR outside of the licensed territory.

BMS (Repotrectinib)

In July 2020, we entered into an exclusive license agreement with Turning Point (a company later acquired by BMS) pursuant to which we obtained an exclusive license to develop and commercialize products containing repotrectinib

(AUGTYRO) as an active ingredient in all human therapeutic indications in Greater China. We will purchase the licensed products exclusively from BMS.

Amgen (Bemarituzumab)

In December 2017, we entered into a license and collaboration agreement with Five Prime (a company later acquired by Amgen), pursuant to which we 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. We will purchase the licensed products exclusively from Amgen.

Pursuant to the terms of the agreement, we are responsible for (i) developing and commercializing licensed products under a territory development plan; and (ii) performing certain development activities to support global development and registration of licensed products, including the bemarituzumab FPA144-004 Study in the licensed territory under a global development plan. If we enroll and treat a specified number of patients in the bemarituzumab FPA144-004 Study in mainland China, we will be eligible to receive a low single-digit percentage quarterly royalty on annual net sales of the licensed products outside of the licensed territory until the tenth anniversary of the first commercial sale of each such licensed product outside of the licensed territory.

Pfizer (Tisotumab Vedotin)

In September 2022, we entered into a collaboration and license agreement with Seagen (a company later acquired by Pfizer), pursuant to which we obtained an exclusive license to develop and commercialize tisotumab vedotin (TIVDAK) in Greater China. We will purchase the licensed products exclusively from Pfizer.

BMS (Xanomeline and Trospium Chloride)

In November 2021, we entered into a license agreement with Karuna (a company later acquired by BMS), pursuant to which we agreed to collaboratively develop xanomeline and trospium chloride (KarXT) in Greater China. Under the agreement, we obtained an exclusive license to develop, manufacture, and commercialize xanomeline and trospium chloride in Greater China.

MediLink (DLL3 ADC)

In April 2023, we entered into a license agreement with MediLink, pursuant to which we obtained an exclusive global license to research, develop, manufacture, and commercialize MediLink's proprietary ADC targeting DLL3.

Intellectual Property

Our commercial success depends, in part, on our ability to obtain and maintain proprietary protection for our know-how and innovation pertaining to our commercial products and product candidates as well as our core technologies; to operate without infringing, misappropriating, or otherwise violating the proprietary rights of others; and to prevent others from infringing, misappropriating, or otherwise violating our proprietary rights. We expect that we will seek to protect our commercial products, product candidates, and core technologies, among other methods, licensing or procuring patent rights to inventions that are important to the development and implementation of our business; relying on trade secrets, know-how, and confidential agreements with third parties; and relying on continuing technological innovation.

Patents

Patent rights are important in our industry to protect innovation pertaining to our commercial products, product candidates, and technologies. We hold patent rights to our commercial products, product candidates, and technologies, in part, through our licenses or other agreements. For our internally developed product candidates, we consider on a case-by-

case basis whether to procure patent rights to protect certain innovation pertaining to our commercial products, product candidates and technologies.

As with other biotechnology and pharmaceutical companies, our ability to protect our commercial products, product candidates, and technologies will depend, in part, on our success in obtaining and maintaining effective patent rights. For more information regarding the risks related to our intellectual property, see *Risk Factors – Risks Related to Intellectual Property*.

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions that we principally operate in, a patent term is 20 years from the earliest filing date of a non-provisional patent application. The laws of each jurisdiction vary, and patent term adjustment or patent term extension may not be available in any or all jurisdictions in which we hold rights. For information on intellectual property included in our license and collaboration agreements for our commercial products, see *Overview of Significant Licensed and Collaboration Arrangements*.

Trade Secrets

We also rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. Such trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our partners, collaborators, scientific advisors, employees, consultants, and other third parties. These confidentiality agreements are designed to protect our proprietary information and generally include clauses requiring assignment of inventions to us to grant us ownership of technologies that are developed through our relationship with the respective counterparty. Such agreements may not provide adequate protection of our proprietary information. If any of the parties we contract with in this manner breaches or violates the terms of any such agreement or otherwise discloses our proprietary information, we may lose our competitive position and ability to protect such proprietary information (e.g., trade secrets). For more information regarding the risks related to our trade secrets, see *Risk Factors – Risks Related to Intellectual Property – If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed*.

Trademarks and Domain Names

We conduct our business using trademarks with various forms of the “ZAI LAB” and “再鼎医药” brands, as well as domain names incorporating some or all of these trademarks.

Government Regulation

Chinese Government Regulation of Pharmaceutical Product Development, Approval, and Marketing

Since mainland China’s entry into the World Trade Organization in 2001, the Chinese government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection.

The Drug Administration Law and related implementing measures established the legal framework for the administration of pharmaceutical products, including the development and manufacturing of new drugs and the medicinal preparations by medical institutions. The Drug Administration Law also regulates the distribution, packaging, labels and advertisements of pharmaceutical products in mainland China. These rules are highly complex and require significant resources, time, and expense for compliance.

Clinical Trials

Clinical trials conducted both within and outside of mainland China, and the data derived from those trials, may be used to obtain marketing approval in mainland China, subject to various rules and regulations, including the regulations for the use of patients’ human genetic resources and derived data. We participate in clinical trials in multiple geographic

locations, and compliance with the complex regulations applicable to the conduct of such trials and the use of data derived therefrom is critical to our ability to obtain approval for our products in mainland China and in our other markets.

Clinical trials on investigational products must be approved by the relevant authorities before their commencement. Following approval of a CTA approval, the applicant (i.e., sponsor) generally conducts the clinical trial at one or more institutions, subject to rules and regulations governing good practices associated with such clinical trial.

With certain governmental approvals, companies may simultaneously perform clinical trials in different centers using the same clinical trial protocol through International Multi-Center Clinical Trials in China. Where the applicant plans to make use of the data derived from the IMCCTs, such IMCCTs shall satisfy certain requirements, including on-site inspections by Chinese regulatory authorities, in addition to other applicable regulatory requirements. IMCCTs are required to adhere to certain principles and ethical requirements and are subject to governmental supervision and disclosure requirements.

Trial sponsors may also use the data of foreign clinical trials to support marketing authorization in mainland China, provided that sponsors satisfy the authenticity, completeness, accuracy, and traceability requirements, and that such data is obtained in accordance with the relevant principles and ethics requirements applicable to IMCCTs. Clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

In addition, investigational products approved outside of mainland China may be approved in mainland China on a conditional basis without pre-approval clinical trials being conducted in mainland China. Applicants are required to establish a risk mitigation plan and may be required to complete post-approval trials in mainland China.

Marketing

We must obtain approval of marketing authorizations before our products can be manufactured and sold in the mainland China market. An applicant may submit an application for marketing authorization to relevant governmental authorities. The NMPA, which monitors and supervises the administration of pharmaceutical products, medical appliances and equipment, and cosmetics, then determines whether to approve the application following a technical review process. Accelerated review and approval procedures are available for certain types of innovative products, such as products with distinctive clinical benefits, which have not been sold within or outside mainland China, and products using advanced technology, innovative treatment methods, or distinctive treatment advantages, and in cases of public health emergency.

Domestic pharmaceutical and medical research and development institutions and individuals are eligible to hold marketing authorizations without having to become manufacturers. The marketing authorization holder is responsible for their products throughout the life cycle, including nonclinical studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals. The marketing authorization holders may engage contract manufacturers for manufacturing and distribution, subject to certain requirements. We serve as the marketing authorization holder and thus have primary regulatory responsibility for the development and approval of certain of our products in China.

Drug Manufacturing Operations

To manufacture pharmaceutical products in mainland China, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the relevant provincial medical products administration where the enterprise is located, which is effective for five years. The grant of such license is subject to annual inspection of the manufacturing facilities, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records, and management of customer complaints and adverse event reports.

Pharmaceutical Distribution

To distribute pharmaceutical products in mainland China, including wholesale and retail distribution, a pharmaceutical distribution enterprise must first obtain a Pharmaceutical Distribution Permit, which is effective for five

years. Any enterprise holding a Pharmaceutical Distribution Permit is subject to periodic review and inspection by the relevant regulatory authorities. Additional rules and regulations govern the process of procurement, storage, sales, and transportation.

Coverage and Reimbursement

Historically, most Chinese healthcare costs had been borne by patients out-of-pocket, which had limited the growth of more expensive pharmaceutical products. However, in recent years, the number of people covered by government and private insurance has increased. According to the NHSA, as of December 2023, approximately 1.33 billion residents in mainland China were enrolled in the Basic Medical Insurance scheme, representing a coverage rate of above 95% of the total population.

Under the applicable regulations, expenses of drugs listed in the Basic Medical Insurance Catalog, typically known in the industry as the “NRDL”, will be paid in full or part from the basic medical insurance fund in accordance with applicable provisions, and the drugs with the same generic names as those specified in the Basic Medical Insurance Catalog will be automatically regulated by the Basic Medical Insurance Catalog and shall also be eligible for the reimbursement by the basic medical insurance fund. The Chinese Ministry of Human Resources and Social Security, together with other government authorities, have the power to determine the medicines included in the NRDL. Admission to the NRDL depends on a number of factors, including on-market experience, scale of patient adoption, physician endorsement, cost effectiveness, and budget impact. Patients purchasing medicines included in the NRDL are entitled to reimbursement of the entire amount or a certain percentage of the purchase price. We currently have five products included in the NRDL: ZEJULA for certain ovarian cancer indications, VYVGART for gMG, NUZYRA for CABP and/or ABSSSI, QINLOCK for 4L GIST, and AUGTYRO for *ROS1*+ NSCLC.

In addition to the NRDL, there is an evolving medical insurance system that makes innovative drugs more affordable and available to the Chinese population, which offers greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as higher-cost cancer therapeutics. This system includes commercial health insurance and various forms of supplementary insurance. We have focused on increasing insurance coverage in the private-pay market for certain of our commercial products and indications, including OPTUNE for GBM.

Inclusion in the NRDL and supplemental insurance coverage can significantly increase the reach and visibility of, and potential market for, our products, and we continue to devote significant resources to increasing access to our products through NRDL listing and/or supplemental insurance coverage, which efforts may not be successful on our desired timeline or at all.

Price Negotiations

The Chinese government has initiated several rounds of price negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply, and oncology drugs since 2016. Once the government agreed with the drug manufacturers on the supply prices, the drugs would be automatically listed in the NRDL and qualified for public hospital purchase. In 2024, the average price reduction of the 117 drugs participating in price reductions was 63%; and in 2023, the average price reduction of the 121 drugs participating in price negotiations was 61.7%.

Regulations Impacting Purchases of Pharmaceutical Products by Medical Institutions

Applicable regulations set forth rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct, and standards or measures of evaluating bids and negotiating prices for public hospitals in mainland China. Under the rules and related guidance, certain not-for-profit medical institutions owned by the government shall purchase pharmaceutical products by online centralized procurement. The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the governmental or state-owned or -controlled enterprise in the relevant region. While participation in this process can

increase the reach and acceptance of our products, it can also result in significant negotiated reductions in the price paid for the products by hospitals or consortiums of hospitals bidding as a group.

In addition, under the “two-invoice system,” there cannot be more than two invoices issued for drug products supplied by manufacturers to public hospitals. To meet this requirement, many drug manufacturers have reduced the tiers of distributors, or converted drug distributors into contracted service organizations. As a result, the system significantly limits the options for companies like us to use multiple distributors to reach a larger geographic area in mainland China. The reduction in distribution tiers resulted in a decrease in distribution mark-ups and an accompanying reduction in prices paid by public hospitals. Compliance with the two-invoice system is a prerequisite for pharmaceutical companies to participate in the tender and procurement processes of public hospitals, which currently provide most of Chinese healthcare services. Manufacturers and distributors that fail to implement the two-invoice system may lose their qualifications to participate in the tender and procurement process and may also be blacklisted from engaging in drug sales to public hospitals. The two-invoice system has been implemented in all provinces, each with its own regional implementation rules.

Regulation of Pharmaceutical Product Development and Approval Outside of China

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and their implementing regulations. Drugs and biologics are also subject to other federal, state, and local statutes and regulations in the United States as well as laws, regulations, and rules in other applicable jurisdictions outside of mainland China. The process of obtaining marketing approvals and the subsequent compliance with applicable laws, regulations, and rules may require the expenditure of substantial time and financial resources. While we do not currently market our products outside of Greater China, we have certain pre-clinical and early-stage clinical products that are undergoing or will undergo testing in the United States and other jurisdictions, and we may in the future seek approval to commercialize our products in the United States and such other jurisdictions. As our business and the number of products we have in the trial and commercial stage grow, we expect that pharmaceutical laws and regulations in the United States and other jurisdictions will have a greater impact on us. Further, U.S. and other pharmaceutical regulations could impact the availability, reputation, and consumer acceptance of the products that we market and sell in our current markets.

Other Significant Regulations Affecting Our Business Activities in Mainland China

We are subject to additional regulations that apply broadly to companies doing business in mainland China, including those described below.

Data Privacy and Data Protection: Since our subsidiaries located in mainland China operate computer networks as part of their normal operations, we are required to comply with the requirements of mainland China’s cyber security, data protection, privacy, and data transfer laws and regulations. In addition, in the ordinary course of our business, we collect and store personal information, including personal information about our clinical trial subjects, customers, and employees in mainland China. We may need to share such personal information with our subsidiaries, licensors, partners, or contractors located outside of mainland China. Mainland China’s network and data protection regime is evolving, and we continue to face uncertainties as to whether our efforts to comply with these requirements will be sufficient. Although we develop and maintain compliance protocols and controls designed to maintain compliance with these requirements, development, implementation, improvement, and maintenance of these protocols and controls is costly and requires significant effort, resources, and time. In addition, in certain cases, our CROs, licensors, licensees, partners, contractors, and other third parties with which we do business are also required to comply with these laws, and our agreements with them require them to comply with these requirements, but there is a risk that they may not fully comply with them.

Foreign Investment: Chinese laws and regulations govern the establishment, operation, and management of corporate entities in mainland China, as well as investment activities by foreign investors in mainland China. To comply with these rules, we must periodically submit certain information regarding our Company and certain investment information to relevant administrative authorities.

Competition Laws: Under Chinese laws governing competition, commercial bribery is prohibited and subject to criminal liability. Further, under certain circumstances, a pharmaceutical company's products may not be purchased by public medical institutions where that pharmaceutical company is involved in a criminal investigation or administrative proceedings related to bribery. These laws also protect "trade secrets," meaning technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders and is maintained as a secret by its legal owners or holders. Unlawfully obtaining or disclosing trade secrets is prohibited. Additionally, a company whose concentration of business violates the anti-monopoly rules in mainland China may be subject to fines of up to 10% of the last year's sales revenue, in addition to other remedial measures.

Product Liability: In addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in mainland China. Under current Chinese law, manufacturers, and vendors of defective products in mainland China may incur civil and liability for loss and injury caused by such products as well as revocation of business licenses.

Tort Law: Under the PRC Civil Code, producers and sellers of defective products are required to take remedial measures such as the issuance of a warning, the recall of products, etc. in a timely manner, and may be held liable under tort law for any failure to do so, or to do so timely.

Intellectual Property Rights: Mainland China has comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights, and domain names. We hold patent rights from third parties for some of our programs as described in the *Overview of Significant License and Collaboration Agreements*. Under certain of our agreements, we rely on third parties to file and prosecute patent applications, maintain patents, and otherwise protect the licensed intellectual property.

Labor Protection: Under applicable rules in mainland China, employers must establish a comprehensive management system to protect the rights of their employees and ensure manufacturing safety, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards, and status of safe production as well as remuneration and other conditions. Employers are also required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, and maternity insurance. Additionally, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Regulations Relating to Foreign Exchange: Approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of mainland China to pay capital expenses such as repayment of foreign currency-denominated loans. For more information, see *Dividends and Other Distributions*.

Regulations on Securities Offering and Listing Outside of China: Laws in mainland China regulate overseas securities offering and listing activities by domestic companies. These regulations include the requirement to submit filing documents including the offering prospectus to the CSRC. Overseas offering and listing are prohibited under certain circumstances, including where (i) the offering and listing are expressly forbidden by applicable Chinese laws, regulations, and rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council; or (iii) there are material disputes with regard to the ownership of the equity held by the domestic company's controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller. If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they may be warned and fined up to RMB10 million.

Rules for the Regulations on Supervision and Administration of Medical Devices: Laws and regulations in mainland China govern certain aspects of the production, distribution, and clinical trials of medical devices, including

reporting, establishment, and maintenance of quality management and quality control measures covering the distribution process, self-inspection, and ethics review.

Other Chinese National- and Provincial-Level Laws and Regulations: We are subject to changing requirements under many other laws and regulations administered by governmental authorities at the national, provincial, and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases or by us to third parties. We are also subject to numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, and fire hazard control.

Anti-Corruption Laws and Regulations: We are subject to anti-corruption laws and rules in China and the United States, including the FCPA. These laws generally prohibit companies and their representatives from making improper payments to government officials for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. The health care professionals we regularly interact with may be considered government officials under Chinese anti-corruption laws or the FCPA. In 2023, Chinese authorities increased their anti-corruption enforcement efforts with respect to the health care sector.

Our Customers

We rely on independent third-party distributors in Greater China to sell our commercial products, which is consistent with the pharmaceutical industry norm. This allows us to execute marketing strategies that are specifically tailored to each product and the geographic location of the hospitals located within the distribution territories of our customers across mainland China. Our five largest customers accounted for approximately 32.4% and 35.0% of our total product revenue in 2024 and 2023, respectively.

We select distributors based on their business qualifications and distribution capabilities, such as distribution network coverage, quality, number of personnel, cash flow conditions, creditworthiness, logistics, compliance standard, past performance, and capacity for customer management. We offer rebates to our distributors, consistent with pharmaceutical industry practice. We retain no ownership control over the products sold to our distributors, and all significant risks (including inventory risks) and rewards associated with the products are generally transferred to our distributors upon delivery to and acceptance by the distributors.

Manufacturing, Suppliers, and Quality Control

As discussed below, we manufacture or source from third parties our commercial products, product candidates, and materials in accordance with the terms of our license and collaboration agreements. We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing, and testing of our commercial products and product candidates.

Our Manufacturing Facilities

We operate two manufacturing facilities in Suzhou, China, which support the commercial and clinical production of certain of our products and product candidates, including ZEJULA.

- We have a small molecule facility that manufactures ZEJULA. The oral solids production line is cGMP-compliant and is capable of performing the entire production process, including blending, granulation (i.e., wet granulation process, fluidized bed process, and roller compaction), tableting, coating, and packaging for oral solid drug products. The facility has capacity to produce up to 50 million units per year for oral solid dosage form.
- We have a large molecule facility for which we have successfully obtained permits and passed inspections to manufacture supplies for certain product candidates. The facility has a biological processing and formulation

production line with an annual production capacity of up to 12 to 22 clinical batches, each batch for 200L or 1000L.

Our two manufacturing facilities comply with both the PRC and PIC/S drug manufacturing standards. We procure our manufacturing equipment from leading domestic and international suppliers.

We believe our two manufacturing facilities are sufficient to support our commercial and clinical needs and our business growth in the near term.

CMOs

We have engaged a limited number of external CMOs to produce certain drug substances and products to meet pre-clinical, clinical, and commercial requirements of our products and product candidates. For example, we have obtained the necessary licenses and engaged CMOs to locally manufacture NUZYRA in mainland China. By outsourcing a portion of our manufacturing activities, we can increase our focus on core areas of competence such as product candidate development, commercialization, and research.

We have adopted procedures to promote compliance by our CMOs with relevant regulatory requirements and internal guidelines with respect to production qualifications, facilities, and processes. When selecting our CMOs, we consider a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability, and proposed terms for the production arrangement. Our CMOs provide services to us on a short-term and project-by-project basis. Our agreements with CMOs typically specify requirements, including product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. Our CMOs procure the necessary raw materials.

Suppliers

Our suppliers may consist of (i) third-party licensors from which we have licenses for commercial products and product candidates; (ii) suppliers of raw materials in our supply chain; and (iii) CROs to support our clinical trials.

- **Licensors:** We are dependent on some of our third-party partners for the manufacture and supply of certain of our commercial products and product candidates. For example, we source VYVGART and VYVGART Hytrulo from argenx, OPTUNE from NovoCure, QINLOCK from Deciphera, XACDURO from Innoviva, AUGTYRO from BMS, bemarituzumab from Amgen, and TIVDAK from Pfizer.
- **Other Suppliers:** We are dependent on third parties for certain raw materials in our supply chain. For example, we obtain raw materials for our clinical trial activities from multiple suppliers who we believe have sufficient capacity to meet our demands. We also believe we would have access to adequate alternative sources for such supplies, if needed. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. While we experience price fluctuations associated with our raw materials, we have not experienced material disruptions in the supply of our raw materials. We have suppliers in both China and the United States.
- **CROs:** We may depend on certain CROs to support our clinical trials.

Quality Control and Assurance

We have established a strict quality control system in accordance with NMPA regulations. We monitor our operations in real time throughout the entire production process, from inspection of raw and auxiliary materials to manufacture and delivery of finished products to clinical testing at hospitals. Our quality assurance team is also responsible for our compliance with applicable regulations, standards, and internal policies. Our senior management team is actively involved in setting quality policies and managing the internal and external quality performance of the Company.

For information on risks related to our manufacturing and commercialization activities as well as our reliance on third parties, including our third-party partners, CMOs, and suppliers, see *Risk Factors*.

Competition

Competition in the biopharmaceutical industry is intense. There are many companies, including biotechnology and pharmaceutical companies, engaged in developing products for the approved indications of our commercial products and the therapeutic areas we are targeting with our research and development activities. Some of our competitors may have substantially greater financial, marketing, research and development, and other resources than we do.

We believe that competition and leadership in the industry is based on managerial and technological excellence and innovation as well as established patent and other proprietary positions through research and development. The achievement of a leadership position also depends largely upon our ability to maximize the approval, acceptance, and use of our product candidates and the availability of adequate financial resources to fund facilities, equipment, personnel, clinical testing, manufacturing, and marketing. Another key aspect of remaining competitive in the industry is recruiting, motivating, and retaining global leaders and top talent to support our research, development, and commercial activities.

Competition among approved products may be based, among other things, on patent position, product efficacy, safety, patient convenience, delivery devices, reliability, availability, reimbursement, and price. In addition, early entry of a new pharmaceutical product into the market may have important advantages in gaining product acceptance and market share. Accordingly, the relative speed with which we can develop products, complete the testing and approval process and supply commercial quantities of products can have a significant impact on our competitive position.

The introduction of new products or technologies, including the development of new processes or technologies by competitors or new information about existing products or technologies, results in increased competition for, and pricing pressure on, our commercial products. The development of new or improved treatment options or standards of care in our therapeutic areas could reduce or eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

We also face increased competitive pressures from the introduction of generic versions, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products, which may significantly reduce both the price that we are able to charge for our products and the volume of products we sell. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenues in a short period of time.

We believe our long-term competitive position depends upon our success in discovering and developing innovative, cost-effective products that serve unmet medical needs, along with our ability to manufacture products efficiently and to launch and market them effectively in a highly competitive environment.

For information on significant risks we face from competition, see *Risk Factors*.

Insurance

We maintain insurance policies that are required under Chinese laws and regulations as well as based on our assessment of our operational needs and industry practice. We maintain liability insurance for certain clinical trials, which covers the patient human clinical trial liabilities such as bodily injury, product liability insurance, general insurance policies covering property loss due to accidents or natural disasters, and D&O insurance. We do not maintain insurance to cover intellectual property infringement or misappropriation.

Human Capital Resources

Our employees are integral to our success, and we are committed to building and maintaining a strong and engaged workforce that is focused on delivering on our mission to become a leading global biopharmaceutical company and to positively impact human health in China and beyond. We seek to attract, retain, and motivate our employees through competitive compensation programs, professional development opportunities, and employee engagement. In evaluating our human capital management, we consider various factors, including employee performance, development, and our ability to recruit well qualified employees to support our business and operations.

As of January 31, 2025, we had 1,869 full-time employees, of which 1,799 were located in Greater China. The number of full-time employees by function as of such date was as follows:

By Function	Number of Employees
Research and Development	578
Commercial	1,090
Manufacturing	68
General and Administrative*	133
Total	1,869

* Includes finance, legal, human resources, information technology, and other general and administrative functions.

Our management executive team is comprised of our CEO and her direct reports who, collectively, have management responsibility for our business. Our management team places significant focus and attention on matters concerning our human capital assets, with a focus on being an employer of choice as well as on diversity, employee capabilities and growth, and succession planning.

The competition for top talent in our industry is intense. To help attract, motivate, and retain well qualified employees, we strive to provide competitive compensation programs and benefits, including cash compensation, stock-based compensation, and other benefits to support the financial, physical, and emotional health of our employees. For our employees in China, consistent with Chinese regulations, we participate in a housing fund and various employee social security plans that are organized by applicable local municipal and provincial governments, including housing, pension, medical, work-related injury, maternity, and unemployment benefit plans, under which we make contributions at specified percentages of the salaries of our employees. For our U.S.-based employees, we provide health and welfare benefits, paid parental leave, and retirement benefits in the form of certain matching contributions to tax-qualified 401(k) plans.

We also provide professional development and training opportunities to our employees to help enhance their competencies and capabilities. These opportunities include formal and comprehensive company-level and department-level training for new employees followed by on-the-job training; periodic trainings to promote awareness and compliance with our policies and procedures; leadership development programs to cultivate leadership excellence; and cross-functional trainings to strengthen and reinforce employee collaborations across different functions, groups, and departments that work together to support our day-to-day operations. We have a performance management and talent development process through which managers provide regular feedback and coaching to develop employees. This process also helps the Company identify our pipeline of talent as well as areas in potential need of additional resources or support. We also engage our employees through employee resource groups, such as our women's leadership community and local diversity, equity, and inclusion committees.

We seek to bring together employees with different backgrounds and expertise while also creating an inclusive culture. We are proud of the diversity, skills, and achievements that our employees bring to our business from various parts of the world. In addition, we are committed to being an equal opportunity employer, where everyone is treated equally and respected, regardless of their gender, nationality, marital status, age, disability, or religious beliefs.

Our worldwide teams are united by a common mission to improve human health. We strive to maintain a good working relationship with our employees. We are committed to encouraging a culture of open communication where employees can ask questions, raise concerns, and contribute creative solutions. Our management team routinely makes themselves available to all employees, including in regular town hall events that encourage open dialogue. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we have not experienced any material work stoppages or labor disputes.

Risk Management

We are committed to acting ethically, which includes identifying and responsibly managing risk. As a result, we have adopted a consolidated risk management methodology and program, which includes three lines of defense for risk management that identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an on-going basis. We have also established a risk governance structure that includes oversight by the Board of Directors, the Audit Committee, and management. Management oversight includes a Risk Coordination Council that is comprised of leaders of governance and quality functions along with operational line leaders and serves as a forum to discuss and monitor risks across the organization as well as other regional, divisional, or functional risk management committees or working groups, as deemed appropriate.

We conduct an annual enterprise risk assessment to identify our top tier risks and, based on that assessment, will develop an enterprise risk management strategy and plans to manage those risks. Our risk management strategy takes into account various factors including our corporate strategic goals and objectives, our risk tolerance levels and thresholds, and applicable legal and regulatory requirements. We also develop and implement risk strategies for new or evolving risks during the year, as deemed appropriate. Management discusses with the Board of Directors or the Audit Committee the results of its annual enterprise risk assessments as well as its enterprise risk management methodology and guidelines and key risk-related developments.

The following provides additional information on our three lines of defense:

- **First Line of Defense:** Our business functions are primarily responsible for identifying and evaluating risks in their areas of responsibility and for developing and implementing a risk management program, including appropriate controls and procedures, to monitor, manage, and communicate to management key information with respect to these risks. Such risk management program should be consistent with our corporate business objectives and should adhere to risk policies, controls, and guidelines established by management and the Board of Directors or Audit Committee, including risk tolerance levels. Our business functions are also responsible for monitoring ongoing risks in their areas and communicating to management, as appropriate.
- **Second Line of Defense:** Our Legal and Ethics and Compliance functions oversee implementation of our enterprise risk management program and monitoring of business activities aligned with the risk outcomes identified during the annual risk assessment process. For example, our Chief Legal Officer is responsible for developing and updating our enterprise risk management program and targets; reviewing and approving management or mitigation plans for major risk management issues; overseeing implementation of risk management measures; providing guidance and support on our risk management approach to the relevant departments in the Company; and reporting to management, the Board of Directors, and the Audit Committee, as deemed appropriate.
- **Third Line of Defense:** Our Internal Audit function is responsible for evaluating the design, adequacy, operational effectiveness, and efficiency of our enterprise risk management program, including our risk governance structure, processes for enterprise risk identification and management, and risk control processes.

The following provides additional information on certain components of our risk governance structure:

- **Risk Coordination Council:** The Risk Coordination Council, which is comprised of governance function leaders as well as business operations leaders, provides a forum to discuss and identify, monitor, and manage

risks across the organization. Potential risks identified through this forum are escalated and managed at the functional line level and communicated directly to executive leadership and/or the Audit Committee, as deemed appropriate.

- **Audit Committee:** The Audit Committee is responsible for assisting the Board of Directors in its oversight of the Company's risk management and internal controls; the integrity of our financial statements; compliance with applicable legal and regulatory requirements; the qualifications, independence, and performance of our auditors; and our internal audit and compliance functions.
- **Board of Directors:** The Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies and is responsible for overseeing our enterprise risk management and internal control system and reviewing its effectiveness. The Board of Directors performs its oversight role through several different levels of review. For example, management reports to the Board on our business strategies, operations, and corporate functions, and each of the Board's Committees reports to the Board on the risks within their areas of responsibility.

Investment Risk Management

To help meet our liquidity needs without significantly increasing our risk, we have an investment policy, which was approved by the Audit Committee and provides guidelines and specific instructions for the investment of our funds. Our investment strategy aims to minimize risks by reasonably and conservatively matching the maturities of the portfolio to anticipated operating cash needs. We make our investment decisions on a case-by-case basis after considering a number of factors, including, but not limited to, our cash flow levels, operational needs, and capital expenditures; the macro-economic environment; general market conditions; and the expected profit or potential loss of the investment. In accordance with our investment policy, we may engage in short-term investments with surplus cash on hand. Our investment portfolio primarily consists of time deposits. We are prohibited from investing in high-risk products, and proposed investments must not interfere with our business operations or capital expenditures.

Dividends and Other Distributions

Zai Lab Limited is 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 their 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 mainland China. In addition, as of the date of this report, none of our subsidiaries have ever issued any dividends or distributions to us or their respective shareholders in or outside of mainland China, and neither Zai Lab Limited nor any of our subsidiaries has 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 mainland China, received \$466.5 million in capital contributions via 24 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2024 to fund its business operations in mainland China. Zai Lab International Trading (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland 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 mainland China. Zai Lab (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB166.5 million in capital contributions via ten separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2015 to 2019 to fund its business operations in mainland China. Zai Lab Trading (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland 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 mainland China. Zai Biopharmaceutical (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$15.0 million in capital contributions via four separate contributions from Zai Lab (Hong Kong) Limited, its sole

shareholder, domiciled outside of mainland China, from 2017 to 2018 to fund its business operations in mainland China. In the future, cash proceeds raised from our overseas financing activities may be transferred by us to our Chinese subsidiaries via capital contributions, shareholder loans or intercompany loans.

According to 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, or RMB, 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 RMB revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of mainland 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 those offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. RMB is currently convertible under the "current account," which includes dividends and 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 RMB), 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 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 the 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 RMB to fund our business activities outside of mainland 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, the 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 *Risk Factors* for a detailed discussion of the Chinese legal restrictions on the payment of dividends, our ability to transfer cash within the Company, and the potential for holders of our securities 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.

Available Information

We file reports and other information with the SEC and the Hong Kong Stock Exchange. We make available on our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and all other SEC reports and amendments to those reports. Additionally, we make available on our website our securities filings with the Hong Kong Stock Exchange. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC and the Hong Kong Stock Exchange, as applicable.

We use our website as a means of disclosing material non-public information – including information on our products; business activities and partnerships; research; Trust for Life strategy, commitments, and reports; and other events and developments – and for complying with our disclosure obligations under Regulation FD. Our website address is www.zailaboratory.com. We do not incorporate the information on or accessible through our website into this report, and you should not consider any information on, or that can be accessed through, our website as part of this report.

Item 1A. Risk Factors

Risk Factors

The following section includes the most significant factors that we believe may adversely affect our business and operations. You should carefully consider these risks and other information contained in this report and our other filings with the SEC before deciding to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could also adversely affect our business and operations.

Summary

This summary provides an overview of material risks that could affect our business, financial condition, results of operations, cash flows, and prospects, which should be read in conjunction with the more detailed discussion of risks that follows this summary.

- Changes in relations between the United States and China, as well as relations between China and other countries, may adversely impact our business, financial condition, and results of operations;
- We are subject to extensive laws, rules, and regulations. Compliance with these laws, including China's Counter-Espionage Law, Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, Regulation on the Administration of Human Genetic Resources, Biosecurity Law, Security Assessment Measures, and any other future laws and regulations or amendments to such laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations, as a result of uncertainties in the Chinese legal system with respect to recent anti-corruption enforcement efforts or otherwise, could lead to government enforcement actions and significant penalties against us, which could materially and adversely impact our business, financial condition, and results of operations;
- We could be adversely affected by risks of doing business globally. For example, business disruptions or other adverse effects caused by economic, political, and social conditions, including market conditions, changing legal and regulatory requirements and government policies, political instability, trade policies and sanctions, public health crises, international war or conflict, natural disasters, extreme weather events, and other geopolitical events or significant disruptions could adversely affect our business, liquidity, and access to capital;
- We have incurred losses since our inception and anticipate that we will continue to incur losses for at least the next few quarters. If we are unable to generate sufficient revenue from our approved commercial products, on the anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability;
- We rely on our licensors, CMOs, and other third parties for the commercial and clinical supply of certain of our products and product candidates. Failure of our third parties to supply us with a sufficient quantity of such products, in a timely matter or at all, will adversely affect us;
- Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which may result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third-party contract manufacturers;
- We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates, on the anticipated timeline or at all, and our business could be substantially harmed;
- If we are unable to obtain and maintain intellectual property protection for our products and product candidates (e.g., through patent property rights), or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us;

- We may not be able to protect our systems and networks, or the confidentiality of our confidential or other information (including personal information), from cyberattacks and other unauthorized access, disclosure, and disruption, which may materially and adversely affect us;
- The pre-approval of, filing, or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether or when we will be able to obtain such approval or complete such filing or other procedures;
- We may be exposed to liabilities under the FCPA and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or reputation;
- Certain of our investments may be subject to CFIUS review, which may delay or block a transaction from closing;
- Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies;
- We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to Zai Lab Limited could have a material and adverse effect on our ability to conduct our business;
- Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us;
- Chinese regulations establish complex procedures for some acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China;
- It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts or for overseas regulators to conduct investigations or collect evidence within mainland China; and
- Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

Risks Related to Doing Business in China

Uncertainties in the Chinese legal system could materially and adversely affect us.

The Chinese government has promulgated a comprehensive system of laws and regulations governing economic matters. Although such legislation has enhanced protections afforded to foreign investments in mainland China, mainland 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 mainland China. In particular, the Chinese 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 Chinese legal system continues to 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 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 Chinese 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 after an alleged violation has occurred. In addition, any administrative and court proceedings in mainland China may be protracted, resulting in substantial costs and diversion of resources and management attention.

In recent years, the General Office of the Communist Party of China Central Committee and the General Office of the State Council have focused on enhancing enforcement against illegal activities in the securities markets and promoting the development of 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 Chinese companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. There are uncertainties with respect 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 mainland China because the Chinese legal system is a civil law system and, unlike common law systems, prior court decisions have limited precedential value. Uncertainties with respect to the scope and interpretation of existing laws, rules, and regulations in China, as well as future laws, rules, and regulations or amendments to such laws, rules, and regulations, may adversely affect our business and results of operations.

Changes in relations between the United States and China, as well as relations between China and other countries, may adversely impact our business, financial condition, and results of operations.

The U.S. government, including the SEC, has made statements and taken certain actions that have impacted, and may continue to impact, companies like us with a substantial presence in China, including by imposing 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 or the possibility of legislation that restricts or prohibits U.S. investment in certain companies operating in China. The Chinese government has, from time to time, responded by imposing its own tariffs, trade restrictions, and other regulations in response. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws, or regulations will be adopted by the United States or China, or the effect that any such actions would have on companies with a significant presence in mainland China, our industry, or us. We conduct pre-clinical and clinical activities and have significant business operations in mainland China. Any unfavorable legislation, laws, regulations, executive orders, 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 have an adverse effect on our business, financial condition, and results of operations, such as by affecting the competitive position of our commercial products and product candidates, the hiring of scientists and other research and development personnel, the demand for or our ability to sell our commercial products, the import or export of raw materials in relation to drug development, our ability to raise capital, and the market price of our securities.

The Chinese government may intervene in or influence our business, which could result in a material change in our operations, strategy, research and development activities, commercial activities, business, financial condition, results of operations, and prospects.

The Chinese government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political, and societal goals. The Chinese government has published policies that significantly affect certain industries, such as the education and internet industries, and it may in the future release regulations or policies regarding the life sciences industry that could require us to seek permission from Chinese authorities to continue to operate our business or that may affect our strategy, research and development activities, or commercial activities, which may adversely affect our business, financial condition, results of operations, and prospects. Furthermore, recent statements made by the Chinese government have indicated an intent to increase the government's oversight and control over securities offerings of companies with significant operations in mainland China that are to be conducted in foreign markets, including the United States, as well as foreign investment in China-based issuers. Any such action by the Chinese government could significantly limit or completely hinder our ability to offer or continue to offer our securities to our investors and could cause the value of our securities to significantly decline or become worthless.

Because the majority of our operations are in mainland China, there have been concerns regarding oversight of audits of our financial statements filed with the SEC.

In recent years, the U.S. Congress and regulatory authorities have expressed concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in mainland China and with auditors located in mainland China. For example, inspections by the PCAOB of auditors located in mainland China and

Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, and limitations on the ability of the PCAOB to inspect or investigate auditors in mainland China or Hong Kong could deprive investors of the benefits of PCAOB inspections. This focus on access to audit and other information for companies with substantial operations in China has resulted in legislation, such as the HFCAA which requires the SEC to identify issuers that have filed an annual report with an audit report issued by a registered public accounting firm that is located in certain foreign jurisdictions and to prohibit any issuers so identified by the SEC for two consecutive years from trading their securities on a national securities exchange or over-the-counter market in the United States. In the past, we have used auditors located in mainland China; however, in May 2022, the Company engaged KPMG LLP, an auditor located in the United States that is inspected by the PCAOB, as our independent registered public accounting firm, and KPMG LLP has been our auditor for all of the periods presented in this report. Although we are not currently at risk of delisting pursuant to the HFCAA, our ability to access the U.S. capital markets and the market price of our securities could be adversely affected as a result of new legislation, different interpretations of existing legislation, or the anticipated negative impacts of legislative or executive or regulatory actions upon, or negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States.

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

In the first quarter of 2023, the CSRC adopted the Archives Rules. According to the Archives Rules, we may be required to complete certain approval, filing, and regulatory procedures if it becomes necessary for us to disclose or provide to KPMG LLP, our U.S. auditor that is subject to inspection by the PCAOB, any documents or materials relevant to KPMG LLP's audit that are deemed to have a sensitive impact (i.e., be detrimental to national security or the public interest if divulged) or contain state secrets or governmental authority work secrets. Under those circumstances, KPMG LLP would also be required to abide by corresponding approval, filing, and compliance procedures. Due to the lack of further interpretation, we are not certain about the scope of materials that would be deemed to have a sensitive impact or contain state or governmental authority work secrets.

We are subject to extensive data protection, privacy, and information security laws, regulations, and policies in China. Compliance with such laws, rules, and regulations, and any other future laws and regulations in these areas, may entail significant expenses and could materially affect our business and results of operations, including as a result of government enforcement actions and significant penalties.

We are subject to extensive data protection, privacy, and information security laws, rules, and regulations in China, such as the Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, Regulation on the Administration of Human Genetic Resources, Biosecurity Law, and Security Assessment Measures. These laws, rules, and regulations require us to take certain measures to promote the security of our networks and data stored on our networks (including with respect to collection, storage, processing, and transfer), to monitor and manage related risks, and to disclose certain incidents to affected parties and appropriate regulators. Establishing and maintaining such systems and complying with such requirements takes substantial time, effort, and cost. These laws, rules, and regulations also impose certain requirements on, and may limit our ability to, transfer certain data, such as personally identifiable information of persons located within mainland China and de-identified or anonymized health data for clinical trials, outside of China, including to our third-party partners and foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. Certain violations of these laws, rules, and regulations could lead to enforcement actions, significant fines, and/or criminal, civil, or administrative penalties. If we are not able to transfer data outside of mainland China to comply with our contractual requirements or requirements of judicial or law enforcement authorities outside of mainland China, as a result of our requirements in China, it could materially and adversely affect our business and operating results.

Although we believe we are compliant with our material legal obligations in these areas, the interpretation, application, and enforcement of these laws, rules, and regulations may evolve over time or change. Our compliance with such existing laws, rules, and regulations, or any future related laws and regulations, could significantly increase our compliance costs, require significant changes to our operations, result in suspensions or delays of our clinical trials or

impair or ability to initiate new clinical trials, or even prevent us from providing certain products in jurisdictions in which we currently operate or may in the future wish to operate. Any actual or perceived failure on our part to comply with such laws, regulations, or obligations relating to privacy, data protection, information security, or national security in China could result in investigations, fines, suspension, or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition, results of operations, and reputation. Further, legal uncertainty created by such laws, rules, and regulations as well as recent Chinese government actions could adversely affect our ability to raise capital in the U.S. on favorable terms or at all.

The economic, political, and social conditions in mainland China, as well as governmental policies, could affect the business environment and financial markets in mainland China and our ability to operate our business, financial condition, results of operations, and prospects.

A substantial portion of our operations, and all of our commercial operations, are conducted in mainland China. Accordingly, our business, financial condition, results of operations, and prospects may be significantly influenced by economic, political, legal, and social conditions in mainland China. Mainland China's economy differs from the U.S. economy in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange, and allocation of resources. While mainland China's economy has experienced significant growth, such growth has been uneven across regions and sectors. The Chinese government has implemented various measures to encourage economic development and allocation of resources. Some of these measures may benefit the overall economy in mainland China but may have a negative effect on our business. For example, 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 transactions, and other regulations that are currently or may in the future apply to us. Recently, Chinese regulators have announced regulatory actions aimed at providing the Chinese government with greater oversight over certain sectors of mainland China's economy, including the for-profit education and technology sectors. Although the biotech industry is already highly regulated in mainland China and there has been no indication of such actions or oversight in our sector, the Chinese government may in the future take regulatory actions that materially adversely affect our business, financial condition, results of operations, or prospects or the business environment and financial markets in mainland China more broadly.

We are required to obtain certain approvals and licenses from Chinese authorities to operate our Chinese subsidiaries.

The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. For example, to conduct our business activities in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the SAMR. Our ability to operate in mainland China could be undermined if our Chinese subsidiaries are not able to obtain or maintain required approvals from Chinese authorities to operate in mainland China. 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. The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could require additional expenditures and efforts on our part to comply with such regulations or interpretations. If in the future our Chinese subsidiaries do not receive or maintain required approvals, such as because we inadvertently conclude that approvals are not required or because of changes in applicable laws and regulations or interpretations of such laws and regulations, the operations of our Chinese subsidiaries, and as a result our business, results of operations, financial condition, and prospects, could be adversely affected.

Under Chinese laws and regulations, we may be required by the CSRC or other Chinese regulatory authorities to obtain approval or follow certain procedures to issue our securities to foreign investors, and we cannot predict whether or when we will be able to obtain such approval or complete such procedures.

We are not currently required under Chinese laws and regulations to obtain prior approval or prior permission from the CSRC or any other Chinese regulatory authority to issue securities to foreign investors, and we do not believe we will be required to submit an application to the CSRC for our previous issuances of securities to foreign investors. Under recent guidelines, however, we are required to submit filings to the CSRC following the submission of future overseas listings and

the completion of future offerings of our equity securities to foreign investors, including for future securities offerings in the same overseas markets as our previous issuances. For example, we were required to file with the CSRC with respect to the registered offering of our ADSs in November 2024. If, for any reason, we were to fail to obtain any approvals or to complete any filings or other procedures required by the CSRC or other Chinese regulatory authorities, future offerings of our equity securities to foreign investors may be delayed or prevented or we may face sanctions, fines, and/or other penalties; limitations on our ability to pay dividends outside of mainland China; limitations on our operations in mainland China; delays or restrictions on the repatriation of the proceeds from our public offerings into mainland China; or other actions that could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be exposed to liabilities under anti-corruption, anti-bribery, and anti-fraud laws in China and the United States, including the FCPA, and any allegation, investigation, or determination that we, or our employees or contracted third parties, have violated such laws could have a material adverse effect on our business or reputation.

We, our employees, and our contracted third parties are subject to anti-corruption laws in China and the United States, including the FCPA, which generally prohibit, among other things, making improper payments to government officials for the purpose of obtaining or retaining business, and Chinese laws governing competition, which prohibit commercial bribery. In addition, we, our employees, and our contracted third parties are subject to laws targeted at medical insurance and other fraud in China and the United States. Although we have implemented controls and procedures to promote compliance with such laws by our Company, employees, and contracted third parties, any failures to comply may harm our business and reputation and may cause us to incur criminal or civil liabilities, penalties, sanctions, and/or other significant expenses, which may have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, under certain circumstances, a pharmaceutical company's products may not be purchased by public medical institutions if that pharmaceutical company is involved in a criminal investigation or administrative proceeding related to bribery.

In addition, Chinese authorities have become increasingly active in enforcing laws affecting the pharmaceutical industry. Specifically, the Chinese authorities have recently increased anti-bribery and anti-fraud efforts to address improper payments and other benefits received by physicians, staff, hospital administrators, and other individuals in connection with the sales, marketing, and purchase of pharmaceutical products. The scope and intensity of such recent anti-corruption and medical insurance fraud enforcement efforts in China have led to increased uncertainty in the healthcare industry, which have impacted and may continue to impact hospital and physician practices. Such uncertainty, and related evaluations and adjustments by hospitals and physicians and other market participants, may adversely affect our business and results of operations.

Furthermore, we have been, and may in the future be, involved in inquiries or investigations by Chinese authorities as part of these enforcement efforts or otherwise. Although we have not experienced a material adverse impact to the Company from such an inquiry or investigation to date, there can be no such assurance that such inquiries or investigations will not have a material adverse effect on our business, reputation, or operations in the future. For example, there have been public reports of recent investigations by Chinese authorities in relation to alleged medical insurance fraud and potential violations of China's data privacy and other laws by a number of persons affiliated with AstraZeneca. Certain of our former and current employees were formerly employed with AstraZeneca. Some of our current and former employees in our ZEJULA sales team are under criminal investigations by Chinese authorities in their personal capacity and have been detained for questioning or otherwise under police compulsory measures in connection with alleged medical insurance fraud, a crime under Chinese law that can be prosecuted only against individuals and not against companies. Such investigations, allegations, and the reporting thereof, and any potential enforcement actions, formal convictions, or administrative penalties or fines in connection therewith, may materially adversely affect our business and reputation. In addition, such investigations may lead to additional allegations or findings or may implicate or expand to additional employees. While we are not currently aware of any allegations or investigations into actions which may result in the criminal liability of the Company, there can be no assurance that such allegations or investigations will not result in a material adverse effect on our business.

Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies effectively.

The ability of our Chinese subsidiaries to exchange currency is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the SAFE. For example, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to exceed the statutory limits, and such loans must be registered with the local counterpart of the SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the SAMR or its local branch, reporting of foreign investment information with the MOFCOM, or registration with other governmental authorities in mainland China.

In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we may not be able to complete the necessary government formalities or obtain the necessary government approvals on timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our Chinese operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund or expand our business.

We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material adverse effect on our business operations.

Zai Lab Limited is 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 holders of our securities or to service any debt we may incur. Certain of our Chinese subsidiaries have incurred debt on their own behalf, and these or others may do so 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 mainland China. In addition, none of our subsidiaries have issued any dividends or distributions to us or their respective shareholders in or outside of mainland China, and neither we nor any of our subsidiaries have 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 mainland China, received \$466.5 million in capital contributions via 24 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2024, to fund its business operations in mainland China. Zai Lab International Trading (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland 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 mainland China. Zai Lab (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB166.5 million in capital contributions via 10 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2015 to 2019 to fund its business operations in mainland China. Zai Lab Trading (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland 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 mainland China. Zai Biopharmaceutical (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$15.0 million in capital contributions via four separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2017 to 2018 to fund its business operations in mainland China. In the future, cash proceeds raised from our overseas financing activities may be transferred by us to our Chinese subsidiaries via capital contributions, shareholder loans or intercompany loans, as the case may be.

According to 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.

RMB 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 RMB revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of mainland 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 those offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. RMB 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 RMB), 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 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 the 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 RMB to fund our business activities outside of mainland 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, the SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit the ability of these subsidiaries to increase their registered capital or distribute profits to us, or otherwise adversely affect us.

Our shareholders that are residents of mainland China are required to register with local branches of the SAFE or competent banks designated by the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents’ legally owned assets or equity interests in domestic enterprises or offshore assets or interests, being considered a “special purpose company.” If such shareholders do not complete their registration with the local SAFE branches or otherwise fail to comply with the SAFE registration requirements, the Chinese subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer, or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its Chinese subsidiaries. Moreover, failure to comply with SAFE registration requirements could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and ability to distribute profits could be materially and adversely affected.

Chinese regulations establish complex procedures for certain acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China.

Chinese regulations establish certain additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, companies must notify the MOFCOM in advance of any change-of-control transaction in which a foreign investor takes control of a Chinese domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national security, (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or Chinese time-honored brand, or (iv) such transaction involves the concentration of business undertakings by way of mergers, acquisitions, or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player. In the future, we may grow our business by acquiring complementary businesses. Complying with the necessary notification and review requirements to complete such transactions may be time consuming, and our ability to obtain any necessary approvals, such as from the MOFCOM or its local counterparts, may delay or

prevent our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises national security concerns. If our business is deemed to be in an industry subject to national security review, our future acquisitions in mainland China may be closely scrutinized or prohibited, and our ability to expand our business through future acquisitions would be materially and adversely affected.

Completing the necessary inspection and approval processes for our Chinese manufacturing facilities, such as by the FDA, NMPA, and EMA, may be time consuming and costly.

As part of obtaining required regulatory approvals for our product candidates, such as by the NMPA in mainland China, FDA in the United States, and EMA in the EU, we will need to undergo strict pre-approval inspections of our manufacturing facilities or the manufacturing facilities of our CMOs, including those located in mainland China and elsewhere. Historically, some manufacturing facilities in mainland China have had difficulty meeting required standards. When inspecting Chinese manufacturing facilities, our regulator(s) might cite GMP deficiencies, both minor and significant. Our efforts to remediate deficiencies to the satisfaction of our regulator(s) can be laborious, time-consuming, and costly and may be unsuccessful. If we cannot satisfy our regulator(s) as to our compliance with GMP, marketing approval for our product candidates could be significantly delayed or prevented, which in turn would delay or prevent commercialization of our product candidates.

Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our business, financial condition, and results of operations.

Local governments within mainland China have granted certain financial incentives to our Chinese subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount, and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty. We received government grants and subsidies of \$8.2 million and \$2.4 million in 2024 and 2023, respectively. Local governments may decide to reduce or eliminate incentives that we are receiving at any time. In addition, some government financial incentives are granted on a project basis and are subject to the satisfaction of certain conditions, including compliance with applicable financial incentive agreements and completion of the specified projects. If we fail to satisfy the necessary conditions, we may be deprived of the relevant incentives. Any reduction or elimination of government incentives may have an adverse effect on our business, financial condition, and results of operations.

It may be difficult for shareholders and regulators outside of mainland China to conduct investigations or collect evidence in mainland China.

It may be difficult for shareholders to pursue claims or for regulators outside of mainland China to conduct regulatory investigations in mainland China as a matter of law or practicality. For example, in mainland China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside of mainland China. Although authorities in mainland China may establish a regulatory cooperation mechanism with authorities of another country or region to implement cross-border supervision and administration, such cooperation with authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanisms. Furthermore, under Chinese securities laws, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities in mainland China, which may further increase difficulties shareholders may face in protecting their interests.

If we are classified as a Chinese resident enterprise for Chinese income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders.

Under the EIT Law, an enterprise incorporated outside of mainland China whose “de facto management bodies” are located in mainland China is considered a “resident enterprise” and will be subject to a uniform 25% enterprise income tax, or EIT, rate on its global income.

We believe that neither Zai Lab Limited nor any of our subsidiaries outside of mainland China is a Chinese resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by Chinese

tax authorities, and uncertainties remain with respect to the interpretation of the term “de facto management body.” If Chinese tax authorities determine that Zai Lab Limited or any of our subsidiaries outside of mainland China is a Chinese resident enterprise for EIT purposes that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly owned subsidiaries in mainland China, a 25% EIT on its global income may increase our tax burden.

In addition, if Zai Lab Limited is classified as a Chinese resident enterprise for Chinese tax purposes, we may be required to withhold tax at a rate of 10% from dividends we pay to our shareholders, including the holders of our ADSs that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% Chinese withholding tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within mainland China. Furthermore, gains derived by our non-Chinese individual shareholders from the sale of our securities may be subject to a 20% Chinese withholding tax. It is unclear whether our non-China-based individual shareholders (including our ADS holders) would be subject to any Chinese tax (including withholding tax) on dividends received by such non-Chinese individual shareholders in the event we are determined to be a Chinese resident enterprise. If any Chinese tax were to apply to such dividends, it would generally apply at a rate of 20%. Chinese tax liability may vary under applicable tax treaties. However, it is unclear whether our non-Chinese shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and mainland China in the event that Zai Lab Limited is treated as a Chinese resident enterprise.

We and our shareholders may face tax consequences and other requirements in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises.

The indirect transfer of equity interests in Chinese resident enterprises by a non-Chinese resident enterprise, or Indirect Transfer, is potentially subject to income tax in mainland China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The Chinese State Administration of Taxation has issued several rules and notices to tighten scrutiny over such acquisition transactions in recent years and has provided certain factors and criteria that will be considered in determining whether an indirect transfer has a bona fide commercial purpose. Failure to withhold and remit required taxes may result in tax liability and a penalty of 50% to 300% of the unpaid tax.

It is unclear how these rules and regulations affect future private equity financing transactions, share exchange, or other transactions involving the transfer of shares in Zai Lab Limited by investors that are non-Chinese resident enterprises or the sale or purchase of shares in other non-Chinese resident companies or other taxable assets by us. As a result, we may be required to expend valuable resources to determine whether we or our non-Chinese resident investors are subject to filing, withholding, or tax obligations for certain transactions, such as offshore restructuring transactions or acquisition transactions, and to otherwise comply with these rules and regulations. This may have a material adverse effect on our financial condition, results of operations, and ability to complete such transactions with non-Chinese resident investors.

Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, which may delay or block a transaction from closing.

The CFIUS has jurisdiction over investments in which a foreign person acquires control over a U.S. company, as well as certain non-controlling investments in U.S. businesses that deal in critical technology, critical infrastructure, or sensitive personal data. Some transactions involving U.S. businesses that deal in critical technology are subject to a mandatory filing requirement. Accordingly, to the extent the U.S. portion of our business decides to take investments from foreign persons, or we decide to invest in or acquire, in whole or in part, a U.S. business, such investments could be subject to CFIUS’s jurisdiction. To date, none of our investments have been subject to CFIUS review, but depending on the particulars of ongoing or future investments, we may be obligated to secure CFIUS approval before closing, which could delay the time period between signing and closing. If we determine that a CFIUS filing is not mandatory (or otherwise advisable), there is a risk that CFIUS could initiate its own review, if it determines that the transaction is subject to its jurisdiction. If an investment raises significant national security concerns, CFIUS has the authority to impose mitigation conditions or recommend that the President block a transaction.

In September 2022, President Biden issued an executive order to instruct CFIUS to consider national security factors when evaluating transactions, specifically a deal's effect on critical U.S. supply chains, U.S. technological leadership in biotechnology and biomanufacturing, cybersecurity risks, or risks to U.S. persons' sensitive data. As a result, companies with significant operations in China will likely face heightened regulatory scrutiny from CFIUS in conducting acquisition of U.S. biotech companies.

Changes in United States and international trade policies and relations, particularly with regard to China, may adversely impact our business, financial condition, and results of operations.

The U.S. government has recently made statements and taken certain actions that have led to changes to United States and international trade policies and relations, including imposing several rounds of tariffs affecting certain products manufactured in China and imposing certain sanctions and restrictions in relation to China. The Chinese government has, from time to time, responded by imposing its own tariffs, sanctions, and restrictions in response. It is unknown whether and to what extent new tariffs or other new executive orders, laws, or regulations will be adopted, or the effect that any such actions would have on us or our industry. We conduct pre-clinical and clinical activities and have business operations both in the United States and mainland China, and any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our products, the competitive position of our products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development or may prevent us from selling our products in certain countries. If any new tariffs, legislation, executive orders, and/or regulations are implemented, existing trade agreements are renegotiated, or the U.S. or Chinese government takes retaliatory actions due to recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition, and results of operations.

It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts.

Zai Lab Limited is a company organized under the laws of the Cayman Islands, and a substantial portion of our assets and operations are located in mainland China. In addition, some of our directors and officers are nationals and residents of countries or regions other than the United States or Hong Kong, and a substantial portion of their assets is located outside of the United States and Hong Kong. As a result, it may be difficult to effect service of process within the United States or Hong Kong upon these persons, or to bring an action against us or these individuals in the United States or Hong Kong in the event of a disagreement, under federal securities laws, or otherwise. Even if a third party successfully obtains a foreign judgment against us or these individuals, the laws of the Cayman Islands and mainland China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is uncertainty as to whether the courts of the Cayman Islands or mainland China would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of securities laws of the United States or any state.

Although there are some protections with respect to enforcement in mainland China of judgments rendered by Hong Kong courts as a result of reciprocal recognition and enforcement of judgment arrangements, mainland China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, most other western countries, or Japan. In addition, according to PRC Civil Procedures Law, mainland China courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of Chinese laws or national sovereignty, security, or public interest. Hence, the recognition and enforcement in mainland China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business.

We lease properties for our offices and manufacturing facilities. We may not be able to successfully extend or renew such leases upon expiration of the current term on commercially reasonable terms or at all and may therefore be forced to relocate our affected operations. This could disrupt our operations and result in significant relocation expenses, which could adversely affect our business, financial condition, and results of operations. In addition, we compete with other

businesses for premises at certain locations or of desirable sizes. As a result, even though we could extend or renew our leases, rental payments may significantly increase as a result of the high demand for the leased properties. In addition, we may not be able to locate desirable alternative sites for our current leased properties as our business continues to grow and failure in relocating our affected operations could adversely affect our business and operations.

Risks Related to Our Financial Position

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for at least the next few quarters. If we are unable to generate sufficient revenue from our commercial products, on the anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability.

We currently have seven commercial programs with products that are approved and marketed for certain indications in mainland China, and we are pursuing regulatory approval of new products and additional indications for our existing products in our global and regional pipelines. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through revenues from the sales of our commercial products and offerings on Nasdaq and the Hong Kong Stock Exchange, including a registered offering of our ADSs in November 2024, as well as private placements. Although our annual product revenues have been increasing for the last few years and we continue to focus on efficiency and productivity, we continue to incur significant development, commercialization, and other expenses related to our ongoing operations. As a result, we have incurred net losses since our inception, including \$257.1 million for 2024. If we are unable to generate sufficient revenue from sales of our approved commercial products, on our anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability.

There are several factors that could impact our ability to achieve and maintain profitability, including the success and costs of our commercial products; our ability to obtain approvals for and commercialize new products or additional indications for existing products and costs of our clinical trials; our ability to build and strengthen our pipeline through internal discovery and business development activities and costs related to any related license and collaboration arrangements; the costs and efficiency of our commercial and R&D teams and other personnel; and our ability to overcome unforeseen challenges or absorb unforeseen expenses that may adversely affect our business. Our failure to become and remain profitable would decrease the value of the Company or our securities and could impair our ability to raise capital, maintain our research and development and commercialization efforts, or expand or maintain our business.

We may seek additional funding, such as for our product development programs and commercialization efforts, which may not be available on acceptable terms or at all. If we are unable to raise capital on acceptable terms when needed, we could be forced to delay, reduce, or terminate certain programs or activities.

Since inception, we have incurred significant costs for our commercialization efforts with respect to our approved products, our research and development efforts related to our product candidates and related clinical or pre-clinical trials, our business development activities and related upfront or milestone fees or royalty payments in our license and collaboration arrangements, and other costs to develop the infrastructure and otherwise support our operations. To date, we have financed our activities primarily through revenues from the sales of our commercial products and offerings on Nasdaq and the Hong Kong Stock Exchange, including a registered offering of our ADSs in November 2024, as well as private placements. Additionally, as discussed below, we and our subsidiaries have also entered into certain debt arrangements with financial institutions in mainland China to support our working capital needs in mainland China. We may require or seek to obtain additional funding in connection with our operations through public or private equity offerings, debt financing, collaborations or licensing arrangements, or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses or be forced to delay, reduce, or terminate certain programs or activities.

Although we believe our cash and cash equivalents and short-term investments as of December 31, 2024 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months, we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- revenues from our approved commercial products and related product costs;
- the cost and timing of future commercialization activities for our products and any other product candidates for which we receive regulatory approval;
- the cost, timing, and outcome of seeking, obtaining, and maintaining regulatory approval for our products and product candidates;
- the scope, progress, timing, results, and costs of researching and developing our product candidates, including additional indications for our existing commercial products, and conducting pre-clinical and clinical trials;
- our ability to establish and maintain strategic partnerships, including collaboration, licensing, or other arrangements and the economic and other terms, timing, and success of such arrangements, such as with respect to any upfront fees, development and regulatory milestones that may be payable prior to commercialization or before we have generated revenue from the related product, and sales-based milestones or royalty payments that may be payable after commercial launch;
- the cost, timing, and outcome of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property related claims;
- cash requirements of any future acquisitions;
- resources and costs required to promote compliance with applicable laws and regulations by us and our third-party partners;
- costs of our personnel; and
- the costs of operating as a public company in both the United States and Hong Kong.

We and our subsidiaries have entered into debt arrangements with certain financial institutions in China, and we may in the future consider additional debt arrangements, to fund our business or working capital needs. Such debt arrangements may restrict our future operations.

We may enter into debt arrangements with certain financial institutions to support our business and working capital needs. To date, we have entered into certain debt arrangements with Chinese financial institutions that allow certain of our wholly-owned subsidiaries to borrow up to approximately \$240.2 million (or RMB1,721.7 million) to support our working capital needs in mainland China, and Zai Lab Limited has agreed to guarantee approximately \$217.7 million (or RMB1,561.7 million) of this debt. Such debt requires us or our subsidiaries to dedicate a portion of our or their cash flow to service interest and principal payments and, if interest rates rise, this amount may increase. As a result, our existing debt may limit our ability to use our cash flow to fund capital expenditures, to engage in transactions, or to meet other capital needs. Additionally, our subsidiaries' debt service obligations may limit their ability to make future distributions to us. Our debt could also limit our flexibility to plan for and react to changes in our business or industry and may increase our vulnerability to general adverse economic and industry conditions, including a downturn in our business or the economy. This debt is denominated in RMB, and some bears interest at variable rates. As a result, increases in market interest rates and changes in foreign exchange rates could require a greater portion of our cash flow to be used to pay interest, which could further hinder our operations. We may also have difficulty refinancing our existing debt or incurring new debt on terms that we would consider commercially reasonable or at all. To the extent that we incur additional indebtedness, the foregoing risks could increase.

We may enter into certain capital raising, business collaboration, or other arrangements that may cause dilution to our shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

We may seek business opportunities or additional funding in the future through equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances, and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, such as our registered offering of our ADSs in November 2024, our shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect rights of our security holders. The incurrence of additional indebtedness or the

issuance of certain equity securities could result in increased fixed payment obligations and additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our securities to decline. Additionally, to finance any acquisitions, licensing arrangements, or strategic alliances, we may choose to issue our securities as consideration, which could dilute the ownership of our shareholders. In the event that we enter into collaboration or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or product candidates.

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

We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business initiatives. The capital and credit markets are experiencing, and have in the past experienced, extreme volatility and disruption, which leads to uncertainty and liquidity issues for borrowers and investors. That volatility and unpredictability in the financial markets has adversely affected, and may in the future adversely affect, access to capital and credit for life sciences companies, particularly for companies like ours with significant operations in China as a result of geopolitical tensions between the United States and China or otherwise. In the event of adverse market conditions, we may be unable to obtain adequate capital or credit market financing, obtain that capital or credit on favorable terms, or access such capital or credit in the market(s) or manner most favorable to the Company.

Our results of operations may be adversely affected by sustained periods of increased inflation.

The global economy, including the U.S. economy, has experienced rising inflation in recent years. We source our products, product candidates, and key materials from third parties located in the United States, including our licensors, other suppliers, and CROs. For example, we rely on argenx for VYVGART and VYVGART Hytrulo, NovoCure for OPTUNE, Deciphera for QINLOCK, Innoviva for XACDURO, and BMS for AUGTYRO. Although we have not been materially affected by inflation in the past, sustained or increased inflation may result in increased product costs or other expenses. As a result, our results of operations may be adversely affected.

Risks Related to Our Business and Industry

Our ability to generate revenues is highly dependent on the success of our commercial products and our ability to obtain regulatory approvals for our product candidates.

Our ability to generate product revenues depends on the success of our commercial products, including our current commercial products as well as new products or additional indications for our current commercial products that we may launch in the future. Our ability to successfully generate revenue from our commercial products will depend on, among other things, our ability to:

- maintain sufficient manufacturing or supply arrangements with third-party licensors or manufacturers;
- produce through a validated process or procure internally or from third-party manufacturers sufficient quantities and inventory of our commercial products;
- build and maintain sufficient internal sales, distribution, and marketing capabilities;
- increase awareness and education for our commercial products to promote acceptance from physicians, healthcare payors, patients, and the medical community;
- improve access to, and affordability of, our commercial products, such as through NRDL listings or supplemental insurance coverage in the private-pay market;
- maintain compliance with ongoing regulatory labeling, packaging, storage, advertising, promotion, recordkeeping, safety, and other post-marketing requirements;

- manage our growth and spending as costs and expenses increase due to commercialization; and
- manage business interruptions resulting from the occurrence of any public health crisis, international war or conflict, natural disaster, extreme weather event, or other significant or catastrophic event outside of our control.

We have several product candidates in late-stage clinical development and various others in earlier stage clinical and pre-clinical development. Our ability to generate revenue from our product candidates is dependent on the results of clinical and pre-clinical development, our receipt of regulatory approval, and successful commercialization of such products, which may not occur on the anticipated timeline or at all. The success of our product candidates will depend on several factors, including the following:

- successful enrollment of patients in, and completion of, clinical trials and pre-clinical studies;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing, and commercialization;
- successful completion of all safety and efficacy studies required to obtain regulatory approval in Greater China, the United States, and other jurisdictions for our product candidates;
- adapting our commercial manufacturing capabilities to the specifications for our product candidates for clinical supply and commercial manufacturing and/or making and maintaining necessary arrangements with third-party manufacturers or suppliers;
- obtaining, maintaining, and successfully enforcing or defending patent, trade secret, and other intellectual property protection and/or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- the success of our marketing efforts and market acceptance of the product candidates by patients, the medical community, and third-party payors;
- effectively competing with any competing products or therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety, tolerability, and efficacy profile of the product candidates following regulatory approval.

We are not permitted to market any of our products or product candidates in mainland China, the United States, the EU, or any other jurisdictions until we have received required regulatory approvals. The process to develop, obtain regulatory approval, and commercialize product candidates is long, complex, and costly and varies among countries. The successful completion of clinical trials or regulatory approval in one country does not mean that clinical trials will be successful, or regulatory approval will be obtained, in any other country. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement regarding the number, design, size, conduct, or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the regulator(s) that a product candidate is safe and effective for its proposed indication, including as a result of safety issues, product recalls, or other incidents related to products approved and marketed in other jurisdictions;
- failure of CROs, clinical study sites, or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the regulator(s);
- failure of the clinical trial results to meet the required level of statistical significance;

- failure to demonstrate that clinical and other benefits outweigh safety risks;
- disagreement regarding the interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA, PMA, or other submission required to obtain regulatory approval in Greater China, the United States, the EU, or elsewhere;
- failure to obtain approval of the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations; and
- actions by our CROs or licensors that materially and adversely affect the clinical trials.

If we are not successful in gaining broad acceptance of our commercial products, our business would be harmed.

Sales of our commercial products will depend on our ability to educate and increase physician awareness of the benefits, safety, and cost-effectiveness of such products, in general and relative to any competing therapies. The degree of market acceptance of our commercial products among physicians, patients, healthcare payors, and the medical community may depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing, cost effectiveness, and value propositions;
- effectiveness of our sales and marketing capabilities and strategies;
- ability to obtain sufficient insurance coverage and reimbursement;
- the clinical indications for which such product are approved, as well as changes in the standard of care for their targeted indications;
- the effectiveness of manufacturing and supply chain;
- warnings and limitations contained in the approved labeling;
- safety concerns with respect to similar or competing products marketed by others;
- our ability to comply with regulatory post-marketing requirements;
- the market size for such product, which may be larger or smaller than expected;
- entry timing and price for any competing products; and
- our ability to manage complications or barriers that inhibit our commercial team from reaching the appropriate audience to promote our product(s), such as because of government actions or business disruptions caused by public health crises, natural disasters, extreme weather events, and other significant or catastrophic events.

We may not obtain regulatory approval of our product candidates, on the anticipated timeline or at all, which could delay or limit our ability to realize the full potential of our product pipeline.

In order to market products in any given jurisdiction, we must obtain regulatory approval and comply with numerous and varying regulatory requirements regarding safety, efficacy, and quality. We have obtained approval for our current commercial products for certain indications in certain jurisdictions in Greater China. We may not obtain regulatory

approval for our product candidates, including new products or additional indications for our current commercial products, on the anticipated timeline or at all, which could delay or limit our ability to realize the full potential of our pipeline.

We have limited experience manufacturing our products and product candidates on a large clinical or commercial scale. We rely on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacture of our products or product candidates could be delayed, which could harm our business and results of operations.

We currently manufacture, or have rights to manufacture, our internally developed products and certain of our licensed commercial products and product candidates under the terms of our licensing arrangements. We rely on our two manufacturing facilities in Suzhou to support the clinical development and commercial production of such products and product candidates, including ZEJULA. If our manufacturing facilities are unable to meet our intended production capacity in a timely fashion, we may have to engage a CMO(s) for the production of clinical supplies of our products or product candidates. We may not be able to identify qualified CMOs or alternative suppliers that are able to meet our product production needs on commercially reasonable terms, in a timely manner, or at all. If we are not able to maintain sufficient quantity of our manufactured products and product candidates, our business and results of operations could be adversely affected.

If our manufacturing facilities are damaged or destroyed, or production at such facilities is otherwise interrupted, or if any new manufacturing facilities are not approved by regulators, our business and prospects would be negatively affected.

We have two manufacturing facilities in Suzhou that have received required approvals from our regulators, and we rely on these facilities for the manufacture of clinical and commercial supply for certain of our products and product candidates. If our facilities were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capabilities. In such event, we would be forced to identify and rely partially or entirely on third-party CMOs for an indefinite period. Any new facility needed to replace an existing production facility would need to comply with necessary regulatory requirements and be tailored to our production requirements and processes. We also would need regulatory approvals before using any products or drugs manufactured at a new facility in clinical trials or selling any products or drugs that have been approved. Any disruptions or delays at our facilities or their failure to comply with regulatory requirements would impair our ability to develop and commercialize certain of our products or product candidates, which may adversely affect our business and results of operations.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business and to assess our future prospects.

We are a commercial-stage biopharmaceutical company with a relatively limited operating history. Consequently, any predictions about our future success, performance, or prospects are subject to significant uncertainty, particularly in light of the dynamic and evolving industry in which we operate. We will encounter risks and difficulties frequently experienced by companies in our industry as we continue to expand or enhance our commercial activities. In addition, as a commercial-stage business, we may be more likely to encounter unforeseen expenses, difficulties, complications, and delays. If we do not address these risks and difficulties successfully, our business will suffer.

We may decide to pursue a particular product, product candidate, or indication and fail to pursue other products, product candidates, or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

We may decide to focus our licensing, research and development, and commercialization programs to specific products and product candidates or to specific indications for those products and product candidates based on our expectations with respect to the potential benefits of the therapies, patient needs and the potential markets, synergies with our existing business, competitive landscape, or otherwise. We may incorrectly assess the benefits, costs, and risks for any potential product or product candidate. As a result, we may forego or delay pursuit of opportunities for other products or product candidates or for other indications that later prove to have greater commercial potential, and our resource allocation

decisions may cause us to fail to capitalize on promising commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Such developments would have an adverse effect on our business, financial conditions, results of operations, and prospects.

The market opportunities for certain of our products and product candidates may be small, such as when those opportunities are limited to patients who are ineligible for other treatment options or who have not responded to prior treatments, and our estimations with respect to these populations may be inaccurate.

The potential markets for certain indications of our commercial products and product candidates may be small, such as when we are seeking approval of our product candidates as a later stage therapy for patients who are ineligible for other treatment options or who have not responded to prior treatments or other approved treatments. We may consider such indications or market indications as an initial entry point for certain of our product candidates or as an additional indication for our current commercial products. We may not be able to achieve such regulatory approval or to generate sufficient revenue from such opportunities to recover related costs, without obtaining regulatory approval for additional indications.

In addition, as part of our evaluation of the commercial prospects for our products and product candidates, we periodically make estimates regarding the incidence and prevalence of our target populations, including with respect to the number of people who have the indications we are targeting, as well as the subset of people with those indications who may be in a position to receive our therapies and who have the potential to benefit from treatment with our products. We also make projections regarding sales, revenues, costs, and reimbursement for our products and product candidates. We may also use such estimates in making decisions regarding our product development strategy, including business development opportunities as well as our research and development activities and the focus of pre-clinical and clinical trials. These estimates and projections are based on our beliefs, internally generated analyses, and third-party sources, and they may prove to be inaccurate or based on imprecise data. For example, the actual size of the potential market opportunity and patient population for a product or product candidate will depend on a variety of factors, including acceptance by the medical community, patient access, product pricing, reimbursement, and availability of other treatment options. Further, new studies or market data may change the estimated incidence or prevalence of these indications. The number of patients may turn out to be lower than expected, such as because patients may not be amenable to treatment with our products and product candidates or new patients may become increasingly difficult to identify or reach. All of this could significantly harm our business, financial condition, results of operations, and prospects.

The pharmaceutical industry is highly regulated, and such regulations are subject to change, which may affect the approval and commercialization of our products and product candidates, and any failure to comply with such regulations could have adverse legal and financial impact.

The pharmaceutical industry in Greater China, the United States, the EU, and some other jurisdictions is subject to extensive and comprehensive regulation and oversight by numerous regulatory authorities, including with respect to approval, manufacturing, distribution, marketing, and other activities related to new drug candidates and certain other therapies and treatments.

In recent years, there have been a number of legislative and regulatory changes in our industry that could prevent or delay regulatory approval of our products and product candidates, restrict or regulate post-approval activities, and affect the commercial prospects of our products and product candidates, including in our primary market of mainland China. We expect evolution in the Chinese healthcare industry to continue. Any changes or amendments, or proposed further changes or amendments, with respect to applicable laws, rules, and regulation and supervision of the pharmaceutical industry in mainland China, including recent anti-corruption enforcement efforts, may result in uncertainties with respect to the interpretation and implementation of applicable laws and regulations and may adversely affect the development or commercialization of our products and product candidates in mainland China. Efforts to comply with these extensive regulatory requirements may involve substantial costs. If our operations were found to be in violation of applicable legal and regulatory requirements, we could be subject to significant civil, criminal, and administrative penalties, including,

without limitation, damages, fines, imprisonment, and exclusion from participation in government healthcare programs or contracting with government authorities and the curtailment or restructuring of our operations, which could significantly harm our business.

In addition, the commercial success of our approved products depends, in part, on adequate insurance coverage and reimbursement by third party payors, including government health benefit programs and authorities. We expect that healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the reimbursement available for any approved product which could adversely affect pricing for such product. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may adversely affect our ability to generate revenue or attain profitability for our commercial products or to successfully launch our product candidates.

If safety, efficacy, manufacturing, or supply issues arise with any therapy or treatment that we use in combination with our products and product candidates, such as chemotherapy drugs, we may be unable to market such products or product candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

Certain of our products are approved for treatment, and certain of our product candidates are being evaluated as a potential treatment, in combination with other products, such as chemotherapy drugs. For example, we have commercially launched OPTUNE GIO in combination with TMZ for the treatment of patients with newly diagnosed GBM, and we are evaluating OPTUNE as a combination therapy in gastric cancer and bevacizumab as a combination therapy for gastric and GEJ cancers.

If the NMPA, FDA, or another regulatory agency were to revoke its approval of any therapeutic we use in combination with our products and product candidates, we would not be able to market our products and product candidates in combination with such revoked therapeutics. If safety or efficacy issues arise with the therapeutics that we seek to combine with our products and product candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the related clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any combination therapeutic, we may not be able to successfully commercialize our products or product candidates on our anticipated timeline or at all.

We face substantial competition, which may result in our competitors discovering, developing, or commercializing drugs before or more successfully than we do, or developing products or therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our products and product candidates.

The development and commercialization of new drug products or medical devices is highly competitive. We face competition with respect to our current products and product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, and medical device companies. Some of these competitive drugs and therapies are based on scientific approaches that are similar to that of our products and product candidates. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Many of the companies against which we are competing or may in the future compete have significantly greater financial resources and may have additional resources or capabilities with respect to research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Additionally, some of our competitors may successfully adopt or use emerging technologies, including artificial intelligence, to enhance their clinical or business operations before we are able to do so, which could leave us at a competitive disadvantage or with higher costs relative to our peers. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in resources being further concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through

collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining global leaders and qualified scientific and management personnel; establishing clinical trial sites and patient registration for clinical trials; and acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than our products or if they are more successful in their marketing and distribution efforts. Our commercial opportunities also may be adversely affected if the availability of competitor products limits or reduces the prices we are able to charge for our products. Our competitors also may obtain regulatory approvals in our target markets before we do, which could allow them to establish a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our products or product candidates uneconomical or obsolete. We may also be adversely affected as a result of the expiration or successful challenge of our patent rights with respect to the validity and/or scope of patents relating to our competitors' products. Any such development could adversely affect our business, financial condition, results of operations, and prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome.

There is a risk of failure for each of our product candidates. It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval, our product candidates must complete pre-clinical studies and extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive, difficult to design and implement, and can take many years to complete.

The outcomes of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Future clinical trials of our product candidates may not be successful.

Before commencing clinical trials, we must finalize the trial design based on ongoing discussions with the NMPA for trials in mainland China, the FDA for trials in the United States, and any other applicable regulatory authorities. The regulatory authorities may subsequently change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose unexpected additional approval conditions. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or equivalent filing) to the NMPA, FDA, or other applicable regulatory authorities and to the ultimate approval and commercial launch of our products or product candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. There are inherent uncertainties associated with the development of our products and product candidates. We do not know whether the clinical trials for our product candidates will begin or be completed on schedule or at all or whether the clinical trial results will be favorable.

We may incur additional costs or experience delays in completing pre-clinical or clinical trials or ultimately be unable to complete the development and commercialization of our product candidates.

We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, such clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of our products and product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may not be able to conduct a companion diagnostic test to identify patients who are likely to benefit from our products and product candidates in a timely manner or at all;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- our products and product candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs, or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other therapies that raise safety or efficacy concerns about our products and product candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or the ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA, FDA, or other applicable regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols; a failure to obtain the regulatory approval and/or complete record filings with respect to the collection, preservation, use, and export of mainland China's human genetic resources; inspection of the clinical trial operations or trial site by the NMPA, FDA, or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects; failure to demonstrate a benefit from using a product candidate; changes in government regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the NMPA, FDA, or other applicable regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. Our business will be adversely affected if we are unable to successfully complete clinical development, obtain regulatory approval, and successfully commercialize our products and product candidates.

If we are required to conduct additional clinical trials or other testing of our products or product candidates beyond those that are currently contemplated, or if we are unable to successfully complete clinical trials of our products or product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our products and product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of our products and product candidates;
- be subject to restrictions on the distribution and/or commercialization of our products and product candidates; or
- have our products and product candidates removed from the market after obtaining regulatory approval.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products and product candidates and may harm our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our products and product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA, or applicable regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future clinical trials, to include some patients with the applicable genomic mutation with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genomic mutation. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials. In addition, some of our competitors have ongoing clinical trials for products or product candidates that treat the same indications as our products or product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' products or product candidates.

Our products and product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable side effects, including adverse safety events, caused by our products or product candidates could have a negative impact on our business. Discovery of safety issues with our products could create issues with respect to product liability, additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician, patient, and/or investor confidence in our products and our reputation. Any of these events could result in liability, loss of revenues, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges, or other adverse impacts on our results of operations.

Furthermore, undesirable side effects could cause us to interrupt, delay, or halt clinical trials or could cause regulatory authorities to interrupt, delay, or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA, or other applicable regulatory authorities. For example, side effects, such as fatigue, nausea, and low blood cell levels, are common in the case of oncology products or product candidates. If trial results for our products or product candidates reveal a high and unacceptable severity and prevalence of these or other side effects, trials of our products or product candidates could be suspended or terminated, and the NMPA, FDA, or other applicable regulatory authorities could order us to cease further development or deny approval of our products or product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Additionally, our products and product candidates could cause undesirable side effects related to off-target toxicity. For example, many of the currently approved PARP inhibitors have been associated with off-target toxicities. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our products or product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. Even after a product or product candidate receives regulatory approval, if we, our partners, or others identify undesirable side effects caused by such product candidates (or any other similar product candidates) after such approval, a number of significant negative consequences could result, including:

- our revenue may be negatively impacted;
- our regulatory authorities may withdraw or limit their approval of such products or product candidates;
- our regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such products or product candidates are distributed or administered, conduct additional clinical trials or change the labeling of our products or product candidates;
- our regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS (or analogous requirement), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such products or product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products or product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected products or product candidates, could substantially increase the costs of commercializing our products and product candidates, if approved, and could otherwise significantly impact our ability to successfully commercialize our products and product candidates and generate revenue.

If we are unable to obtain NMPA approval for our products and product candidates to be eligible for an expedited registration pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive a Category 1 drug designation, it may not lead to a faster development, review, or approval process.

The NMPA can designate innovative drugs as Category 1 drugs. To qualify for a Category 1 designation, a drug needs to have a new and clearly defined structure, pharmacological property, and apparent clinical value and to have not been marketed anywhere in the world. Our CTAs for ZEJULA and NUZYRA were approved as Category 1 drugs by the NMPA. A Category 1 designation by the NMPA may not be granted for any of our other product candidates that will not be first approved in mainland China or, if granted, such designation may not lead to a faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our product or product candidates will receive regulatory approval.

Furthermore, despite positive regulatory changes in mainland China which have significantly accelerated time to market for innovative drugs, the regulatory process is still relatively ambiguous and unpredictable. The NMPA might

require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our product candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions, or contraindications, or we may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our product candidates in our target markets, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our other product candidates or to in-license, acquire, or develop additional product candidates in the future.

We continue to be subject to ongoing obligations and continued regulatory review with respect to our commercial products, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our commercial products, we may be subject to penalties.

After obtaining regulatory approval, our commercial products are subject to, among other things, ongoing regulatory requirements governing the labeling, packaging, promotion, recordkeeping, data management, and submission of safety, efficacy, and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. Such post-approval development and regulatory requirements may limit how our commercial products are manufactured and marketed, and could materially impair our ability to generate revenue. As such, we and our partners and any of our and their respective contract manufacturers will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. To the extent we want to make changes to the approved products, product labeling, or manufacturing processes, we will need to submit new applications or supplements to the applicable regulatory authority and obtain their approval.

Additionally, any regulatory approvals that we receive for our products or product candidates may be subject to limitations on the approved indications for which the products may be marketed or to the conditions of approval or may contain requirements for potentially costly post-marketing studies, including Phase IV studies for the surveillance and monitoring of the safety and efficacy of the products. For example, we are collecting additional safety and efficacy data for post-market safety and efficacy analysis for OPTUNE and monitoring adverse effects related to skin irritation, and we continue to collect safety events for all approved products.

In addition, once a product is approved by the applicable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the product, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product or drug from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- drug seizure, detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil, administrative, or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change, or additional government regulations may be enacted, that could prevent, limit, or delay regulatory approval of our products or product candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost, and we may not achieve or sustain profitability, which may harm our business, financial condition, and prospects significantly.

Our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel.

We are highly dependent on the expertise of our global leaders, including Samantha (Ying) Du, our Founder, Chief Executive Officer, and Chairperson of the Board of Directors, our executive management team, and members of our research and development and commercial teams. Although we have entered into employment agreements with our executive officers, they may terminate their employment with us at any time following a reasonable notice of not less than thirty days. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing, and sales and marketing personnel is critical to our success. In addition, our management will be required to devote significant time to compliance initiatives from our dual primary listing on Nasdaq and the Hong Kong Stock Exchange. The loss of the services of certain of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing certain of our executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions, and failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

As the Company develops globally, we may increase the size and capabilities of our organization, and we may experience difficulties in managing such growth.

As the Company develops globally, we may experience growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of product development, product commercialization, regulatory affairs, and business development. To manage future growth, we may continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and could have a materially adverse effect on our business.

We may explore additional regional or global licensing or collaboration arrangements for the development and/or commercialization of product candidates, which may expose us to significant additional costs, such as upfront fees, milestone payments, royalty payments, and the costs of related clinical or pre-clinical trials, may divert management attention or resources away from our other products and product candidates, and may expose us to additional risks of conducting business in additional international markets.

The majority of our products and product candidates are in-licensed for development and commercialization in Greater China. We have and may in the future explore additional global or regional licensing or collaboration agreements, including in territories outside of Greater China. Efforts to enter into license or collaboration with third parties may divert our management’s attention away from other corporate strategic goals or objectives, business operations, or potential acquisition or development opportunities for additional product candidates. Further, these arrangements involve significant costs, including upfront fees; development, regulatory, and sales-based milestones; and certain royalties at tiered percentage rates based on annual net sales. Such milestone payments are contingent on product performance, and upfront fees, certain development and regulatory milestones, and costs of clinical or pre-clinical trials may occur before we have commercialized or received any revenue from the related product candidate.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our business, including:

- difficulty of effective enforcement of contractual provisions in other jurisdictions;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, including the loss of normal trade status between mainland China and the United States;
- economic weakness, including inflation;
- compliance with tax, employment, immigration, and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with anti-bribery laws in mainland China, Office of Foreign Asset Control rules and regulations and the FCPA and other anti-bribery and corruption laws; and
- business interruptions resulting from geopolitical actions, including trade disputes, public health crises, international war or conflict, natural disasters, extreme weather events, and other significant or catastrophic events outside of our control.

These and other risks may materially adversely affect our business, results of operations, and financial condition.

We may engage in future partnerships, in-licensing arrangements, joint ventures, or other types of business acquisitions that could disrupt our business, cause dilution to holders of our securities, and harm our financial condition and operating results.

We have engaged, and may again in the future engage, in partnership or strategic collaboration opportunities or investments, including those that require acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business and corporate strategic goals. In connection with such partnership or collaboration opportunities, acquisitions, or investments, we may:

- issue securities that would dilute the percentage of ownership of the holders of our securities;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

For example, in January 2021, we entered into a strategic collaboration with argenx pursuant to which we obtained an exclusive license for the development and commercialization of efgartigimod in Greater China in exchange for a combination of cash and ordinary shares.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our research, development, and commercialization efforts with respect to our products and product candidates. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. Additionally, establishment of a joint venture involves significant risks and uncertainties, including (i) our ability to cooperate with our strategic partner, (ii) our strategic partner having economic, business, or legal interests or goals that are inconsistent with ours, and (iii) the potential that our strategic partner may be unable to meet its economic or other obligations, which may require us to fulfill those obligations alone.

We may be unable to find suitable acquisition candidates, and we may not be able to complete partnership or strategic collaboration opportunities or investments on favorable terms, if at all. If we do enter into partnerships or strategic collaborations or make other investments, such arrangements may not ultimately strengthen our competitive position or

may be viewed negatively by customers, financial markets, or investors. Further, future partnerships, strategic collaborations, or other investments could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products, personnel, or technologies;
- increases to our expenses;
- failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, including those of the acquired entity.

We may not be able to realize the benefit of current or future collaborations, strategic partnerships, or licensed products and product candidates if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. Following a strategic transaction or license, we may not be able to achieve sufficient revenue or net income to justify such transaction. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop or commercialize our products and product candidates, which would harm our business, financial condition, results of operations, and prospects.

We may need to significantly reduce our prices for our approved products in mainland China and face uncertainty of reimbursement, which could diminish our sales or adversely affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceutical drugs and devices vary widely from country to country. In mainland China, the NHSA is responsible for administering mainland China's social security system, including price negotiations with drug companies seeking to include their products in the NRDL. Such price negotiations have resulted in average price reductions ranging from around 53% to 63% over the past few years. The NHSA, together with other government authorities, review the inclusion or removal of drugs from the NRDL, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. In connection with obtaining NRDL listing for ZEJULA, VYVGART, NUZYRA, QINLOCK, and AUGTYRO for certain indications, we lowered the selling price of each product in preparation. Although NRDL listing may increase patient access to, and demand for, our commercial products, the lower reimbursement rate could negatively affect our revenues or product margins and may not be sufficient to cover our costs, including licensing fees and research, development, manufacturing, marketing, and distribution expenses. We may also continue to experience additional pricing pressure for our products, including as a result of the centralized tender process or otherwise, which may further adversely affect our revenues or results of operations.

Prior to any potential NRDL listing, revenues for our commercial products will depend on sales that are self-paid by patients or otherwise covered by insurance in the private-pay market. Higher patient prices or lower patient access may reduce demand for, and sales of, our commercial products.

Companies in mainland China that manufacture or sell drugs and medical devices are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our products and product candidates.

The life sciences industry in mainland China is subject to extensive government regulation and supervision. In order to manufacture and distribute drug and medical device products in mainland China, we are required to:

- obtain a manufacturing permit for each production facility from the NMPA and its relevant branches for the manufacture of drug and device products domestically;
- obtain a marketing authorization, which includes an approval number, from the NMPA for each drug or device for sale in mainland China;
- obtain a Pharmaceutical Distribution Permit from the provincial medical products administration if we were to sell drugs manufactured by third parties; and
- renew the Pharmaceutical Manufacturing Permits, the Pharmaceutical Distribution Permits, and marketing authorizations every five years, among other requirements.

Laws governing medical devices continue to evolve in China, including with the publication of the draft Medical Devices Administration Law in 2024. New or revised regulations may be more onerous or costly for us to comply with and may expose us to additional regulatory oversight.

If we are unable to obtain or renew such permits or any other permits or licenses required for our operations, we will not be able to engage in the commercialization, manufacture, and distribution of our products and product candidates and our business may be adversely affected.

If we fail to maintain our licenses or other intellectual property-related agreements for our products or product candidates or if we otherwise experience disruptions or disputes relating to our business relationships, we could lose the ability to continue the development and commercialization of our products and product candidates, and such disputes could cause us to use substantial resources.

Our business relies, in large part, on our ability to develop and commercialize products and product candidates from third parties in accordance with our license and collaboration agreements and other intellectual property-related agreements. If we fail to maintain such licenses or other intellectual-property-related agreements that are relevant to our products and product candidates, we may be unable to develop and commercialize the affected products or product candidates, and our business, financial condition, results of operations, and prospects could be materially harmed. If we fail to comply with our obligations under such agreements or if our licensors or collaboration partners fail to comply with obligations under such agreements or other agreements from which our rights are based, we may be unable to successfully develop and commercialize the affected products or product candidates, and our business, financial condition, results of operations, and prospects could be materially harmed.

Failure to meet obligations under any of the aforementioned agreements may result in termination of same by the other contracting party. Even though we may exercise all rights and remedies available to us and otherwise seek to preserve our rights, we may not be able to do so in a timely manner, at an acceptable cost, or at all. Any uncured, material breach under such agreements could result in loss of our rights and may lead to a complete termination of our rights to applicable products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we have had, and may in the future have, disputes regarding our rights under license, collaboration, or other intellectual property related agreement, including but not limited to:

- the scope of rights granted under such agreement;
- the use of intellectual property rights under such agreement;
- the satisfaction of diligence obligations under such agreement;
- the ownership of inventions or know-how resulting from such agreement; and
- the payments due under such agreement.

Such dispute may disrupt our business relationships or otherwise hinder our ability to successfully develop and commercialize the affected products or product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Such disputes may also require or result in substantial costs and diversion of resources, including the consumption of significant management and other personnel time, to defend or assert our contractual rights or interpretation or to settle, arbitrate, or litigate such disputes. Any such settlements of contractual disputes, and the negotiations in connection therewith, could have a material adverse effect on our business, reputation, financial condition, results of operations, and prospects.

In addition, the resolution of any disputed contractual interpretation of any of the foregoing agreements could result in a narrower interpretation of the scope of our rights or increase our financial or other obligations and thereby may prevent or impair our ability to maintain our current agreement on commercially acceptable terms. Accordingly, we may be unable to successfully develop and commercialize the affected products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Reputational harm to our products, including product liability claims or lawsuits against us or any of our licensors, could cause us to incur substantial liabilities or loss of revenue or harm our reputation.

We face an inherent risk related to the use of our products and product candidates anywhere in the world. If we or our licensors cannot successfully defend the reputation of our licensed products, including against product liability or other claims, then we may incur substantial liability, loss of revenue, or loss of reputation. Regardless of merit or eventual outcome, the consequences to us from those claims (whether resulting from our sales in our licensed territories, or those of our licensors' sales elsewhere in the world) may result in:

- significant negative media attention and reputational damage;
- withdrawal of clinical trial subjects and inability to continue clinical trials;
- significant costs to defend related litigation;
- substantial monetary awards to trial subjects or patients;
- the inability to commercialize any products or product candidates that we may develop;
- initiation of investigations by regulators;
- a diversion of management's time and our resources; and
- a decline in the market price of our securities.

Any litigation or investigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), product liability insurance to cover our product liability claims and general liability and D&O insurance to cover other commercial liability claims, these insurance policies may not fully cover our potential liabilities. Additionally, inability to obtain sufficient insurance coverage at an acceptable cost could prevent or inhibit the successful commercialization of products or drugs we develop, alone or with our collaborators. Any negative reputational harm to our licensors' products anywhere in the world may have an adverse impact on our ability to sell those same products in our licensed territories. If our licensors incur such harm or liability, it may also cause damage to our revenues and reputation which may not be covered by insurance.

Potential cybersecurity threats are changing rapidly and advancing in sophistication. We may not be able to protect our systems and networks, or the confidentiality of our confidential or other information (including personal information), from cyberattacks and other unauthorized access, disclosure, and disruption.

Cybersecurity risks for companies like ours have significantly increased in recent years, in part because of the proliferation of new technologies, the use of the internet and certain technologies to conduct business, and the increased

sophistication and activities of organized crime, hackers, terrorists, and other external parties, including foreign state-sponsored actors.

Like many companies, from time to time we have been, and expect to continue to be, the target of attempted cyberattacks and other cybersecurity incidents. Such incidents may include malware, ransomware, denial-of-service attacks, social engineering, unauthorized access, human error, theft or misconduct, fraud, and phishing, as part of an effort to disrupt operations, potentially test cybersecurity capabilities, or obtain confidential, proprietary, or other information (including personal information). Our cybersecurity risk and exposure depend on various factors, including the evolving nature and increasing frequency, levels of persistence, sophistication, and intensity of these threats, the outsourcing of some of our business operations, and the current global economic and political environment. The increase in remote work environments also may increase our cybersecurity risk if our employees, vendors, service providers, and other third parties with which we interact are working remotely on less secure systems and environments.

Because we are dependent on third parties for certain elements of our business and operations, we could also be adversely affected if any of them are subject to a successful cyberattack or other cybersecurity incident. Third parties with which we do business may also be sources of cybersecurity or other technology risks. We routinely transmit and receive confidential, proprietary, and other information (including personal information) by electronic means. This information could be subject to interception, misuse, or mishandling. Our exposure to these risks could increase as a result of our migration of core systems and applications to a third-party cloud environment. While we generally perform cybersecurity diligence on our key vendors, because we do not control third parties with whom we do business and our ability to monitor their cybersecurity posture is limited, the cybersecurity measures they take may not be sufficient to protect any information we share with them.

Although we devote significant resources to protect our systems, network, and information, the security measures we have implemented may not provide effective security. Our internal computer systems, software, devices, and networks – and those of our CROs, CMOs, and other third-party providers – may be vulnerable to cyberattacks and other cybersecurity incidents, business or supply chain disruptions, or other attempts to harm our business or reputation or misuse or steal information (including personal information). We routinely identify cybersecurity threats as well as vulnerabilities in our system and work to address them, but these efforts may be insufficient. Outside parties may attempt to induce employees, third-party partners, vendors, service providers, or other users of our systems or networks to disclose confidential, proprietary, or other information (including personal information) in order to gain access to our systems and networks and the information they contain. Unauthorized access or disclosure, or breaches of our security, also may result from human error. We may not be able to anticipate, prevent, detect, recognize, or react to threats to our systems, networks, and assets, or implement effective preventative measures against cyberattacks or other security incidents, especially because the techniques used change frequently or are not recognized until launched.

A cyberattack or other cybersecurity incident could occur and persist for an extended period of time without detection. We expect that any investigation of such an incident would take time, during which we would not necessarily know the extent of the harm or how best to remediate it. Although we have not experienced any such incident resulting in a material impact to the company to date, our cybersecurity risk management program may not prevent such an incident from having a material impact in the future. We have obtained insurance coverage relating to cybersecurity risks, but this insurance may not be sufficient to provide adequate loss coverage (including if the insurer denies future claims) and may not continue to be available to us on economically reasonable terms, or at all. Further, any limitations of liability provisions in our agreements with vendors, customers, and other third parties with which we do business may not be enforceable or adequate or otherwise protect us from any liabilities or damages with respect to any particular claim in connection with a cyberattack or other security incident of a third party on which we rely.

The occurrence of one or more cyberattacks or other cybersecurity incidents could result in the unauthorized disclosure, misuse, or corruption of confidential, proprietary, and other information (including personal and other information about our employees and patients and company and vendor confidential data) or could otherwise cause interruptions or malfunctions in our operations or the operations of our partners, customers, vendors, and other third parties with which we do business. This could result in significant losses or reputational damage, adversely affect our relationships

with our partners, customers, vendors, and other third parties, negatively affect our competitive position, or otherwise harm our business. We could also face regulatory and other legal action, including for any failure to provide timely disclosure concerning, or appropriately to limit trading in our securities following, an incident. We may be required to expend significant additional resources to repair or replace information systems or networks, modify our internal controls, and implement or enhance other protective measures or to investigate or remediate vulnerabilities or other exposures. We also may be subject to litigation and financial losses that are not fully insured.

We, our employees, and our contracted third parties are subject to laws and government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future laws and regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

We, our employees, and our contracted third parties are subject to data privacy and security laws in the various jurisdictions in which we operate, obtain, or store personally identifiable information, including in mainland China, the United States, and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

We could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims under the laws described, as well as for alleged unfair or deceptive practices. If our operations are found to be in violation of any of the privacy laws, rules, or regulations that apply to us, we could be subject to penalties, including civil penalties, damages, injunctive relief, and other penalties, which could adversely affect our ability to operate our business and our financial results. We will continue to review these and all future privacy and other laws and regulations to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

While we maintain and enforce policies and practices designed so that we and our employees comply with such data privacy and security laws in the various jurisdictions in which we operate, we have identified, and may in the future identify, instances of non-compliance with such policies and practices by our employees. Such non-compliance may result in a material adverse effect on our business, reputation, or operations, and our policies and practices may not prevent such an incident from having a material adverse impact in the future. In addition, our employees and contracted third parties may become subject to regulatory actions involving privacy issues related to data collection and use practices and other data privacy laws and regulations. Such regulatory actions may result in criminal or civil penalties, convictions, or sanctions, which may materially adversely affect our business and reputation. Such investigations of our employees and contracted third parties could also lead to allegations against, or investigations into, the Company and our practices with respect to such data and privacy laws and regulations.

We may face further restrictions (or even prohibitions) on our ability to transfer our scientific data abroad if Chinese regulators impose new restrictions (or change their interpretation of existing restrictions) on life sciences companies like us and the scientific data we obtain, generate, and maintain.

The Scientific Data Administrative Measures promulgated by the General Office of the State Council provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality, and security of scientific data. 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 broad, and the Chinese government has not issued further guidance to clarify if clinical study data would fall within this definition. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data center or prevented the cross-border transmission and sharing of clinical study data. None of our clinical study or other scientific data has been created or managed with government funds or funded by any source that concerns state secrets, national security, or social and public

interests. To date, we have received requisite permissions to transfer clinical study data abroad. We are closely monitoring 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 or other scientific data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

Risks Related to Our Dependence on Third Parties

We rely on third parties, including our licensors, CMOs, and other suppliers, to support the commercial and clinical supply of our products and product candidates. Failure of such third parties to supply us with a sufficient quantity of products, in a timely matter or at all, may adversely affect our business.

We rely on third-party manufacturers to manufacture some of our products and product candidates. For example, with respect to our commercial products, we rely on argenx for VYVGART and VYVGART Hytrulo, NovoCure for OPTUNE, Deciphera for QINLOCK, Innoviva for XACDURO, and BMS for AUGTYRO. We also rely on CMOs for the local production in mainland China of certain drug substances and products, including NUZYRA.

Such reliance on third-party manufacturers entails risks to which we would not be subject to if we manufactured products or product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing or supply agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our products or product candidates in accordance with our specifications), and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the NMPA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP standards. Any failure by our third-party manufacturers to comply with cGMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. We currently source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers, as well as through our licensors. Any significant disruption in our potential supplier relationships, whether due to price increases, manufacturing, or supply-related issues, could harm our business. We anticipate that, in the near term, our key materials will be sourced through third parties. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture some of our products and product candidates. Such suppliers may not sell these key materials to us or our manufacturers at the times we need them or on commercially reasonable terms. We currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product or product candidate or its key materials could considerably delay completion of our clinical studies, product or drug testing, and potential regulatory approval of our products or product candidates. If we or our manufacturers are unable to purchase key materials after regulatory approval has been obtained, the commercialization or the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of such products.

Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost, in quantities, or in a timely manner necessary to make our products commercially successful. In addition, as our product pipeline develops, we may have a greater need for clinical study and commercial manufacturing capacity or third-party supply of our products and product candidates. We may not be able to increase our scale of production or supply on commercially reasonable terms, in a timely manner, or at all.

We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates and our business could be substantially harmed.

Our internal capacity to perform pre-clinical and clinical trials is limited. As a result, we have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these third parties for execution of our pre-clinical and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocols and legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices, and the Regulations for the Administration of Affairs Concerning Experimental Animals. We and our CROs are required to comply with Good Clinical Practice and relevant guidelines enforced by the NMPA, and other applicable regulatory authorities for all of our products or product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable, and the NMPA and other applicable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products or drugs produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our on-going clinical, nonclinical, and pre-clinical programs. Our CROs may not perform contracted services to our standards, may not produce results in a timely manner, or may fail to perform at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products or product candidates. As a result, our results of operations, and the commercial prospects for our products and product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed or compromised.

If we lose our relationships with CROs, our product development efforts could be delayed.

We rely on third-party vendors, including CROs, for some of our pre-clinical studies and clinical trials related to our product development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if they can reasonably demonstrate that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs in a timely manner, on commercially reasonable terms, or at all. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Any such developments could cause our product development efforts to be delayed, which could adversely affect our business and operations.

We depend on other parties to manage certain intellectual property rights that are material to our business. Any failure to effectively protect these rights could adversely affect our business and operations.

We depend on other parties to manage certain of our intellectual property rights that are material to our business. In accordance with certain of our licensing agreements, we rely on other parties to manage responsibility for protection of certain intellectual property rights that we hold rights to for our products and product candidates. If such parties fail to procure or maintain intellectual property rights, the rights we hold may be reduced or eliminated, which could materially harm our business, financial conditions, results of operations, and prospects.

Pursuant to the terms of certain of our licensing agreements, we may rely on others to procure, maintain, enforce, or defend certain patent rights we hold that are material to our business. Additionally, even if we are contractually permitted to pursue the enforcement or defense of a patent we hold rights to under an agreement, we require the cooperation of any applicable patent owners to enforce such patent, and such cooperation may not be provided to us. Furthermore, even if we are able to participate in any such legal actions, an adverse outcome could materially harm our business, financial conditions, results of operations, and prospects.

We rely on third-party distributors to sell our commercial products, and a limited number of customers have generated a substantial portion of our revenue. If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.

We rely on third-party distributors to sell our commercial products, which is consistent with the general practices of the pharmaceutical industry. A substantial amount of our revenue is derived from sales to a limited number of customers, which are distributors. For 2024 and 2023, our five largest customers accounted for approximately 32.4% and 35.0% of our product revenue, respectively. Product revenue generated from our largest customer for the same periods accounted for approximately 16.9% and 19.9% of our product revenue, respectively. We have relatively limited control over our distributors, and they may fail to distribute our products in a timely manner or in the manner we contemplate. Further, while we believe alternative distributors are readily available, if any of our major customers significantly reduces its purchase volume or ceases to purchase from us, and we are not able to identify new customers in a timely manner, our business, financial condition, and results of operation may be materially and adversely affected. In addition, our major customers may seek to negotiate more favorable terms for them in the future. Under such circumstances, we may have to agree to less favorable terms in order to maintain the ongoing cooperative relationships with our major customers. If we are unable to reduce our production costs accordingly, our profitability, results of operations, and financial condition may be materially and adversely affected.

The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit products sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants, or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business.

Our business, results of operations, and financial condition may be adversely affected by deterioration in the credit quality of, or defaults by, our customers, and our deposits and investments may be negatively affected by fluctuations in interest rates.

We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure, or other reasons. As our business evolves, the amount and duration of our credit exposure may increase, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee.

The carrying amounts of cash and cash equivalents, restricted cash, and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2024 and 2023, we had cash and cash equivalents of \$449.7 million and \$790.2 million, restricted cash of \$101.1 million and \$1.1 million, and short-term investments of \$330.0 million and \$16.3 million, respectively, most of which are deposited in financial institutions outside of mainland China. Although our cash and cash equivalents in mainland China, Hong Kong, Australia, Taiwan, and the United States are deposited with various major reputable financial institutions, deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. We are also exposed to risks related to changes in interest rates on our cash and

cash equivalents, restricted cash, and short-term investments, as a decrease in interest rate may impact our investment income and related cash flows.

Although we believe that U.S. Treasury securities are of high credit quality, concerns about, or a default by, one or more institutions in the market could lead to significant liquidity problems, losses, or defaults by other institutions, which in turn could adversely affect us.

Risks Related to Intellectual Property

If we are unable to obtain and maintain protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in part, on our ability to protect our products, product candidates, and technologies from competition by obtaining, maintaining, and enforcing our intellectual property rights. We seek to protect our products and product candidates as well as technologies that we consider commercially important through intellectual property rights, such as patents and trade secrets.

We do not own or hold an exclusive license to patent rights in all of the territories in which we plan to commercialize certain of our products and product candidates. Further, we cannot predict whether patent applications that we hold rights to or any of our other owned or in-licensed pending patent applications will result in the issuance of patents that effectively protect our products, product candidates, and technologies, or whether our issued patents will effectively exclude competitors. It is also possible that we do not identify and/or secure patent rights to certain patentable aspects of our products, product candidates, or technologies. If we do not secure patent rights with respect to our products, product candidates, and technologies, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, license, or defend all necessary or desirable patent rights at a reasonable cost or in a timely manner, and patents may be invalidated, in whole or in part, and thereby rendered unenforceable. In addition, our licenses may not provide us with exclusive rights to products and product candidates in all relevant fields of use and in all territories in a manner which we may wish to develop or commercialize products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future have issued or do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit the scope and/or duration of patent protection for our product(s) or product candidate(s). Consequently, we may not be able to exclude others from using certain technology without compensating us or possibly may be unable to exclude a competitor from commercializing a competitive product which may materially adversely impact our sales and may also cause us to reduce, more than we otherwise might, the price at which we sell our products. For example, granted claims in two Chinese patents that pertain to certain aspects related to OPTUNE have been the subject of a successful invalidation proceeding, which is currently being appealed. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology, products or product candidates will be protectable or remain protected by valid and

enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the term of a patent is finite and generally expires 20 years from its earliest non-provisional filing date provided that associated fees are timely paid. Given the amount of time required for the development, testing, and regulatory review of products and new product candidates, patents protecting such products and product candidates might expire before or shortly after such products or product candidates are commercialized. For example, certain of our in-licensed patents related to OPTUNE will be expiring over the next two years. As a result, the patent rights we hold may be insufficient to protect our products and product candidates from competitors' products, including those that are generic.

Moreover, in the case of any patent rights that are jointly owned by us and another party, if we are unable to obtain an exclusive license or otherwise limit the other party's right to license such patent rights to a third party, such patent rights may be licensed to third parties, including our competitors. In addition, we may need the cooperation of any joint owner of such jointly-owned patent to enforce it against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office or other foreign authority.

We or our licensors or collaboration partners may become involved in patent litigation against third parties, for example, to enforce our patent rights, to invalidate patents held by such third parties, or to defend against such claims. Further, third parties could claim that we infringed, misappropriated, or otherwise violated their intellectual property rights or that a patent we or our licensors or collaboration partners have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are common, and there are numerous grounds upon which a party can assert invalidity or unenforceability of a patent. In addition to court proceedings, in certain jurisdictions, parties may initiate legal proceedings before administrative bodies to assert challenges to intellectual property rights, including patent rights. Such proceedings could result in revocation, cancellation, or amendment to the scope of our patent rights and could negatively affect our business.

The outcome of any such proceeding is generally unpredictable. Furthermore, even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our products or product candidates, we may lack sufficient patent coverage of our products or product candidates to prevent others from marketing competing products. Any of these outcomes could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, granted claims in two Chinese patents that pertain to certain aspects related to OPTUNE have been the subject of a successful invalidation proceeding, which is currently being appealed.

We may not be able to protect our intellectual property.

The extent to which intellectual property rights provide adequate protection as available under the relevant intellectual property laws is uncertain, particularly in light of possible challenges to any patents in a given jurisdiction. Any such challenge to our patent rights could have a material adverse effect on our business, results of operations, and prospects. Notably, the experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant financial expenditure and could divert management's attention from other aspects of our business and operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, financial condition, results of operations, prospects, and reputation.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including mainland China. The legal systems, particularly in certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to enforce our intellectual property and proprietary rights generally. Proceedings to enforce such intellectual property and proprietary rights could result in substantial costs, divert our efforts and attention from other aspects of our business, put our patents at risk of being invalidated or interpreted narrowly, and provoke third parties to assert counterclaims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we hold rights to.

Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Developments or uncertainties in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws could diminish the value of patents, thereby impairing our ability to protect our products, product candidates, and technologies. Changes in patent laws and regulations in various jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces them may weaken our ability to obtain new patents or patent rights through our licensors or to enforce any patents in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by any legislative body. Such changes could materially affect our patent rights and could have a material adverse effect on our business, results of operations, and prospects.

If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed.

We rely upon proprietary information, including trade secrets and know-how to maintain our competitive position. However, such information can be difficult to protect. We seek to protect our proprietary confidential information, in part, by entering into confidentiality agreements with parties that have access to such information, including our partners, collaborators, scientific advisors, employees, consultants, and other third parties. We may not be able to enter into such agreements with each party that may have or have had access to our trade secrets or other proprietary information. Further, we may not be able to prevent the unauthorized disclosure or use of our trade secrets or other proprietary information (such as know-how) by the parties to these agreements, despite their existence and any other contractual restrictions. If any of these parties breaches or violates the terms of such agreement or otherwise discloses our proprietary confidential information, we may not have adequate remedies for such breach or violation and could lose any competitive advantage such confidential information afforded us. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets is difficult, expensive, and time-consuming, with the outcome being unpredictable.

Our trade secrets could become known or even be independently discovered by other parties, including our competitors. If any of our trade secrets were to be disclosed or independently developed, we would have no right to prevent others from using that information to compete against us, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our products or product candidates infringe, misappropriate, or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell or commercialize these products and product candidates.

Our success depends significantly on our ability to develop, manufacture, market, and sell our commercial products and use our proprietary technologies without infringing, misappropriating, or otherwise violating the patents and other

proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, litigation or other proceedings regarding intellectual property rights with respect to our products, product candidates, or technologies that could negatively affect our business.

Third parties may assert claims of patent infringement against us, regardless of merit, based on their existing patents or based on later issued patents. Even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of patent infringement or counterclaims pertaining to the underlying patent(s) asserted against us. A court of competent jurisdiction could hold that a third-party patent is valid, enforceable, and infringed by us, which could have a material adverse effect on our business.

If we are found to have infringed a third party's patent rights, and we are unsuccessful in demonstrating that such patent(s) are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party to the relevant patent(s), which may not be available on commercially reasonable terms, require substantial licensing and royalty payments, or may not be available at all, and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us;
- defend against additional litigation or administrative proceedings in the same and/or other jurisdiction(s);
- reformulate affected product(s) so that they do not infringe the intellectual property rights of others, which may not be possible or could be expensive and time consuming;
- cease developing, manufacturing, and commercializing any infringing products, product candidates, or technologies; and
- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed their patent.

Similarly, claims by third parties that we have misappropriated their confidential information, such as trade secrets, could have a material adverse effect on our business. Even if we are ultimately successful in defending against such claims via litigation(s) or administrative proceeding(s), any such litigation or proceeding may be costly and could result in a substantial diversion of management resources. Consequently, any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other such legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Additionally, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can, for example, because of greater financial or other resources. Moreover, uncertainties resulting from the initiation and continuation of such litigation or other proceedings could have a material adverse effect on our business.

We may be subject to claims that we or our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or are in breach of confidentiality, non-disclosure, non-use, non-competition, or non-solicitation agreements with such current or former employers, some of whom may be our competitors or potential competitors.

We could in the future be subject to claims that we or our employees, consultants, or advisors have inadvertently or otherwise improperly used or disclosed alleged trade secrets or other proprietary information of current or former employers of our employees, consultants, or advisors. For example, many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to prevent our employees, consultants, and advisors from improperly using the intellectual property or other proprietary information of their current or former employers in their work for us, these efforts may not be successful.

Litigation may be necessary to defend against such claims, and even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using certain technologies or features that are essential to our products and product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another party. An inability to incorporate such technologies or features could have a material adverse effect on our business and may prevent us from successfully commercializing our affected products and product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat of such litigation may adversely affect our ability to hire employees or contract with necessary personnel. A loss of key personnel or their work product could hamper or prevent our ability to develop or commercialize our products and product candidates, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in enforcing such agreements. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against our employees, contractors, or other third parties, or defend claims that they may bring against us, to determine the ownership of certain intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not be successful in obtaining intellectual property rights for acquired or in-licensed product candidates.

Our business model depends, in part, on our ability to successfully identify and acquire or in-license product candidates to enhance and strengthen our product pipeline. For such acquired or in-licensed product candidates, we may be unable to secure intellectual property rights relating to, or necessary for, commercialization of any such product candidates from third parties on commercially reasonable terms or at all. In such event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for the Company and/or obtain intellectual property protection relating to such product candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations, and prospects.

The in-licensing and acquisition of intellectual property rights for product candidates is a competitive area, and a number of other companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These other companies may have a competitive advantage over us, for example due to their size, cash resources, and clinical development and commercialization capabilities. Furthermore, certain companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations, and prospects could suffer.

If we or our licensors or collaboration partners do not obtain patent term extension and data exclusivity for our products or their products or any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any regulatory marketing approval of our products or any product candidates we may develop, one or more of our owned or in-licensed patents may be eligible for limited patent term extension in a particular jurisdiction. For example, in the United States, a single patent (provided it claims the approved drug or method for using it, or a method for manufacturing the drug) may be eligible for patent term extension of up to five years, although it cannot extend the remaining term of a patent beyond a total of 14 years from the date of

product approval. However, patent term extension might not be granted due to failure to meet applicable requirements (for example, due to failure to meet applicable deadlines or prior to expiration of the relevant patent) or might be less than requested (for example, due to failure to exercise due diligence during the testing phase or regulatory review process).

The China Patent Law provides for patent term extension, patent term adjustment, and a patent linkage system. However, the lack of operational guidelines has hindered enforcement of the 6-year period of data exclusivity protection for eligible drugs containing a new chemical entity in China. Likewise, expansion of the 6-year period of data exclusivity has been proposed for biologics but has not yet been implemented in practice due to the absence of detailed guidelines and rules. Until new provisions of the China Patent Law providing the proposed framework for data exclusivity can be implemented, a lower-cost generic or biosimilar drug can emerge onto the market more quickly. Consequently, the absence of currently implemented laws and regulations on data exclusivity or the cancellation of the previous five-year administrative exclusivity for domestically manufactured new drugs could result in much weaker protection for us against generic competition in mainland China. If we are unable to obtain patent term extension or patent term adjustment for any eligible patent or the term of any such patent term extension or patent term adjustment is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. If we were to pursue patent linkage litigation, such litigation could take several months to conclude and require additional months thereafter for the decision to be made publicly available. We will monitor future administrative rulings / court decisions on patent linkage in mainland China. Any decision against our interests could adversely affect our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Over the lifetime of any patent rights we hold, certain government fees will be paid to a patent office in the respective jurisdiction for any patent application(s) and on any patent(s) resulting therefrom. In some of our licensed matters, we rely on our licensors to pay these fees. In addition to the payment of fees, during the patent application process, the patent office of any given jurisdiction requires compliance with procedural and documentary provisions. In some of our licensed matters, we rely on our licensors to comply with these requirements. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules of a jurisdiction. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or product candidates or utilize similar technology that are not covered by the claims of the patents that we hold rights to;
- patent rights we currently hold or that we may hold in the future might be from inventors that are not the first to file patent applications covering such inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights;
- patent rights we currently hold to any patent applications that are pending or such patent applications that we may hold patent rights to in the future may not result in issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may impede our ability to exploit our innovations and may harm our business; and
- we may choose to maintain certain trade secrets or know-how, and a third party may discover such trade secrets or know-how through independent research and development, which may harm our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our ADSs and Ordinary Shares

If we fail to maintain proper internal control over financial reporting, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete, and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If we fail to maintain effective internal control over financial reporting in the future, our management and our independent registered public accounting firm may not be able to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of our securities could decline, and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, our ADSs may not be able to remain listed on Nasdaq.

We have incurred losses and have not paid dividends on our securities since our inception, and we do not currently intend to pay dividends on our securities. The success of an investment in our securities will depend on appreciation in the price of our securities.

We have incurred losses since inception and have never declared or paid any dividends on our securities. We currently intend to invest our future earnings, if any, to fund our business. Therefore, investors are not likely to receive any dividends on their securities, at least in the near term, and the success of an investment in our securities will depend upon any future appreciation in their value compared to their purchase price. There is no guarantee that our securities will appreciate in value or even maintain the price at which they were purchased. Further, investors may need to sell all or part of their holdings of our securities to realize any future gains on their investment.

The market price of our securities may be volatile, which could result in substantial losses for our investors.

The market price of our securities has been volatile, and will likely continue to be volatile and subject to wide fluctuations in response to a variety of factors, including the following:

- announcements of competitive developments;

- regulatory developments affecting us, our licensors and partners, our customers, or our competitors;
- announcements regarding litigation or administrative proceedings involving us or our licensors and partners;
- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiration of lock-up or other transfer restrictions on our outstanding securities; and
- sales or perceived sales of additional securities.

In addition, the securities markets have experienced, and may in the future experience, significant price and volume fluctuations that are not related to the operating performance of particular companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. For example, in the last few years, tensions between the United States and China, the COVID-19 pandemic, and other geopolitical factors have negatively affected stock market and investor sentiment and resulted in significant volatility, including temporary trading halts. Prolonged global capital markets volatility may affect overall investor sentiment towards our securities, which would also negatively affect the trading prices for our securities.

Fluctuations in the value of the RMB or Hong Kong dollars may have a material adverse effect on our results of operations and the value of our securities.

The value of the RMB or HK dollar against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. With the development of the foreign exchange market and progress towards interest rate liberalization and RMB internationalization, the Chinese government has announced, and may again in the future announce, changes to the exchange rate system. There is no guarantee that the RMB will not appreciate or depreciate significantly in value against the U.S. dollar. It is difficult to predict how market forces or Chinese or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

The value of our securities may, therefore, be affected by 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 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 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, the Company'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 the Company's assets denominated in HK dollars will be adversely affected.

Significant revaluation of the RMB or HK dollar may have a material adverse effect on our business. For example, to the extent that we need to convert U.S. dollars into RMB or HK dollars for our operations, appreciation of the RMB or HK dollar against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB or HK dollars into U.S. dollars for the purpose of making payments for business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount

available to us. In addition, appreciation or depreciation in the value of the RMB relative to U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in mainland China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by Chinese exchange control regulations that restrict our ability to convert RMB into foreign currency.

Holders of our ADSs have fewer rights than shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our amended and restated articles of association, an annual general meeting and any extraordinary general meeting may be called with not less than fourteen days' notice. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date, and the depositary will send a notice to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to instruct the depositary to vote the ordinary shares underlying your ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a holder or beneficial owner of ADSs, you may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if you wish us or the depositary to participate in legal proceedings. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

Under the deposit agreement, for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying your ADS at shareholders' meeting if you do not give instructions to the depositary, unless (i) we have failed to timely provide the depositary with our notice of meeting and related voting materials, (ii) we have instructed the depositary that we do not wish a discretionary proxy to be given, (iii) we have informed the depositary that there is a substantial opposition as to a matter to be voted on at the meeting, or (iv) a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that, if you fail to give voting instructions to the depositary, you cannot prevent the ordinary shares underlying your ADSs from being voted, except under the circumstances described above. This may adversely affect your interests and make it more difficult for ADS holders to influence the management of the Company. Holders of our ordinary shares are not subject to this discretionary proxy.

Holders of our ADSs may not receive distributions or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distributions.

Although we do not have any present plan to pay any dividends, if we achieve profitability and were to decide to pay dividends in the future, the depositary of our ADSs has agreed to pay our ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. Our ADS holders will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption

from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights, or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights, or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of our ADSs.

Rights of our shareholders in the United States to participate in any future rights offerings may be limited, which may cause dilution to their holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to our shareholders in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to our U.S. shareholders unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, our U.S. shareholders may be unable to participate in our rights offerings and may experience dilution in their holdings.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are organized under the laws of the Cayman Islands and currently have subsidiaries in mainland China, Hong Kong, Taiwan, the Cayman Islands, the United States, Australia, and the British Virgin Islands. If we further grow our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us, our parent company, and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

A tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest, and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

There is no assurance that we will not be a passive foreign investment company, or PFIC for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our securities to significant adverse U.S. federal income tax consequences.

In general, a non-U.S. corporation will be a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income, or (ii) 50% or more of the value of its assets (generally determined on a quarterly average basis) consists of assets that produce, or are held for the production of, passive income (the “asset test”). For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes interest, dividends, and gains from certain property transactions, rents, and royalties (other than certain rents or royalties derived in the active conduct of a trade or business). For these purposes, cash is generally a passive asset and the value of a non-U.S. corporation’s goodwill (which may be determined by reference to the excess of the sum of its market capitalization and liabilities over its booked assets) generally should be an active asset to the extent attributable to business activities that produce non-passive income.

Based on the current market price of our ADSs and our current and expected composition of income and assets, we do not expect the Company and its subsidiaries to be PFICs for our current taxable year. However, our assets other than goodwill are expected to consist primarily of cash and cash equivalents for the foreseeable future. Therefore, whether we will satisfy the asset test for the current or any future taxable year will depend largely on the quarterly value of our goodwill (which may be determined by reference to the market price of our ADSs, which could be volatile given the nature and early stage of our business). If our market capitalization declines while we continue to hold a significant amount of cash, the risk that we will be a PFIC will increase. Furthermore, we may be a PFIC for any taxable year in which our interest and other investment income constitutes 75% or more of the sum of (i) such interest and investment income, and (ii) the excess of our revenue over cost of goods sold. In addition, a company’s PFIC status is an annual determination that can be made only after the end of each taxable year. Therefore, we cannot give any assurance as to whether we are a PFIC for the current or any future taxable year.

Subject to the discussion below, if we are or become a PFIC, U.S. investors generally would be subject to adverse U.S. federal income tax consequences, such as increased tax liabilities on capital gains and certain distributions, and interest charges on taxes deemed to be deferred. If we are a PFIC for any taxable year during which a U.S. investor owns our securities, we will generally continue to be treated as a PFIC with respect to such investor for all succeeding years during which the investor owns our securities (unless the investor timely makes a valid “deemed sale” election), even if we cease to meet the threshold requirements for PFIC status. A mark-to-market election may be available with respect to our securities, which would result in U.S. federal income tax consequences to holders of our securities that are different from those described above.

If a U.S. investor owns our securities during any year in which we are a PFIC, such investor generally will be required to file annual reports on IRS Form 8621 (or any successor form) with respect to us, generally with their U.S. federal income tax return for that year. U.S. investors should consult their tax advisors regarding the determination of whether we are a PFIC for any taxable year and the potential application of the PFIC rules.

If a U.S. investor is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. investor is treated as owning (directly, indirectly, or constructively) at least 10% of either the total value or total combined voting power of our ADSs or our ordinary shares, such U.S. investor may be treated as a “U.S. shareholder” with respect to each controlled foreign corporation, or CFC, in the Company (if any). Because the Company includes at least one U.S. subsidiary (Zai Lab (US) LLC), certain of our non-U.S. subsidiaries will be treated as CFCs (regardless of whether Zai Lab Limited is treated as a CFC). A U.S. shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by CFCs, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. shareholder that is a U.S. corporation. We may not assist investors in determining whether any of our non-U.S. subsidiaries are treated as a CFC or whether such investor is treated as a U.S. shareholder with respect to any of such CFCs. Further, we may not furnish to any investors information that may be necessary to comply with the reporting and tax

paying obligations discussed above. Failure to comply with these reporting obligations may subject a U.S. investor to significant monetary penalties and may prevent the statute of limitations with respect to their U.S. federal income tax return for the year for which reporting was due from starting. U.S. investors should consult their tax advisors regarding the potential application of these rules to their investment in our securities.

Changes in tax law may adversely affect our business and financial results.

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations, or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our actual tax rate may vary from our expectation, and that variance may be material. A number of factors may increase our future effective tax rates, including: (i) the jurisdictions in which profits are determined to be earned and taxed; (ii) the resolution of issues arising from any future tax audits with various tax authorities; (iii) changes in the valuation of our deferred tax assets and liabilities; (iv) our ability to use net operating loss carryforwards to offset future taxable income and any adjustments to the amount of the net operating loss carryforwards we can utilize; and (v) changes in tax laws or the interpretation of such tax laws, and changes in U.S. GAAP.

Our corporate actions are substantially controlled by our directors, executive officers, and other principal shareholders, who can exert significant influence over important corporate matters, which may reduce the price of our securities.

Our directors, executive officers, and other principal shareholders could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, or other business combination transactions. This may discourage, delay, or prevent a change in control of the Company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of the Company and reduce the price of our securities. Such actions may be taken even if they are opposed by certain of our other shareholders. In addition, our directors, executive officers, and other principal shareholders could divert business opportunities away from us to themselves or others.

Investors may be subject to limitations on transfers of their ADSs.

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer, or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Substantial future sales or perceived potential sales of our ordinary shares, ADSs, or other equity or equity-linked securities could cause the price of our securities to decline.

Sales of our ordinary shares, ADSs, or other equity or equity-linked securities, or the perception that these sales could occur, could cause the market price of our securities to decline significantly. All of our ordinary shares represented by ADSs were freely transferable by persons other than our affiliates without restriction or additional registration under the U.S. Securities Act. The shares held by our affiliates are also available for sale, subject to volume and other restrictions as applicable under Rule 144 of the U.S. Securities Act, under trading plans adopted pursuant to Rule 10b5-1 or otherwise.

Divestiture in the future of our securities by shareholders, the announcement of any plan to divest our securities, or hedging activity by third-party financial institutions in connection with similar derivative or other financing arrangements entered into by shareholders could cause the price of our securities to decline.

Furthermore, any major disposal of our securities by any of our directors or executive officers (or the perception that such disposals may occur) may cause the prevailing market price of our securities to fall, which could negatively impact our ability to raise capital in the future.

The different characteristics of the capital markets in Hong Kong and the United States may negatively affect the trading prices of our securities.

We are dual primary listed on Nasdaq and the Hong Kong Stock Exchange. Nasdaq and the Hong Kong Stock Exchange have different listing rules and requirements, trading hours, trading characteristics (including trading volume and liquidity), trading rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares on the Hong Kong Stock Exchange and our ADSs on Nasdaq may not be the same, even after allowing for currency differences. Fluctuations in the price of our securities due to circumstances unique to the one market could materially and adversely affect the price of our securities on the other market.

The depositary for our ADSs is entitled to charge holders fees for various services, including annual service fees. Dealings in the ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty.

The depositary for our ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust Company, or DTC, the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time. Additionally, dealings in the ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty.

Exchange between our ordinary shares and our ADSs may adversely affect the liquidity and/or trading price of our securities.

Subject to compliance with U.S. securities law and the terms of the deposit agreement, holders of our ordinary shares may deposit such ordinary shares with the depositary in exchange for the issuance of our ADSs. Any holder of ADSs may also withdraw the underlying ordinary shares represented by the ADSs pursuant to the terms of the deposit agreement for trading on the Hong Kong Stock Exchange. If a substantial number of our ordinary shares are deposited with the depositary in exchange for ADSs or vice versa, the liquidity and trading price of our ordinary shares on the Hong Kong Stock Exchange and our ADSs on Nasdaq may be adversely affected.

The time required for the exchange between our ordinary shares and ADSs might be longer than expected and investors might not be able to settle or effect any sale of their securities during this period, and the exchange of ordinary shares into ADSs involves costs.

There is no direct trading or settlement between Nasdaq and the Hong Kong Stock Exchange on which our ADSs and ordinary shares are respectively traded. In addition, the time differences between Hong Kong and New York and unforeseen market circumstances or other factors may delay the deposit of ordinary shares in exchange of ADSs or the withdrawal of ordinary shares underlying the ADSs. Investors will be prevented from settling or effectuating the sale of their securities during such periods of delay. In addition, there is no assurance that any exchange of ADSs into ordinary shares (and vice versa) will be completed in accordance with the timelines investors may anticipate.

Furthermore, the depositary for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. As a result, shareholders who exchange ADSs into ordinary shares, and vice versa, may not achieve the level of economic return they may anticipate.

There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of our ADSs.

We have established a branch register of members in Hong Kong (the “Hong Kong share register”) for our ordinary shares that are traded on the Hong Kong Stock Exchange, and the trading of these ordinary shares on the Hong Kong Stock

Exchange will be subject to the Hong Kong stamp duty. In addition, to facilitate ADS-ordinary share conversion and trading between Nasdaq and the Hong Kong Stock Exchange, we have moved a portion of our issued ordinary shares from our register of members maintained in the Cayman Islands to our Hong Kong share register.

Under the Hong Kong Stamp Duty Ordinance, any person who effects any sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2% of the greater of the consideration for, or the value of, shares transferred, with 0.1% payable by each of the buyer and the seller. To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual-listed companies constitutes a sale or purchase of the underlying Hong Kong-registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of our ADSs, the trading price and the value of any investment in our securities may be affected.

General Risk Factors

We are subject to the risks of doing business globally, such as from economic or political tensions between the United States and China and other business disruptions or other adverse effects caused by economic downturns, market conditions, changing legal and regulatory requirements, political instability, trade sanctions, public health crises, international war or conflict, natural disasters, extreme weather events, and other geopolitical events or significant disruptions outside of our control.

Because we operate in Greater China, the United States, and other countries, our business is subject to risks associated with doing business globally. For example, our business and financial results could be adversely affected by changes in global, economic, and industry conditions, including currency fluctuations, changes in interest rates, capital and exchange controls, inflation, recession, market volatility, and restrictive government actions such as changes in laws and regulatory requirements, intellectual property, legal protections and remedies, trade regulations, tax laws and regulations, and procedures and actions affecting approval, production, pricing, marketing, reimbursement, and access for our products or product candidates.

In addition, we, as well as our customers, vendors, partners, and patients, may be impacted by geopolitical events, including economic or political tensions between the United States and China; international war or conflicts; and other instances of political or civil unrest, such as major hostilities or acts of terrorism. For example, as a result of economic or political conditions or tensions between the United States and China, the United States and other nations have raised the possibility of tariffs and trade or other sanctions on China, Chinese banks, and companies with operations in China as well as legislation that restricts or prohibits U.S. investment in certain companies operating in China. Such actual or threatened sanctions on us or third parties with which we do business, such as customers, suppliers, intermediaries, services providers, or banks, and other geopolitical factors could adversely affect our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our securities. We, as well as our customers, vendors, partners, and patients, may also be impacted by public health crises, such as the COVID-19 pandemic, as well as earthquakes, hurricanes, floods, drought, wildfires, and other extreme weather or catastrophic events.

The occurrence of one or more of the events described above could disrupt our studies, supply chain, manufacturing facilities, distribution network, and sales and marketing efforts or result in increased costs or decreased demand for our products. Such developments could have a material adverse effect on our business, including our clinical development, financial condition, results of operations, ability to raise capital or raise capital on favorable terms, and the market price of our securities.

If we or our CROs or CMOs fail to comply with applicable environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We, our CROs, CMOs, or other contractors are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health, and safety have been completed. Our development operations primarily occur in mainland China and the United States and involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We are therefore subject to Chinese and U.S. laws and regulations concerning the discharge of wastewater, gaseous waste, and solid waste during our research and development of our products and product candidates. We generally contract with third parties for the disposal of these materials and wastes. If we fail to comply with environmental regulations and contamination or injury from these materials results from our use of hazardous materials, we could be held liable for any resulting damages, and any such liability could exceed our resources or insurance coverage (such as workers' compensation insurance for injuries to our employees). We also could incur significant costs associated with civil, administrative, or criminal fines and penalties.

Furthermore, the Chinese or U.S. government may adopt more stringent environmental regulations. If this occurs, we may incur substantial capital expenditures to install, replace, upgrade, or supplement our facilities and equipment or make operational changes to comply with such environmental protection laws and regulations. If such costs were to become prohibitively expensive, we may be forced to cease certain aspects of our business or operations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use, or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future health and safety laws and regulations, which could impair our research, development, or production efforts. Failure to comply with such laws and regulations may result in substantial fines, penalties, or other sanctions.

Because of volatility in the price of our securities and the share price of biotechnology and biopharmaceuticals companies more broadly, we may be at increased risk of securities class action litigation.

In recent years, our company as well as other companies in our industry have experienced significant share price volatility. As a result, we may be at increased risk of securities class action litigation. Historically, securities class action litigation, whether warranted or not, often follows a decline in the market price of a company's securities. If we were to become subject to class action litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price and/or trading value of our securities could decline.

The market for our securities relies in part on research and reports that equity research analysts publish about us or our business. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, the market price for our securities would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our securities to decline significantly.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products.

There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Further, there is a risk that unmerited or unsupported claims about our products may circulate on social media. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions, or incur other harm to our business, including damage to the reputation of our products or Company.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Cybersecurity risks are a growing threat to us and other businesses, including our CROs, CMOs, and other third-party providers, which are vulnerable to cyberattacks, malware, and other system failures that may result in unauthorized access, damage, and other harms to our business or reputation. Protecting the confidentiality, integrity, and availability of our business information, intellectual property, customer, patient and employee data, and technology systems is critical to our business and operations, ability to comply with regulatory requirements, and reputation. Accordingly, cybersecurity is an important and integrated part of the Company's enterprise risk management function that identifies, monitors, and mitigates business, operational, and legal risks.

Accordingly, we have established cybersecurity standards, policies, and operating procedures, including our Global IT Policy and Information Security Policy and our incident response plan, for the purpose of implementing information protection processes and technologies; carrying out cybersecurity risk detection, identification, assessment, response, and monitoring; assigning responsibility within our organization for risk detection and oversight; implementing cybersecurity training; governing internal communications regarding cybersecurity risks; and making required public and regulatory disclosures regarding cybersecurity threats and incidents. We oversee risks from cybersecurity threats associated with our use of third-party service providers by requiring our vendors to agree that they have and will maintain appropriate cybersecurity controls, such as through standard contractual provisions, and by coordinating with key vendors with respect to integration with our systems. Our cybersecurity risk management program is based on the NIST framework.

Key components of our cybersecurity risk management program include the use of third-party service providers, as appropriate, to assess, test, or otherwise assist with aspects of our security processes. For example, we employed a third-party cyber risk consultant to assess our overall cybersecurity risk framework against NIST standards. We have also engaged third-party experts to perform penetration testing of our IT systems, and we have considered the results of such tests to enhance our cybersecurity systems and controls, as appropriate.

Our management, including leaders from our IT, information security, legal, and compliance teams, is responsible for implementing our cybersecurity standards, policies, and operating procedures, under the ultimate oversight of our Chief Operating Officer. We regularly discuss and assess cybersecurity risks as part of our Risk Coordination Council, which brings together senior leaders across the Company to address various risk issues. In addition, our Global Compliance Committee, which is comprised of leaders from senior management, legal, compliance, finance, HR, and internal audit, discusses significant risk issues affecting the Company, including with respect to cybersecurity issues, as appropriate. Members of our information security team, which includes personnel in the United States and China, collectively have decades of experience with information technology and cybersecurity systems, implementation, and oversight in the jurisdictions in which we operate. Under our incident response plan and our related information security policies and procedures, our information security personnel are responsible for promptly notifying senior management, including leaders in our legal and compliance departments, about any new cybersecurity incident or threat that may require management evaluation or response.

Our Audit Committee assists our Board in overseeing cybersecurity risk management and the integrity of our information technology systems, processes, and data. Periodically, the Audit Committee reviews and discusses with management, our internal auditor, and, in its discretion, third party vendors or other external experts, the adequacy of

security for our information technology systems, processes, and data; our incident response and contingency plans in the event of a breakdown or security breach affecting the security of our information technology systems or data or the information technology systems, processes, and data of our clients; and any new threats or incidents that have or may impact us. The Audit Committee receives reports on the operation of such programs from the Chief Operating Officer, Chief Legal Officer, and/or the IT Department, as appropriate. The Audit Committee also reviews management reports regarding the evolving threat environment, vulnerability assessments, and specific cybersecurity incidents. Periodically, the Audit Committee reports on cybersecurity matters, incidents, and risk oversight to the Board. The Board also receives briefings from management on our cybersecurity risk management program.

Although we have not experienced a cyberattack or other cybersecurity incident that has materially affected us, we have been subject to cybersecurity attacks in the past, and we cannot guarantee that we will not experience cybersecurity incidents that may have a material effect on us in the future. For more information, see *Risk Factors – Potential cybersecurity threats are changing rapidly and advancing in sophistication. We may not be able to protect our systems and networks, or the confidentiality of our confidential or other information (including personal information), from cyberattacks and other unauthorized access, disclosure, and disruption.*

Item 2. Properties

We lease our principal executive offices in Shanghai and Cambridge, Massachusetts as well as various administrative offices in Shanghai, Beijing, Guangzhou, Hong Kong, Taiwan, and South San Francisco, California and research and development facilities in Shanghai and a small site in San Diego, California. We also lease two manufacturing facilities, including a small molecule and a large molecule facility, in Suzhou to support production of certain of our products and product candidates. In addition, we have completed the construction of a new office and research building in Suzhou. We believe these facilities are sufficient to meet our near-term needs.

Item 3. Legal Proceedings

We are, from time to time, subject to various claims, lawsuits, and other legal and administrative proceedings arising in the ordinary course of business. Some of these claims, lawsuits, and other proceedings may involve highly complex issues that are subject to substantial uncertainties, and could result in damages, fines, penalties, non-monetary sanctions, or relief. However, we do not consider any such claims, lawsuits, or proceedings that are currently pending, individually or in the aggregate, to be material to our business or likely to result in a material adverse effect on our future operating results, financial condition, or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our ADSs are traded on Nasdaq under the symbol "ZLAB." Our ordinary shares are publicly traded on the Hong Kong Stock Exchange under the stock code "9688."

Shareholders

As of February 21, 2025, we had approximately 11 holders of record of our ordinary shares. Citibank, N.A. is the depository for our ADSs. This disclosure does not include beneficial owners whose ordinary shares or ADSs are held by nominees in street name.

Dividends

We have incurred losses since inception and never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends.

Securities Authorized for Issuance under Equity Compensation Plans

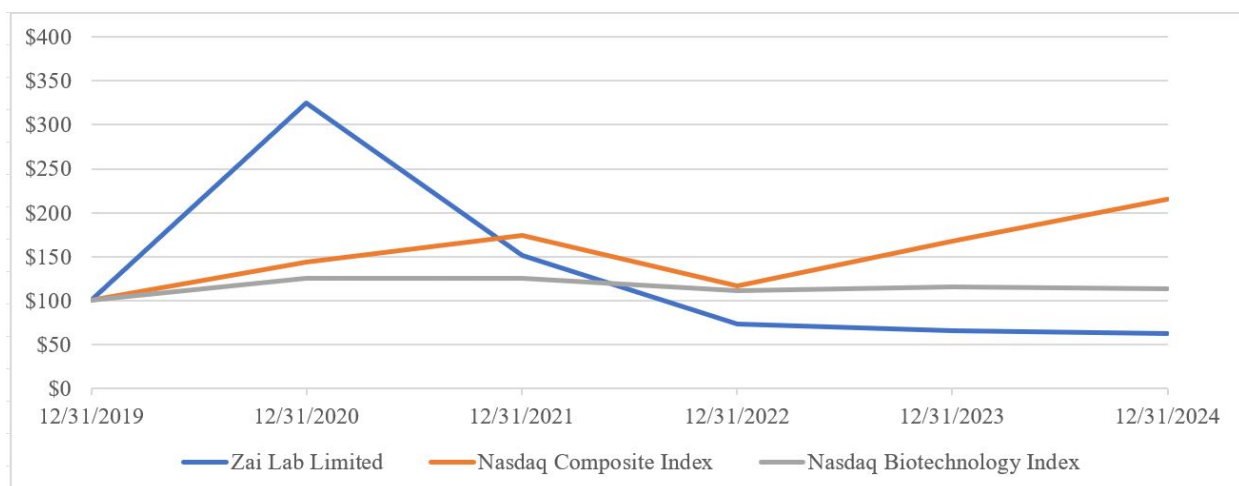
Our equity compensation plan information is incorporated by reference in the information in *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*.

Performance Graph

This graph is not "soliciting material," is not deemed "filed" with the SEC, and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the yearly percentage change in the cumulative total shareholder return of our ADSs with the cumulative total return of the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index for the past five years. The graph assumes an investment of \$100 at market close on December 30, 2019 and reinvestment of any dividends. The cumulative total shareholder returns over the indicated period are based on historical data and should not be considered indicative of future shareholder returns.

The shareholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future shareholder returns.



	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24
Zai Lab Limited	100.00	325.41	151.12	73.82	65.71	62.97
Nasdaq Composite Index	100.00	143.64	174.36	116.65	167.30	215.22
Nasdaq Biotechnology Index	100.00	125.69	124.89	111.27	115.42	113.84

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

There were no repurchases of our equity securities during the fourth quarter of 2024.

Item 6. [Reserved]

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the accompanying notes in this report. This section generally discusses year-over-year comparisons between 2024 and 2023. For a discussion of year-over-year changes in our financial condition and results of operations between 2023 and 2022, see Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed on February 27, 2024. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences elsewhere in this report, including in Forward-Looking Statements and Risk Factors.

Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are focused on discovering, developing, and commercializing products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. We currently have seven commercial programs – ZEJULA, VYVGART / VYVGART Hytrulo, NUZYRA, OPTUNE, QINLOCK, XACDURO, and AUGTYRO – with products that have received marketing approval and that we have commercially launched in one or more territories in Greater China. We also have multiple programs in late-stage product development and a number of ongoing pivotal trials across our portfolio. For more information on our business, products and product candidates, and operations, see *Business*.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and selling, general and administrative costs associated with our operations. Developing high quality product candidates requires significant investment in our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and positive cash flow from operations over the next several years depends upon our ability to successfully market our commercial products and to successfully expand the indications for these products and develop and commercialize our other product candidates. As discussed further below, we expect to continue to incur substantial costs related to our research and development and commercialization activities.

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

Business Developments and Corporate Strategic Goals

In 2024, we continued to demonstrate strong financial performance, with a 50% increase in total revenue to \$399.0 million and a 23% decrease in net loss to \$257.1 million compared to the prior year. Our revenue increase was primarily driven by VYVGART, which has steadily increased sales since its strong commercial launch in September 2023 and initial NRDL listing in January 2024, ZEJULA, which continued to lead PARP inhibitor sales for ovarian cancer in the hospital setting, and NUZYRA, which was supported by the inclusion in the NRDL of its IV formulation for the treatment of CABP and/or ABSSI in January 2023 and its oral formulation for these indications in January 2024. Since the fourth quarter of 2024, we are excited to have expanded our commercial portfolio with the launch in mainland China of VYVGART Hytrulo, the subcutaneous formulation of VYVGART, for gMG and CIDP, XACDURO for HABP and VABP caused by ABC, and AUGTYRO for *ROS1+* NSCLC. AUGTYRO was included in the NRDL for this indication in January 2025. In 2025, we expect our revenues to continue to increase for our existing and more recently launched commercial products.

We also continued to make progress across our product pipeline. For our global assets, we had promising results from the global Phase I study of ZL-1310, a potential first-in-class and best-in-class DLL3-targeted ADC for the treatment of extensive stage SCLC, and promising pre-clinical data for ZL-1503, our internally developed IL-13/IL-31R bispecific antibody for atopic dermatitis. For our late-stage regional pipeline, we had positive data readouts during the year, including for KarXT in schizophrenia, and we completed enrollment for the second Phase III study of bemarituzumab for the treatment of gastric cancer. We have also expanded and strengthened our global and regional pipelines through synergistic business development activities, including a strategic collaboration and worldwide license agreement with MediLink to use MediLink's TMALIN ADC platform for the development of ZL-6201, a novel potential first-in-class LRRC15 ADC consisting of an antibody discovered by Zai Lab, for the treatment of certain solid tumors and a strategic collaboration with Vertex for the license of povetacept, a potential best-in-class treatment for IgAN and other B-cell mediated diseases, in mainland China, Hong Kong, Macau, Taiwan, and Singapore. For more information on our commercial products and product pipeline, including status and developments in 2024, see *Business – Our Commercial Products and Operations* and *Business – Our Pipeline of Product Candidates and R&D Activities*.

We also continued to strengthen our business through key new additions to our global leadership team. For example, after we promoted Dr. Rafael Amado to President, Head of Global Research and Development, expanding his role to encompass our R&D efforts across all of our therapeutic areas in June 2024, we appointed Dr. Prista Charuworn as our Vice President, Immunology, Global R&D to provide strategic leadership and support with respect to the development of our immunology, neuroscience, and infectious disease pipeline.

We further discuss in MD&A below key factors affecting our results of operations, key components and primary drivers of changes in our results of operations in 2024, and our liquidity and capital resources. In 2025, we seek to continue advancing our mission of becoming a leading global biopharmaceutical company, driving innovation in treatment options for patients in China and beyond, by focusing on the following corporate strategic goals: accelerate medicines to patients through our R&D activities; expand and strengthen our global and regional pipelines through our internal discovery efforts and synergistic collaborations and corporate development activities; and continue our commercial excellence and execution, including by delivering strong financial performance as we prepare to launch additional products or new indications for existing products and seek to achieve profitability by the end of 2025. We also intend to continue building and maintaining the trust of our stakeholders by further developing and integrating our Trust for Life strategy into our business and operations. For additional information on our Mission and Corporate Strategic Goals, see *Business – Our Mission and Corporate Strategic Goals*.

Basis of Presentation

Our consolidated statement of operations data for the years ended December 31, 2024 and 2023 and our consolidated balance sheet data as of December 31, 2024 and 2023 have been derived from our audited consolidated financial statements included in *Financial Statements and Supplementary Data*. Our consolidated financial statements appearing elsewhere in this report have been prepared in accordance with U.S. GAAP.

Factors Affecting Our Results of Operations

Our Commercial Products

We generate product revenue through the sale of our commercial products in Greater China, net of any related sales returns and rebates to distributors. Our cost of product revenue mainly consists of the costs of manufacturing ZEJULA and NUZYRA, costs of purchasing VYVGART / VYVGART Hytrulo, OPTUNE, QINLOCK, XACDURO, and AUGTYRO from our collaboration partners, any royalty fees incurred as a result of sales of our commercial products under our license and collaboration agreements, and amortization of capitalized post-approval milestone fees incurred under our license and collaboration agreements. We expect our product revenue to increase in coming years as we continue to focus on increasing patient access to our existing commercial products, such as through NRDL listing or increased supplemental

insurance coverage in the private-pay market, and as we launch additional commercial products, if and when we obtain required regulatory approvals. We expect our cost of product revenue to increase as the volume of products sold increases.

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time. We are committed to advancing and expanding our pipeline of potential best-in-class and first-in-class products, such as through clinical and pre-clinical trials and business development activities. As a result, we expect to continue making significant investments in research and development, including internal discovery activities.

Elements of research and development expenditures primarily include:

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

Selling, General, and Administrative Expenses

Our selling, general, and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general, and administrative expenses include product distribution and promotion costs, and professional service fees for legal, intellectual property, consulting, auditing, and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies used in selling, general, and administrative activities. We expect these costs to continue to be significant to support sales of our commercial products and preparation to launch and subsequent sales of additional product candidates if and when approved.

Our Ability to Commercialize Our Product Candidates

We have multiple product candidates in late-stage clinical development and various others in clinical and pre-clinical development in Greater China and globally. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such product candidates, which may not occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, manufacturing supply, and significant marketing efforts before we generate any revenue from product sales.

License and Collaboration Arrangements

Our results of operations have been, and will continue to be, affected by our license and collaboration agreements. In accordance with these agreements, we may be required to make upfront payments and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones for the relevant products as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. As of December 31, 2024, we may in the future be required to pay development and regulatory milestone payments of up to an additional aggregate amount of \$211.5 million for our current clinical programs and \$766.9 million for other programs. Such development and regulatory milestone payments are contingent on the progress of our product candidates prior to commercialization, and we see these payments as favorable because they indicate that product candidates are advancing. As of December 31, 2024, we also may in the future be required to pay sales-based milestone payments of up to an

additional aggregate amount of \$2,620.0 million as well as certain royalties at tiered percentage rates on annual net sales. Such sales-based milestone and royalty payments are contingent on the performance of our commercial products, and we see these payments as favorable because they signify that a product is achieving higher sales levels.

Results of Operations

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

	Year Ended December 31		Change	
	2024	2023	\$	%
Revenues				
Product revenue, net	397,614	266,719	130,895	49 %
Collaboration revenue	1,374	—	1,374	NM
Total revenues	398,988	266,719	132,269	50 %
Expenses				
Cost of product revenue	(147,118)	(95,816)	(51,302)	54 %
Cost of collaboration revenue	(742)	—	(742)	NM
Research and development	(234,504)	(265,868)	31,364	(12)%
Selling, general and administrative	(298,741)	(281,608)	(17,133)	6 %
Gain on sale of intellectual property	—	10,000	(10,000)	(100)%
Loss from operations	(282,117)	(366,573)	84,456	(23)%
Interest income	37,105	39,797	(2,692)	(7)%
Interest expenses	(2,254)	—	(2,254)	NM
Foreign currency losses	(15,137)	(14,850)	(287)	2 %
Other income, net	5,300	7,006	(1,706)	(24)%
Loss before income tax	(257,103)	(334,620)	77,517	(23)%
Income tax expense	—	—	—	— %
Net loss	(257,103)	(334,620)	77,517	(23)%

NM - Not Meaningful

Revenues

Product Revenue, Net

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

	Year Ended December 31		Change	
	2024	2023	\$	%
ZEJULA	187,082	168,843	18,239	11 %
VYVGART / VYVGART Hytrulo	93,639	10,011	83,628	835 %
NUZYRA	43,199	21,656	21,543	99 %
OPTUNE	40,475	46,969	(6,494)	(14)%
QINLOCK	28,826	19,240	9,586	50 %
XACDURO	3,305	—	3,305	NM
AUGTYRO	1,088	—	1,088	NM
Total	397,614	266,719	130,895	49 %

NM - Not Meaningful

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

Our net product revenue increased by \$130.9 million in 2024, primarily driven by increased sales for VYVGART since its launch in September 2023 and NRDL listing in January 2024 for the treatment of gMG. Other key drivers of net product revenue growth include increased sales volumes for ZEJULA and NUZYRA in 2024. ZEJULA sales remained strong as it continued to be the leading PARP inhibitor in hospital sales for ovarian cancer in mainland China. The growth in NUZYRA sales was supported by the inclusion in the NRDL for its IV formulation for the treatment of CABP and/or ABSSSI in the first quarter of 2023 and for its oral formulation for these indications in the first quarter of 2024.

Research and Development Expenses

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

	Year Ended December 31		Change	
	2024	2023	\$	%
Personnel compensation and related costs	106,154	115,749	(9,595)	(8)%
Licensing fees	30,997	19,291	11,706	61 %
CROs/CMOs/Investigators expenses	69,870	103,333	(33,463)	(32)%
Other costs	27,483	27,495	(12)	— %
Total	234,504	265,868	(31,364)	(12)%

Research and development expenses decreased by \$31.4 million in 2024 primarily due to:

- a decrease of \$33.5 million in CROs/CMOs/Investigators expenses related to ongoing clinical trials; and
- a decrease of \$9.6 million in personnel compensation and related costs primarily driven by the Company's ongoing resource prioritization and efficiency efforts; partially offset by
- an increase of \$11.7 million in licensing fees in connection with increased upfront and milestone payments for our license and collaboration agreements.

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

	Year Ended December 31		Change	
	2024	2023	\$	%
Clinical programs	86,126	112,158	(26,032)	(23)%
Pre-clinical programs	31,913	17,356	14,557	84 %
Unallocated research and development expenses	116,465	136,354	(19,889)	(15)%
Total	234,504	265,868	(31,364)	(12)%

Research and development expenses attributable to clinical programs decreased by \$26.0 million in 2024 primarily driven by a decrease of \$28.7 million in CROs/CMOs/Investigators expenses related to the progress of existing studies, offset by an increase of \$2.7 million in licensing fees. Research and development expenses attributable to pre-clinical programs increased by \$14.6 million in 2024, primarily driven by an increase of \$9.0 million in licensing fees and an increase of \$5.6 million in CROs/CMOs/Investigators expenses related to newly initiated studies.

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

Selling, General, and Administrative Expenses

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

	Year Ended December 31		Change	
	2024	2023	\$	%
Personnel compensation and related costs	174,958	173,389	1,569	1 %
Other costs	123,783	108,219	15,564	14 %
Total	298,741	281,608	17,133	6 %

Selling, general, and administrative expenses increased by \$17.1 million in 2024 primarily due to higher general selling expenses and personnel compensation and related costs for VYVGART, which was launched in September 2023, and NUZYRA, which was first included in the NRDL for its IV formulation in January 2023 and for its oral formulation in January 2024.

Gain on Sale of Intellectual Property

We had a gain on sale of intellectual property of \$10.0 million in 2023 in connection with our sale of certain patent rights and related know-how to a third party. We had no such gain or loss in 2024.

Interest Income

Interest income decreased by \$2.7 million in 2024, primarily due to decreased cash and cash equivalents.

Interest Expense

Interest expense increased by \$2.3 million in 2024, primarily due to interest expense on short-term debt we entered into in 2024. We had no such interest expense in 2023.

Foreign Currency Losses

Foreign currency losses increased by \$0.3 million in 2024, primarily driven by increased remeasurement loss due to depreciation of the RMB against the U.S. dollar.

Other Income, Net

Other income, net decreased by \$1.7 million in 2024 primarily due to the shift from a gain of \$2.8 million in 2023 to a loss of \$6.1 million in 2024 for our investment in MacroGenics as a result of changes in its stock price, partially offset by an increase of \$5.7 million in government grants.

Income Tax Expense

Income tax expense was nil in both 2024 and 2023.

Net Loss

Net loss was \$257.1 million in 2024, or a loss per ordinary share attributable to common stockholders of \$0.26 (or loss per ADS of \$2.60), compared to a net loss of \$334.6 million in 2023, or a loss per ordinary share of \$0.35 (or loss per ADS of \$3.46).

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

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

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

Significant judgments are required in making these estimates. In determining the appropriate accrual amount, we consider our contracted rates, sales volumes, levels of distributor inventories, and historical experiences and trends. If actual results vary from our estimates or our expectations change, we will adjust these estimates accordingly, which would affect net product revenue and earnings in the period such variances become expected or known.

Research and Development Expenses

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

We contract with third parties to perform various pre-clinical and clinical trial activities on our behalf in the ongoing development of our product candidates. Expenses related to pre-clinical and clinical trial activities are accrued based on the Company's estimates of the actual services performed by the third parties, such as CROs and CMOs.

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

Share-Based Compensation

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

Significant assumptions are required in determining the fair value of share options, which we estimate using the Black-Scholes option valuation model. These assumptions include: (i) the volatility of our ADS price, (ii) the periods of time over which grantees are expected to hold their options prior to exercise (expected term), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates. Since we do not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term is derived from the average midpoint between the weighted average vesting and the contractual term, also known as the simplified method. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future, and risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the expected term. If actual results vary from our estimates or our expectations change, our reported expenses and earnings for the corresponding period may be affected.

Income Taxes

We recognize deferred tax assets and liabilities for temporary differences between the financial statement and income tax bases of assets and liabilities, which are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some or all of a deferred tax asset will not be realized. Significant judgements are required when evaluating tax positions in accordance with ASC 740, *Income Taxes*.

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

We consider positive and negative evidence when determining whether some or all of our deferred tax assets will not be realized. This assessment considers various factors, including the nature, frequency, and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Our estimates may be affected by changing interpretations of laws, rulings by tax authorities, changes and/or developments with respect to tax audits, and expiration of the statute of limitations. If actual benefits vary from our estimates or our expectations change, we will adjust the recognition and measurement estimates accordingly, which would affect reported expenses and earnings in the corresponding period.

Liquidity and Capital Resources

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering and various follow-on offerings on Nasdaq, and our September 2020 secondary listing and initial public offering on the Hong Kong Stock Exchange. In addition, we have raised approximately \$164.6 million in private equity financing and approximately \$2,677.8 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering and subsequent follow-on offerings on Nasdaq and our initial public offering on the Hong Kong Stock Exchange. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$214.9 million and \$198.2 million in 2024 and 2023, respectively. For information on our research and development activities and related expenditures see the *Research and Development Expenses*, *Selling, General, and Administrative Expenses*, *License and Collaboration Arrangements*, and *Results of Operations* sections above. In addition, as of December 31, 2024, we had commitments for capital expenditures of \$6.8 million mainly for the purpose of commercial manufacturing development and facilities construction and improvement activities.

As of December 31, 2024, we had cash and cash equivalents, current restricted cash, and short-term investments of \$879.7 million, which we expect will enable us to meet our cash requirements including the funding of operating expenses, capital expenditures, and debt obligations for at least the next 12 months.

Although we believe that we have sufficient capital to fund our operations for at least the next twelve months, we may, from time to time, identify opportunities to access capital through debt arrangements on favorable commercial terms. In 2024, we entered into four such debt arrangements with Chinese financial institutions that allow certain of our subsidiaries to borrow up to approximately \$198.9 million (or RMB1,421.7 million) to support our working capital needs in mainland China. As of December 31, 2024, we had short-term debt of approximately \$131.7 million (or RMB946.8 million) pursuant to these debt arrangements. In January 2025, we entered into a working capital loan contract with another Chinese financial institution with respect to a revolving credit facility of up to RMB300.0 million (approximately \$41.1

million). These debt arrangements will provide us with additional capital capacity that gives us enhanced flexibility to execute on our corporate strategic goals. For more information, see *Note 12 and Note 22*.

We may consider, or we may ultimately need, additional funding sources to bring to fruition our strategic objectives, and there can be no assurances that such funding will be made available to us on acceptable terms or at all.

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

	Year Ended December 31,		Change
	2024	2023	\$
Net cash used in operating activities	(214,869)	(198,178)	(16,691)
Net cash used in investing activities	(375,193)	(10,776)	(364,417)
Net cash provided by (used in) financing activities	349,889	(6,433)	356,322
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(310)	(2,622)	2,312
Net decrease in cash, cash equivalents and restricted cash	(240,483)	(218,009)	(22,474)

Net Cash Used in Operating Activities

Net cash used in operating activities increased by \$16.7 million in 2024, primarily due to a decrease of \$77.5 million in net loss and an increase of \$13.8 million in adjustments to reconcile net loss to net cash used in operating activities, partially offset by a decrease of \$108.0 million in net changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities increased by \$364.4 million in 2024, primarily due to an increase of \$196.0 million purchases of short-term investments, a decrease of \$101.4 million in proceeds from maturity of short-term investments, an increase of \$54.6 million in acquisition of intangible assets, a decrease of \$10.0 million in proceeds from sale of intellectual property, and a decrease of \$3.9 million in proceeds from land use right, partially offset by a decrease of \$1.6 million in purchases of property and equipment.

Net Cash Used in Financing Activities

Net cash provided by financing activities was \$349.9 million in 2024, compared to net cash used in financing activities of \$6.4 million in 2023. This shift was primarily due to an increase of \$216.1 million in proceeds from issuance of ordinary shares upon public offerings net of offering costs, an increase of \$131.6 million in proceeds from short-term debt, and a decrease of \$8.8 million in taxes paid related to settlement of equity awards.

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, see *Part II - Item 8. Financial Statements and Supplementary Data – Recent Accounting Pronouncements*.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the PBOC, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the

China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts of \$19.0 million and \$25.1 million, which were denominated in RMB, representing 4% and 3% of the cash and cash equivalents as of December 31, 2024 and 2023, respectively.

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

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in Greater China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC.

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

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

Credit Risk

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of losses due to credit risk. As of December 31, 2024 and 2023, we had cash and cash equivalents of \$449.7 million and \$790.2 million, restricted cash of \$101.1 million and \$1.1 million, and short-term investments of \$330.0 million and \$16.3 million, respectively. As of December 31, 2024 and 2023, all of our cash and cash equivalents, restricted cash, and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and for which we monitor continued credit worthiness.

Accounts receivable are typically unsecured and are derived from product revenue. We manage credit risk related to our accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and credit worthiness. Historically, we have collected receivables from customers within the credit terms with no significant credit losses incurred. As of December 31, 2024, our two largest customers accounted for approximately 23% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of December 31, 2024, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These

notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

Interest Rate Risk

We are exposed to risks related to changes in interest rates on our cash and cash equivalents, restricted cash, and short-term investments. As of December 31, 2024 and 2023, we had cash and cash equivalents of \$449.7 million and \$790.2 million, restricted cash of \$101.1 million and \$1.1 million, and short-term investments of \$330.0 million and \$16.3 million, respectively. Our investment portfolio, which relates to cash equivalents and short-term investments, primarily consists of time deposits. The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significantly increasing risk. Given the short-term nature of our deposits and investments, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. For example, a hypothetical 10% relative change in interest rates during any of the periods presented would not have a material impact on future interest income.

We are also exposed to risks related to changes in interest rates on our short-term debt, which is currently subject to a mix of fixed and floating interest rates. We had \$131.7 million of short-term debt as of December 31, 2024. A 100-basis point increase in interest rates as of December 31, 2024 would not materially increase our interest expense. Our interest rate exposure from short-term debt is also offset by our exposure in cash and cash equivalents, restricted cash, and short-term investments, as discussed above. For more information on our short-term debt, see *Note 12* and *Note 22*.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this item are appended to this report. An index of those financial statements is in *Exhibits, Financial Statement Schedules*.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

(a) Management's Evaluation of Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this report. Our disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or furnish under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based upon that evaluation, our management has concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP and includes those policies and procedures that (i) pertain to the maintenance of

records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

Internal control over financial reporting, no matter how well designed, has inherent limitations. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control – Integrated Framework (2013)." Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

(c) Report of Registered Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by KPMG LLP, an independent registered public accounting firm, who has also audited our consolidated financial statements for the year ended December 31, 2024, as stated in their report which is included in *Financial Statements and Supplementary Data*.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such item is defined in Exchange Act Rule 13a-15(f)) during the fiscal quarter ended December 31, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On November 20, 2024, Dr. Samantha (Ying) Du, the Company's Founder, Chief Executive officer, and Chairperson of the Board, adopted a new written Rule 10b5-1 trading arrangement, for (1) the acquisition and sale of up to 589,165 ADSs upon the exercise of previously awarded options that are scheduled to expire in 2025 and (2) for the acquisition of up to 604,376 ADSs upon the exercise of previously awarded options that are scheduled to expire in 2025. This Rule 10b5-1 trading arrangement is scheduled to terminate no later than November 20, 2025.

On November 20, 2024, William Lis, one of the Company's directors, adopted a new written Rule 10b5-1 trading arrangement for the sale of up to 26,690 ADSs. This Rule 10b5-1 trading arrangement is scheduled to terminate no later than June 1, 2026.

On November 22, 2024, Rafael Amado, the Company's President and Head of Global Research and Development, adopted a new written Rule 10b5-1 trading arrangement for the sale of up to 9,000 ADSs. This Rule 10b5-1 trading arrangement is scheduled to terminate no later than December 17, 2025.

On November 22, 2024, F. Ty Edmondson, the Company's Chief Legal Officer, adopted a new written Rule 10b5-1 trading arrangement for the sale of up to 28,872 ADSs. This Rule 10b5-1 trading arrangement is scheduled to terminate no later than November 21, 2025.

Other than as described above, during the fourth quarter of 2024, none of our directors or executive officers (as defined in Rule 16a-1(f) under the Exchange Act) has adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The Company has adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by directors, officers, employees, or the Company itself that we believe are reasonably designed to promote compliance with applicable insider trading laws, rules, regulations, and listing standards. Additional information required by this item will be set forth in the 2025 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be set forth in the 2025 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in the 2025 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the 2025 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the 2025 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The financial statements listed in the Index to Consolidated Financial Statements beginning on page F-1 are filed as part of this report.

We have included Additional Financial Information of Parent Company - Financial Statements Schedule I for the year ended December 31, 2024, 2023, and 2022 on page F-39. No other financial statement schedules have been filed as part of this report because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

The exhibits filed as part of this report are set forth on the Exhibit Index below. The Exhibit Index is incorporated herein by reference.

Exhibit Number	Exhibit Title
3.1	<u>Sixth Amended and Restated Memorandum and Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed on June 22, 2022)</u>
4.1	<u>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 on September 1, 2017)</u>
4.2	<u>Form of American Depositary Receipt (incorporated by reference to Form 424B3 (File No. 333-220256) filed on March 30, 2022)</u>
4.3	<u>Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-8 (File No. 333-264800) filed on May 9, 2022)</u>
4.4	<u>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 on August 15, 2017)</u>
4.5	<u>Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act</u>
10.1#	<u>Zai Lab Limited 2015 Omnibus Equity Incentive Plan as amended on February 3, 2016 and April 10, 2016 (incorporated by reference to Exhibit 10.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed on September 1, 2017)</u>
10.2#	<u>Zai Lab Limited 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed on September 1, 2017)</u>
10.3#	<u>Zai Lab Limited 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed on June 22, 2022)</u>
10.4#	<u>Zai Lab Limited 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed on June 18, 2024)</u>
10.5#	<u>Form Restricted Share Unit Award Agreement (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on August 6, 2024)</u>
10.6#	<u>Form Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on August 6, 2024)</u>
10.7#	<u>Form of Non-Statutory Stock Option Award Agreement (incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on August 6, 2024)</u>
10.8#	<u>Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on May 8, 2024)</u>
10.9 ⁺	<u>Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 28, 2016 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-219980) filed on August 15, 2017)</u>

Exhibit Number	Exhibit Title
10.10	<u>Amendment to Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd., dated February 26, 2018 (incorporated by reference to Exhibit 4.3 to our Annual Report on Form 20-F (File No. 001-38205) filed on April 30, 2018)</u>
10.11 [^]	<u>Collaboration and License Agreement between argenx BV and Zai Auto Immune (Hong Kong) Limited dated January 6, 2021 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on May 10, 2021)</u>
10.12 [^]	<u>Addendum to Collaboration and License Agreement between argenx BV and Zai Auto Immune (Hong Kong) Limited dated June 30, 2024 (incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on August 6, 2024)</u>
10.13 ⁺	<u>License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed on August 15, 2017)</u>
10.14 ⁺	<u>License and Collaboration Agreement by and between Novocure Limited and Zai Lab (Shanghai) Co., Ltd. dated September 10, 2018 (incorporated by reference to Exhibit 10.15 to our Annual Report on Form 20-F (File No. 001-38205) filed on March 29, 2019)</u>
10.15 [^]	<u>License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated June 10, 2019 (incorporated by reference to Exhibit 10.17 to our Annual Report on Form 20-F (File No. 001-38205) filed on April 29, 2020)</u>
10.16 [^]	<u>Amendment to License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated January 17, 2020 (incorporated by reference to Exhibit 10.18 to our Annual Report on Form 20-F (File No. 001-38205) filed on April 29, 2020)</u>
10.17 ⁺	<u>License and Collaboration Agreement by and between Entasis Therapeutics Holdings Inc. and Zai Lab (Shanghai) Co., Ltd. dated April 25, 2018 (incorporated by reference to Exhibit 10.12 to our Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-227159) filed on September 5, 2018)</u>
10.18 [^]	<u>License Agreement between Turning Point Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated July 6, 2020 (incorporated by reference to Exhibit 10.21 to our Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2021)</u>
10.19 ⁺	<u>License Agreement by and between Five Prime Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated December 19, 2017 (incorporated by reference to Exhibit 4.11 to our Annual Report on Form 20-F (File No. 001-38205) filed on April 30, 2018)</u>
10.20 [^]	<u>Collaboration and License Agreement by and between Seagen Inc. and Zai Lab (Hong Kong) Limited dated September 20, 2022 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on November 9, 2022)</u>
10.21 [^]	<u>License Agreement by and between Zai Lab (Shanghai) Co., Ltd. and Karuna Therapeutics, Inc. dated November 8, 2021 (incorporated by reference to Exhibit 10.24 to our Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2022)</u>
10.22 [^]	<u>License Agreement by and between Zai Lab (US) LLC and MediLink Therapeutics (Suzhou) Co., Ltd. dated April 24, 2023</u>
10.23 [#]	<u>Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (File No. 333-219980) filed on August 15, 2017)</u>
10.24 [#]	<u>Employment Agreement between Samantha (Ying) Du and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.18 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed on September 1, 2017)</u>
10.25 [#]	<u>Letter Agreement between Samantha (Ying) Du and Zai Lab (US) LLC dated December 11, 2017 (incorporated by reference to Exhibit 4.16 to our Annual Report on Form 20-F (File No. 001-38205) filed on April 30, 2018)</u>

Exhibit Number	Exhibit Title
10.26#	<u>Fourth Amended and Restated Founder Employment Agreement between Samantha (Ying) Du and Zai Lab Limited dated December 1, 2018 (incorporated by reference to Exhibit 10.18 to our Annual Report on Form 20-F (File No. 001-38205) filed on March 29, 2019)</u>
10.27#	<u>Letter Agreement between Yajing Chen and Zai Lab (US) LLC dated July 6, 2023 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-38205) filed on November 7, 2023)</u>
10.28#	<u>Employment Agreement between Rafael Amado and Zai Lab (US) LLC dated December 30, 2022 (incorporated by reference to Exhibit 10.41 to our Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2023)</u>
10.29#	<u>Employment Agreement between F. Ty Edmondson and Zai Lab (US) LLC dated August 15, 2020 (incorporated by reference to Exhibit 10.29 to our Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2021)</u>
10.30#	<u>Employment Agreement between Joshua Smiley and Zai Lab (US) LLC dated August 1, 2022 (incorporated by reference to Exhibit 10.39 to our Annual Report on Form 10-K (File No. 001-38205) filed on March 1, 2023)</u>
10.31	<u>Facility Letter by and between Zai Lab Limited and Bank of China (Hong Kong) Limited dated February 5, 2024 (incorporated by reference to Exhibit 10.33 to our Annual Report on Form 10-K (File No. 001-38205) filed on February 27, 2024)</u>
10.32	<u>Unofficial English Translation of Working Capital Loan Agreement by and between Zai Lab (Shanghai) Co., Ltd. and Bank of China Pudong Development Zone Sub-Branch dated February 7, 2024 (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (File No. 0001-38205) filed on February 8, 2024)</u>
10.33^	<u>Unofficial English Translation of Maximum-Amount Guarantee Contract by and between Zai Lab Limited and Shanghai Pudong Development Bank Co., Ltd. Zhangjiang Hi-Tech Park Sub-Branch dated February 6, 2024 (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K (File No. 001-38205) filed on February 8, 2024)</u>
10.34	<u>Unofficial English Translation of Maximum Credit Contract by and between Zai Lab (Suzhou) Co., Ltd. and Bank of Ningbo Co., Ltd. Suzhou Branch dated February 6, 2024 (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K (File No. 001-38205) filed on February 8, 2024)</u>
10.35^	<u>Unofficial English Translation of Electronic Commercial Draft Discounting Master Agreement Standard Terms by and between Zai Lab (Suzhou) Co., Ltd. and Bank of Ningbo Co., Ltd. Suzhou Branch dated February 6, 2024 (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K (File No. 001-38205) filed on February 8, 2024)</u>
10.36^	<u>Unofficial English Translation of Online Working Capital Loan Master Agreement by and between Zai Lab (Suzhou) Co., Ltd. and Bank of Ningbo Co., Ltd. Suzhou Branch dated February 6, 2024 (incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K (File No. 001-38205) filed on February 8, 2024)</u>
10.37^	<u>Unofficial English Translation of Maximum-Amount Irrevocable Letter of Guarantee issued by Zai Lab Limited to China Merchants Bank Co., Ltd., Shanghai Branch dated July 5, 2024 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed on July 9, 2024)</u>
10.38^	<u>Unofficial English Translation of Credit Agreement by and between Zai Lab (Shanghai) Co., Ltd. and China Merchants Bank Co., Ltd., Shanghai Branch dated July 5, 2024 (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (File No. 001-38205) filed on July 9, 2024)</u>
10.39^	<u>Unofficial English Translation of Guarantee Contract by and between Zai Lab Limited and Bank of Communications Co., Ltd. Shanghai Zhangjiang Sub-Branch dated January 2, 2025 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-38205) filed on January 3, 2025)</u>

Exhibit Number	Exhibit Title
10.40[^]	<u>Unofficial English Translation of Working Capital Loan Contract by and between Zai Lab (Shanghai) Co., Ltd. and Bank of Communications Co., Ltd. Shanghai Zhangjiang Sub-Branch dated January 2, 2025 (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (File No. 001-38205) filed on January 3, 2025)</u>
19.1	<u>Insider Trading Policy</u>
21.1	<u>Subsidiaries of the Registrant</u>
23.1	<u>Consent of KPMG LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited</u>
31.1	<u>Certification of Chief Executive Officer Required by Rule 13a-14(a)</u>
31.2	<u>Certification of Chief Financial Officer Required by Rule 13a-14(a)</u>
32.1	<u>Certification of Chief Executive Officer Required by 18 U.S.C. Section 1350</u>
32.2	<u>Certification of Chief Financial Officer Required by 18 U.S.C. Section 1350</u>
97.1	<u>Dodd-Frank Policy on Recoupment of Incentive Compensation (incorporated by reference to Exhibit 97.1 to our Annual Report on Form 10-K (File No. 001-38205) filed on February 27, 2024)</u>
101.INS	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
#	Management contract or compensatory plan, contract, or arrangement
+	Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.
[^]	Portions of this exhibit have been redacted pursuant to Regulation S-K Item 601(b)(10)(iv).

Item 16. Form 10-K Summary

Not applicable.

GLOSSARY

This Glossary includes acronyms and defined terms that are used throughout this report.

ABC: *Acinetobacter baumannii-calcoaceticus* complex

ABSSSI: Acute bacterial skin and skin structure infections

AChR: Anti-acetylcholine receptor

AD: Atopic dermatitis

ADC: Antibody-drug conjugate

ADP: Psychosis associated with Alzheimer's Disease

ADS: American Depositary Share, each representing ten of the Company's ordinary shares

Amgen: Amgen Inc.

Archives Rules: Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies

argenx: argenx BV

ASC: Accounting Standard Codification

Asia Pacific: Refers to Greater China, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand, and Japan, collectively

Audit Committee: The Audit Committee of the Board of Directors

AUGTYRO (Repotrectinib): A next-generation TKI of ROS proto-oncogene 1 (ROS1) tyrosine-protein kinase and of the tropomyosin receptor tyrosine kinases (TRKs) TRKA, TRKB, and TRKC

Bemarituzumab: A humanized anti-FGFR2b IgG1 monoclonal antibody

Bemarituzumab FPA144-004 Study: A global Phase III registrational trial of bemarituzumab (FPA144) in combination with FOLFOX in front-line gastric and gastroesophageal cancer

BLA: Biologics License Application

BMS: Bristol-Myers Squibb Company

Board of Directors (or Board): The Board of Directors of Zai Lab Limited

BOC HK: Bank of China (Hong Kong) Limited

BOCOM: Bank of Communications Co., Ltd. Shanghai Zhangjiang Sub-Branch

BOC Pudong Branch: Bank of China Pudong Development Zone Sub-Branch

BTB: Breakthrough Therapy Designation

CABP: Community-acquired bacterial pneumonia

CAC: Cyberspace Administration of China

CC: Cervical cancer

CCR8: Human chemokine (C-C motif) receptor 8

cGMPs: Current Good Manufacturing Practices

CI: Confidence interval

CIDP: Chronic inflammatory demyelinating polyneuropathy

CFIUS: U.S. Committee on Foreign Investment

CMB: China Merchants Bank Co., Ltd. Shanghai Branch

CMO: Contract Manufacturing Organization

Code: The Company's Code of Business Conduct and Ethics

Commercial Committee: The Commercial Committee of the Board of Directors

Company: Zai Lab Limited and its subsidiaries, collectively

Compensation Committee: The Compensation Committee of the Board of Directors

CPP: Chronic plaque psoriasis

CRAB: Carbapenem-resistant *Acinetobacter* strains

CRO: Contract Research Organization

CSRC: China Securities Regulatory Commission

CTA: Clinical trial application

Current Articles: The Sixth Amended and Restated Memorandum and Articles of Association of Zai Lab Limited

D&O: Director and officer

Deciphera: Deciphera Pharmaceuticals, LLC, a subsidiary of Deciphera Pharmaceuticals, Inc.

DLL3: An inhibitor of the Notch ligand that is overexpressed in SCLC and other neuroendocrine neoplasms

Efgartigimod (efgartigimod alfa fcab or efgartigimod alfa injection): A human IgG1 antibody fragment that binds to FcRn

Efgartigimod SC: The subcutaneous formulation of efgartigimod

EIT: Enterprise income tax

EIT Law: The Enterprise Income Tax Law of the People's Republic of China

EMA: European Medicines Agency

Entasis: Entasis Therapeutics Holdings Inc.

EU: European Union

Exchange Act: U.S. Securities Exchange Act of 1934, as amended

FASB: Financial Accounting Standards Board

FCPA: U.S. Foreign Corrupt Practices Act, as amended

FcRn: The neonatal fragment crystallizable receptor

FDA: U.S. Food and Drug Administration

FGFR2b: Human fibroblast growth factor receptor 2 isoform IIb

Five Prime: Five Prime Therapeutics, Inc.

GBM: Glioblastoma multiforme, an aggressive form of brain tumor

GC: Gastric cancer

GCPs: Good Clinical Practices

GEJ: Gastroesophageal junction

GIST: Gastrointestinal stromal tumors

gMG: Generalized myasthenia gravis

GMPs: Good Manufacturing Practices

Greater China: Mainland China, Hong Kong, Macau, and Taiwan, collectively

GSK: GlaxoSmithKline plc

HABP: Hospital-acquired bacterial pneumonia

Hanhui: Hanhui Pharmaceutical Co., Ltd.

HFCAA: U.S. Holding Foreign Companies Accountable Act, as amended

HGRAC: Human Genetic Resources Administration Office of China

HK Listing Rules: The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended

HKMA: Hong Kong Monetary Authority

HNTE: High and new technology enterprises

Hong Kong (or HK): Hong Kong Special Administrative Region

Hong Kong Stock Exchange (or HKEx): The Stock Exchange of Hong Kong Limited

Huizheng: Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

ICI: Immune checkpoint inhibitor

IL: Interleukin

IMCCTs: International multi-center clinical trials

IND: Investigational New Drug

Innoviva: Innoviva, Inc.

IPO: Initial public offering

IV: Intravenous

IVIg: Intravenous immunoglobulin

Karuna: Karuna Therapeutics, Inc.

KarXT: Xanomeline and trospium chloride, a combination of an oral M1/M4-preferring muscarinic acetylcholine receptor agonist and an antimuscarinic agent

KPMG LLP: KPMG LLP, an auditor located in the United States that is inspected by the PCAOB

LN: Lupus nephritis

LRRC15: Leucine-rich repeat-containing protein 15, a type 1 transmembrane protein involved in cell-cell and cell-extracellular matrix interactions that is overexpressed in various mesenchymal tumors where it promotes tumor metastases

MAA: Marketing Authorization Application

Macau: Macau Special Administrative Region

MacroGenics: MacroGenics, Inc.

MediLink: MediLink Therapeutics (Suzhou) Co., Ltd.

MG: Myasthenia gravis

MMAE: Microtubule-disrupting agent monomethyl auristatin E

MOFCOM: China's Ministry of Commerce

mOS: Median overall survival

mPFS: Median progression-free survival

Nasdaq: Nasdaq Global Market

NDA: New Drug Application

NHSA: China's National Healthcare Security Administration

Ningbo Bank: Bank of Ningbo Co., Ltd. Suzhou Sub-Branch

Ningbo Bank Agreements: Maximum Credit Contract, Electronic Commercial Draft Discounting Master Agreement and Online Working Capital Loan Master Agreement between Zai Lab Suzhou and Ningbo Bank, collectively

NIST: National Institute of Standards and Technology

NMPA: China's National Medical Products Administration

Nominating and Corporate Governance Committee: The Nominating and Corporate Governance Committee of the Board of Directors

NovoCure: NovoCure Ltd.

Novo Holdings: Novo Holdings A/S

NRDL: China's National Reimbursement Drug List

NSCLC: Non-small cell lung cancer

NTRK: Neurotrophic tropomyosin-receptor kinase

NUZYRA (Omadacycline): A novel tetracycline-class antibacterial with both oral and IV formulations that is a broad-spectrum antibiotic

OPTUNE: Tumor Treating Fields (or TTFields) devices marketed under various brand names, including OPTUNE GIO® for GBM

ORR: Overall response rate

OS: Overall survival

Our commercial products / programs: ZEJULA, VYVGART / VYVGART Hytrulo, NUZYRA, OPTUNE, QINLOCK, XACDURO, and AUGTYRO, collectively

Our securities: Our ADSs and/or ordinary shares, individually or collectively

Ovarian cancer: Epithelial ovarian, fallopian tube, and primary peritoneal cancer, collectively

Paratek: Paratek Bermuda Ltd., a subsidiary of Paratek Pharmaceuticals, Inc.

PANSS: Positive and Negative Syndrome Scale

PARP / PARP Inhibitor: PARP (poly (ADP-ribose) polymerase) is a protein that helps repair DNA damage in cells; PARP inhibitors block PARP from repairing DNA damage, such as may be caused by radiation and/or certain chemotherapies, which may lead to cancer cell death and slow the return or progression of cancer

PBOC: People's Bank of China

PCAOB: U.S. Public Company Accounting Oversight Board

PDGFR α : Platelet-derived growth factor receptor alpha

PDUFA: U.S. Prescription Drug User Fee Act

PFIC: Passive foreign investment company

Pfizer: Pfizer Inc.

PMA: Premarket Approval

POC: Proof of Concept

QINLOCK (Ripretinib): An orally administered switch-control TKI that broadly inhibits KIT and PDGFR α tyrosine kinases, including wild-type and forms with multiple primary mutations or secondary mutations

R&D Committee: The Research and Development Committee of the Board of Directors

RMB: Chinese Renminbi

r/m: Recurrent or metastatic

SAFE: State Administration of Foreign Exchange of China

SAMR: China's State Administration for Market Regulation

sBLA: Supplemental Biologics License Application

SC: Subcutaneous

SCLC: Small cell lung cancer

Seagen: Seagen Inc.

SEC: U.S. Securities and Exchange Commission

Securities Act: U.S. Securities Act of 1933, as amended

Security Assessment Measures: The Measures on Security Assessment of Cross-Border Data Transfer

sNDA: Supplemental new drug application

sn-gMG: Seronegative gMG

SOC: Standard of care

SPD Bank: Shanghai Pudong Development Bank Co., Ltd. Zhangjiang Hi-Tech Park Sub-Branch

TEAE: Treatment emergent adverse events

TED: Thyroid eye disease

Tesaro: Tesaro, Inc.

TIVDAK (Tisotumab Vedotin): An ADC composed of Genmab's human monoclonal antibody directed against cell surface tissue factor and Seagen's ADC technology that utilizes a protease-cleavable linker that covalently attaches MMAE to the antibody

TKI: Tyrosine kinase inhibitor

TMZ: Temozolomide, a chemotherapy drug

TREA: Treatment-related adverse event

Trial Measures: Trial Measures for the Administration of Overseas Issuance and Listing of Securities by Domestic Enterprises

Trust for Life: Our sustainability strategy, which includes three pillars: improve human health, create better outcomes, and act right now with ethical business practices and strong governance

Turning Point: Turning Point Therapeutics, Inc.

U.S.: United States

U.S. GAAP: Generally Accepted Accounting Principles in the United States

VABP: Ventilator-associated bacterial pneumonia

Vertex: Vertex Pharmaceuticals Inc.

VIEs: Variable interest entities

VYVGART: The brand name for the IV formulation of efgartigimod

VYVGART Hytrulo: The brand name for the SC formulation of efgartigimod

XACDURO (SUL-DUR): A combination of a beta-lactam antibiotic (sulbactam) and beta-lactamase inhibitor (durlobactam)

Zai Lab: Zai Lab Limited, holding company, and its subsidiaries on a consolidated basis

Zai Lab Limited: Zai Lab Limited, a holding company

Zai Lab Shanghai: Zai Lab (Shanghai) Co., Ltd., a wholly-owned subsidiary of the Company

Zai Lab Suzhou: Zai Lab (Suzhou) Co., Ltd., a wholly-owned subsidiary of the Company

ZEJULA (Niraparib): An orally administered PARP 1/2 inhibitor

ZL-1102: An early clinical stage human VH antibody fragment that binds to IL-17

ZL-1218: An early clinical stage humanized anti-CCR8 IgG1 monoclonal antibody

ZL-1310: An early-stage next generation DLL3 ADC

ZL-1503: A pre-clinical IL-13 / IL-31 bi-specific antibody

1L: First line

2L: Second line

4L: Fourth Line

2015 Plan: Zai Lab Limited 2015 Omnibus Equity Incentive Plan, as amended

2017 Plan: Zai Lab Limited 2017 Equity Incentive Plan

2022 Plan: Zai Lab Limited 2022 Equity Incentive Plan

2024 Annual Report: Annual Report on Form 10-K for the year ended December 31, 2024

2024 Plan: Zai Lab Limited 2024 Equity Incentive Plan

2025 Proxy Statement: Our definitive proxy statement pursuant to Regulation 14A to be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2024

\$: U.S. Dollar

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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

Date: February 27, 2025

By: /s/ Samantha (Ying) Du

Name: Samantha (Ying) Du

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated below:

Signature	Title	Date
<u>/s/ Samantha (Ying) Du</u> Samantha (Ying) Du	Chief Executive Officer and Chairperson of the Board of Directors <i>(Principal Executive Officer)</i>	February 27, 2025
<u>/s/ Yajing Chen</u> Yajing Chen	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 27, 2025
<u>/s/ John Diekman</u> John Diekman	Director	February 27, 2025
<u>/s/ Richard Gaynor</u> Richard Gaynor	Director	February 27, 2025
<u>/s/ Nisa Leung</u> Nisa Leung	Director	February 27, 2025
<u>/s/ William Lis</u> William Lis	Director	February 27, 2025
<u>/s/ Leon O. Moulder, Jr.</u> Leon O. Moulder, Jr.	Director	February 27, 2025
<u>/s/ Scott Morrison</u> Scott Morrison	Director	February 27, 2025
<u>/s/ Michel Vounatsos</u> Michel Vounatsos	Director	February 27, 2025
<u>/s/ Peter Wirth</u> Peter Wirth	Director	February 27, 2025

Zai Lab Limited

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Zai Lab Limited

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Zai Lab Limited and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes and financial statement Schedule I - Condensed Financial Information of Registrant (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2025 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of accrued preclinical and clinical trial expenses

As discussed in Note 2 to the consolidated financial statements, the Company's research and development expenses include costs associated with payments to contract research organizations (CROs) and contract manufacturing organizations (CMOs) for various preclinical and clinical trial activities. Expenses related to preclinical and clinical trial activities are accrued based on the Company's estimates of the actual services performed by the CROs and CMOs. As disclosed in the consolidated financial statements, as of December 31, 2024, the Company recorded \$100.9 million in accounts payable which included the accrued preclinical and clinical trial expenses.

We identified the evaluation of accrued preclinical and clinical trial expenses as a critical audit matter. Specifically, evaluating the estimate of services performed for certain research and development activities at year-end required subjective auditor judgment.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to accrued preclinical and clinical trial expenses. This included controls related to the estimation of the services performed by the CROs and CMOs during the period that are included in accounts payable balances at the end of each reporting period. On a sample basis, we examined contracts, purchase orders, invoices, and third-party confirmations and compared them to the Company's estimation of services performed by the CROs and CMOs. We also examined certain invoices received and/or payments made after year-end and evaluated whether they were associated with services received prior to that date and whether they were included in the Company's estimate of costs incurred at year-end.

/s/ KPMG LLP

We have served as the Company's auditor since 2022.

Short Hills, New Jersey

February 27, 2025

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Zai Lab Limited

Opinion on Internal Control Over Financial Reporting

We have audited Zai Lab Limited and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes and financial statement Schedule I - Condensed Financial Information of Registrant (collectively, the consolidated financial statements), and our report dated February 27, 2025 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

Short Hills, New Jersey

February 27, 2025

Zai Lab Limited
Consolidated Balance Sheets

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

		December 31,	
	Notes	2024	2023
Assets			
Current assets			
Cash and cash equivalents	3	449,667	790,151
Restricted cash, current		100,000	—
Short-term investments	4	330,000	16,300
Accounts receivable (net of allowance for credit losses of \$25 and \$17 as of December 31, 2024 and 2023, respectively)		85,178	59,199
Notes receivable		4,233	6,134
Inventories, net	5	39,875	44,827
Prepayments and other current assets		41,527	22,995
Total current assets		1,050,480	939,606
Restricted cash, non-current		1,114	1,113
Long-term investments	6	3,115	9,220
Prepayments for equipment		18	111
Property and equipment, net	7	47,961	53,734
Operating lease right-of-use assets	8	21,496	14,844
Land use rights, net		2,907	3,069
Intangible assets, net	9	56,027	13,389
Long-term deposits		1,284	1,209
Value added tax recoverable		1,351	—
Total assets		1,185,753	1,036,295
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable		100,906	112,991
Current operating lease liabilities	8	8,048	7,104
Short-term debt	12	131,711	—
Other current liabilities	13	58,720	82,972
Total current liabilities		299,385	203,067
Deferred income		31,433	28,738
Non-current operating lease liabilities	8	13,712	8,047
Other non-current liabilities		325	325
Total liabilities		344,855	240,177
Commitments and contingencies (Note 20)			
Shareholders' equity			
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized, 1,082,614,740 and 977,151,270 shares issued as of December 31, 2024 and 2023, respectively; 1,077,702,540 and 972,239,070 shares outstanding as of December 31, 2024 and 2023)		7	6
Additional paid-in capital		3,264,295	2,975,302
Accumulated deficit		(2,453,083)	(2,195,980)
Accumulated other comprehensive income		50,515	37,626
Treasury stock (at cost, 4,912,200 shares as of both December 31, 2024 and 2023)		(20,836)	(20,836)
Total shareholders' equity		840,898	796,118
Total liabilities and shareholders' equity		1,185,753	1,036,295

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

Zai Lab Limited
Consolidated Statements of Operations
(in thousands of \$, except for number of shares and per share data)

		Year Ended December 31,		
	Notes	2024	2023	2022
Revenues				
Product revenue, net	10	397,614	266,719	212,672
Collaboration revenue		1,374	—	2,368
Total revenues		398,988	266,719	215,040
Expenses				
Cost of product revenue		(147,118)	(95,816)	(74,018)
Cost of collaboration revenue		(742)	—	—
Research and development		(234,504)	(265,868)	(286,408)
Selling, general and administrative		(298,741)	(281,608)	(258,971)
Gain on sale of intellectual property		—	10,000	—
Loss from operations		(282,117)	(366,573)	(404,357)
Interest income		37,105	39,797	14,582
Interest expenses		(2,254)	—	—
Foreign currency losses		(15,137)	(14,850)	(56,403)
Other income, net	17	5,300	7,006	3,113
Loss before income tax and share of loss from equity method investment		(257,103)	(334,620)	(443,065)
Income tax expense	11	—	—	—
Share of loss from equity method investment		—	—	(221)
Net loss		(257,103)	(334,620)	(443,286)
Loss per share — basic and diluted	14	(0.26)	(0.35)	(0.46)
Weighted-average shares used in calculating net loss per ordinary share — basic and diluted		989,477,730	966,394,130	958,067,140

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

Zai Lab Limited**Consolidated Statements of Comprehensive Loss****(in thousands of \$)**

	Year Ended December 31,		
	2024	2023	2022
Net loss	(257,103)	(334,620)	(443,286)
Other comprehensive income, net of tax of nil:			
Foreign currency translation adjustments	12,889	11,941	49,330
Comprehensive loss	<u>(244,214)</u>	<u>(322,679)</u>	<u>(393,956)</u>

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

Zai Lab Limited
Consolidated Statements of Shareholders' Equity
(in thousands of \$, except for number of shares)

	Ordinary shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total
	Number of Shares	Amount				Number of Shares	Amount	
Balance at January 1, 2022	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956
Issuance of ordinary shares upon vesting of restricted shares	1,940,680	0	0	—	—	—	—	—
Exercise of share options	5,151,190	0	5,870	—	—	—	—	5,870
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(1,853,350)	(7,577)	(7,577)
Share-based compensation	—	—	61,302	—	—	—	—	61,302
Net loss	—	—	—	(443,286)	—	—	—	(443,286)
Foreign currency translation	—	—	—	—	49,330	—	—	49,330
Balance at December 31, 2022	962,455,850	6	2,893,120	(1,861,360)	25,685	(2,236,280)	(11,856)	1,045,595
Issuance of ordinary shares upon vesting of restricted shares	8,178,500	0	0	—	—	—	—	—
Exercise of share options	6,516,920	0	2,548	—	—	—	—	2,548
Receipt of shares netted to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(2,675,920)	(8,980)	(8,980)
Share-based compensation	—	—	79,634	—	—	—	—	79,634
Net loss	—	—	—	(334,620)	—	—	—	(334,620)
Foreign currency translation	—	—	—	—	11,941	—	—	11,941
Balance at December 31, 2023	977,151,270	6	2,975,302	(2,195,980)	37,626	(4,912,200)	(20,836)	796,118
Issuance of ordinary shares upon vesting of restricted shares	10,120,260	0	0	—	—	—	—	—
Exercise of share options	5,147,140	0	3,269	—	—	—	—	3,269
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of \$2,277	90,196,070	1	215,073	—	—	—	—	215,074
Share-based compensation	—	—	70,651	—	—	—	—	70,651
Net loss	—	—	—	(257,103)	—	—	—	(257,103)
Foreign currency translation	—	—	—	—	12,889	—	—	12,889
Balance at December 31, 2024	1,082,614,740	7	3,264,295	(2,453,083)	50,515	(4,912,200)	(20,836)	840,898

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

Zai Lab Limited
Consolidated Statements of Cash Flows
(in thousands of \$)

	Year Ended December 31,		
	2024	2023	2022
Cash flows from operating activities			
Net loss	(257,103)	(334,620)	(443,286)
Adjustments to reconcile net loss to net cash used in operating activities:			
Allowance for credit losses	8	6	1
Inventory write-down	815	973	477
Depreciation and amortization expenses	11,856	9,029	8,227
Impairment of property and equipment	—	57	—
Amortization of deferred income	(3,520)	(3,383)	(2,602)
Share-based compensation	70,651	79,634	61,302
Share of loss from equity method investment	—	—	221
Loss (gain) from fair value changes of equity investment with readily determinable fair value	6,105	(2,789)	8,952
Losses on disposal of property and equipment	453	159	560
Gain on disposal of land use right	—	(408)	—
Noncash lease expenses	8,419	8,708	8,350
Gain from sale of intellectual property	—	(10,000)	—
Foreign currency remeasurement impact	15,137	14,850	56,403
Amortization of debt issuance cost	700	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(26,975)	(20,040)	4,330
Notes receivable	1,762	2,352	(1,976)
Inventories	3,896	(14,907)	(15,382)
Prepayments and other current assets	(18,729)	12,246	(19,258)
Long-term deposits	(75)	187	(527)
Value added tax recoverable	(1,367)	—	22,781
Accounts payable	(2,209)	36,803	(53,773)
Other current liabilities	(22,022)	19,810	7,392
Operating lease liabilities	(9,259)	(8,351)	(8,455)
Deferred income	6,588	11,181	(1,379)
Other non-current liabilities	—	325	—
Net cash used in operating activities	(214,869)	(198,178)	(367,642)
Cash flows from investing activities			
Purchases of short-term investments	(330,000)	(134,000)	(260,274)
Proceeds from maturity of short-term investment	16,300	117,700	705,274
Purchases of property and equipment	(5,657)	(7,212)	(24,585)
Proceeds from the sale of property and equipment	29	122	—
Acquisition of intangible assets	(55,865)	(1,279)	(399)
Proceeds from sale of intellectual property	—	10,000	—
Proceeds from disposal of land use right	—	3,893	—
Net cash (used in) provided by investing activities	(375,193)	(10,776)	420,016
Cash flows from financing activities			
Proceeds from short-term debt	131,606	—	—
Repayment of short-term bank borrowings	(284)	—	—
Payment of debt issuance cost	(700)	—	—
Proceeds from exercises of stock options	3,200	2,369	5,870
Proceeds from issuance of ordinary shares upon public offerings	217,350	—	—
Payments of public offering costs	(1,283)	—	—
Taxes paid related to settlement of equity awards	—	(8,802)	(7,600)
Net cash provided by (used in) financing activities	349,889	(6,433)	(1,730)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(310)	(2,622)	(6,274)
Net (decrease) increase in cash, cash equivalents and restricted cash	(240,483)	(218,009)	44,370
Cash, cash equivalents and restricted cash — beginning of the year	791,264	1,009,273	964,903
Cash, cash equivalents and restricted cash — end of the year	550,781	791,264	1,009,273

	Year Ended December 31,		
	2024	2023	2022
Supplemental disclosure of cash flow information			
Cash paid for interest	2,021	—	—
Supplemental disclosure on non-cash investing and financing activities			
Payables for purchase of property and equipment	449	2,474	5,269
Payables for acquisition of intangible assets	2,721	11,516	163
Payables for public offering costs	994	—	—
Right-of-use asset acquired under operating leases	15,150	3,668	14,801
Receivables for stock option exercise under equity incentive plans	70	—	—

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

Zai Lab Limited

Notes to the Consolidated Financial Statements

For the Years Ended December 31, 2024, 2023, and 2022

1. Organization and Principal Activities

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

The Company’s principal operations and geographic markets are in Greater China. The Company has a substantial presence in Greater China and the United States.

As of December 31, 2024, the Company’s significant operating subsidiaries were as follows:

Name of Company	Place of Incorporation	Date of Incorporation	Percentage of Ownership	Principal Activities
Zai Lab (Hong Kong) Limited	Hong Kong	April 29, 2013	100%	Operating company for business development and R&D activities and commercialization of innovative medicines and device
Zai Lab (Shanghai) Co., Ltd.	Mainland China	January 6, 2014	100%	Development and commercialization of innovative medicines and devices
Zai Lab (AUST) Pty. Ltd.	Australia	December 10, 2014	100%	Clinical trial activities
Zai Lab (Suzhou) Co., Ltd.	Mainland China	November 30, 2015	100%	Development and commercialization of innovative medicines
Zai Biopharmaceutical (Suzhou) Co., Ltd.	Mainland China	June 15, 2017	100%	Development and commercialization of innovative medicines
Zai Lab (US) LLC	United States	April 21, 2017	100%	Operating company for business development, R&D activities and certain business activities, including legal, compliance and communication functions of the Company
Zai Lab International Trading (Shanghai) Co., Ltd.	Mainland China	November 6, 2019	100%	Commercialization of innovative medicines and devices
Zai Auto Immune (Hong Kong) Limited	Hong Kong	November 4, 2020	100%	Operating company for business development and R&D activities
Zai Lab (Taiwan) Limited	Taiwan	December 10, 2020	100%	Commercialization of innovative medicines and devices
Zai Lab Trading (Suzhou) Co., Ltd.	Mainland China	October 27, 2020	100%	Commercialization of innovative medicines

2. Summary of Significant Accounting Policies

(a) Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). Significant accounting policies followed by the Company in the preparation of the accompanying consolidated financial statements are summarized below.

(b) Principles of Consolidation

The consolidated financial statements include the accounts of Zai Lab Limited and its subsidiaries, which are wholly owned. All intercompany transactions and balances are eliminated upon consolidation.

(c) Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, accrual of rebates, recognition of research and development expenses based on the Company’s estimates of the actual services performed by the CROs and CMOs, fair value of share-based compensation expenses, recoverability of deferred tax assets, and useful life of intangible assets for commercial products. These estimates, judgments, and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Actual results could differ from these estimates.

(d) Foreign Currency Translation

The functional currency of Zai Lab Limited, Zai Lab (Hong Kong) Limited, Zai Lab (US) LLC, and Zai Auto Immune (Hong Kong) Limited are the U.S. dollar (“\$”). The Company’s subsidiaries in mainland China determined their functional currency to be the Chinese Renminbi (“RMB”). The Company’s subsidiary in Australia determined its functional currency to be the Australian dollar (“A\$”). The Company’s subsidiary in Taiwan determined its functional currency to be the Taiwan dollar (“TWD”). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification (“ASC”) 830, *Foreign Currency Matters*. The Company uses the U.S. dollar as its reporting currency.

Assets and liabilities are translated from each entity’s functional currency to the reporting currency at the exchange rate on the balance sheet date. Equity amounts are translated at historical exchange rates. Revenues, expenses, gains, and losses are translated using the average rate for the period presented. The resulted foreign currency translation adjustments are recorded as a component of other comprehensive loss in the consolidated statements of comprehensive loss, and the accumulated foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) in the consolidated statements of shareholders’ equity.

Monetary assets and liabilities denominated in currencies other than the applicable functional currencies are translated into the functional currencies at the prevailing rates of exchange at the balance sheet date.

Non-monetary assets and liabilities are translated into the applicable functional currencies at historical exchange rates. Transactions in currencies other than the applicable functional currencies during the year are converted into the functional currencies at the applicable rates of exchange prevailing at the transaction dates. Transaction gains and losses are recognized in the consolidated statements of operations.

(e) Cash, Cash Equivalents, and Restricted Cash

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand, demand deposits, and highly liquid investments with maturity of less than three months and are stated at cost, which approximates fair value.

Restricted Cash

Restricted cash mainly consists of bank deposits held as collateral for issuances of letters of credit for the Company's loan facility (see *Note 12*).

(f) Short-Term Investments

Short-term investments are time deposits with original maturities between three months and one year. Short-term investments are stated at cost, which approximates fair value. Interest earned is included in interest income.

(g) Accounts Receivable

The Company's accounts receivable arise from product sales and represent amounts due from its customers. From January 1, 2020, the Company adopted the ASU 2016-13, *Credit Losses, Measurement of Credit Losses on Financial Instruments*. Accounts receivable are recorded at the amounts net of allowances for credit losses. The allowance for credit losses reflects the Company's current estimate of credit losses expected to be incurred over the life of the receivables. The Company considers various factors in establishing, monitoring, and adjusting its allowance for credit losses including the aging of receivables and aging trends, customer creditworthiness, and specific exposures related to particular customers. The Company also monitors other risk factors and forward-looking information, such as country-specific risks and economic factors that may affect a debtor's ability to pay in establishing and adjusting its allowance for credit losses. Accounts receivable are written off when deemed uncollectible.

(h) Notes Receivable

Notes receivable are equal to contractual amounts owed from signed, secured promissory notes issued from customers to the Company. The Company considers the notes receivable to be fully collectible. Accordingly, no allowance for credit loss has been established as of December 31, 2024 and 2023.

(i) Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a weighted average basis. The Company periodically reviews the composition of inventory and shelf life of inventory to identify obsolete, slow-moving, or otherwise non-saleable items. The Company will record a write-down to its net realizable value in cost of product revenue in the period that the decline in value is first identified.

(j) Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful life
Office equipment	3 years
Electronic equipment	1.25-3 years
Vehicles	4 years
Laboratory equipment	5 years
Manufacturing equipment	10 years
Leasehold improvements	lesser of useful life or lease term

Construction in progress represents property and equipment under construction and pending installation and is stated at cost less impairment losses, if any.

(k) Leases

The Company leases facilities for its offices, research and development center, and manufacturing facilities in mainland China, Hong Kong, Taiwan and the United States. On January 1, 2019, the Company adopted the ASC 842, *Leases* (“**ASC 842**”), using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating historical periods before the adoption date.

The Company assessed whether an arrangement contains a lease at inception. The Company’s leases are all classified as operating leases with fixed lease payments, or minimum payments, as contractually stated in the lease agreements. The Company’s leases do not contain any material residual value guarantees or material restrictive covenants.

Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheets. Operating lease liabilities that become due within one year of the balance sheet date are classified as current operating lease liabilities. Operating lease expense is recognized on a straight-line basis over the lease term.

At the commencement date of a lease, the Company recognizes a lease liability for future fixed lease payments and a right-of-use (“ROU”) asset representing the right to use the underlying asset during the lease term. The lease liability is initially measured as the present value of the future fixed lease payments that will be made over the lease term. The lease term includes periods for which the Company is reasonably certain that the renewal options will be exercised and the termination options will not be exercised. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company’s leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. The Company considered information available at the adoption date of ASC 842 to determine the incremental borrowing rate for leases in existence as of this date.

The ROU asset is measured at the amount of the lease liability with adjustments, if applicable, for lease prepayments made prior to or at lease commencement, initial direct costs incurred by the Company, and lease incentives. Under ASC 842, land use rights agreements are also considered to be operating lease contracts.

The Company elected to apply each of the practical expedients described in ASC 842 which allow companies (i) not to reassess prior conclusions on whether any expired or existing contracts are or contain a lease, lease classification, and initial direct costs upon adoption of ASC 842, (ii) combine lease and non-lease components for all underlying assets

groups, and (iii) not recognize ROU assets or lease liabilities for short term leases. A short-term lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

(l) Land Use Rights

All land in mainland China is subject to government or collective ownership. Land use rights can be purchased for a specified period of time. The purchase price of land use rights represents the operating lease prepayments under ASC 842 and is recorded as land use rights on the consolidated balance sheet, which is amortized over the remaining lease term.

The Company acquired land use rights in 2019 for a term of 30 years from the local Bureau of Land and Resources in Suzhou for the purpose of constructing and operating a research center and biologics manufacturing facility in Suzhou. In 2023, the Company returned a portion of the land use rights and received cash in an amount equal to the respective portion of the original acquisition cost.

(m) Long-Term Deposits

Long-term deposits represent amounts paid in connection with the Company's long-term lease agreements.

(n) Intangible Assets

Intangible assets for commercial products include capitalized post-approval milestone fees and acquired commercial manufacturing know-how and related development costs. The Company is amortizing intangible assets for commercial products as cost of product revenue over the estimated remaining useful life of the related products, which is generally based on expected patent life, the contractual period of the underlying license agreement, and expected commercial benefits of the products. Intangible assets for externally purchased software are amortized over three to five years on a straight-line basis.

(o) Impairment of Long-Lived Assets

The Company evaluates long-lived assets, which includes intangible assets, tangible assets, and ROU assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of the related asset group to its future undiscounted cash flows. The Company measures the amount of impairment, if any, based on the difference between the carrying value and the estimated fair value of the impaired asset group.

(p) Fair Value Measurements

The Company applies ASC Topic 820, *Fair Value Measurements and Disclosures*, in measuring fair value ("**ASC 820**"). 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: (i) market approach; (ii) income approach; and (iii) 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.

Equity investments with readily determinable fair value are measured using level 1 inputs and were \$3.1 million and \$9.2 million as of December 31, 2024 and 2023, respectively. The unrealized gains and losses from fair value changes are recognized in other income, net in the consolidated statements of operations.

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

(q) Revenue Recognition

In 2018, the Company adopted ASC Topic 606, *Revenue from Contracts with Customers* (“**ASC 606**”). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration expected to be received in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs 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) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes 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.

The Company’s revenue is mainly from product sales. The Company recognizes revenue from product sales when the Company has 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 consumers. Cost of product revenue mainly consists of the acquisition cost of products, the manufacturing cost of products, royalty fees, and amortization of intangible assets for commercial products.

The Company has applied the practical expedients under ASC 606 with regard to assessment of the financing component 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.

In mainland China, the Company sells these products to distributors, who ultimately sell the products to health care providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the delivery of the products to distributors. Rebates are offered to distributors, consistent with pharmaceutical industry practices. The

estimated amount of unpaid or unbilled rebates, if any, are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates and sales volumes and to a lesser extent, distributor inventories. The Company regularly reviews the information related to these estimates and adjusts the amount accordingly.

In Hong Kong, the Company sells the products to customers, which are typically healthcare providers such as oncology centers. The Company utilizes a third party for warehousing services. Based on the nature of the arrangements, the Company has determined that it is a principal in the transaction since the Company is primarily responsible for fulfilling the promise to provide the products to the customers, maintains inventory risk until delivery to the customers, and has latitude in establishing the price. Revenue is recognized upon delivery to customers at mutually agreed upon prices. Consideration paid to the third party is recognized in operating expenses.

The Company did not recognize any contract assets or contract liabilities as of December 31, 2024 and 2023.

(r) Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (“**ASC 808**”). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

(s) Research and Development Expenses

Elements of research and development expenses primarily include (i) payroll and other related costs of personnel engaged in research and development activities; (ii) in-licensed patent rights fees for exclusive development rights for products granted to the Company; (iii) costs related to pre-clinical testing of the Company’s technologies under development and clinical trials such as payments to CROs and CMOs, investigators, and clinical trial sites that conduct its clinical studies; (iv) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility-related expenses; and (v) other research and development expenses. Research and development expenses are charged to expense as incurred when they have no alternative future uses. Liabilities related to third-party research and development expenses are primarily included in accounts payable on the consolidated balance sheet.

The Company has acquired rights to develop and commercialize certain product candidates. Upfront payments that relate to the acquisition of a new product compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new product compound does not also include processes or activities that would constitute a “business” as defined under U.S. GAAP. Milestone payments made to third parties subsequent to regulatory approval which meet the capitalization criteria would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product, which is generally based on expected patent life, the contractual period of the underlying license agreement, and expected commercial benefits of the products.

(t) Deferred Income

Deferred income is mainly related to upfront payments received from collaborative partners and government grants.

The Company received certain upfront payments from collaborative partners, which are being amortized over the terms of the contracts. The Company had \$30.7 million and \$26.7 million in deferred income related to the upfront payments as of December 31, 2024 and 2023, respectively.

Government grants consist of cash subsidies received by the Company's subsidiaries in mainland China from local governments for conducting business in certain local districts. Grant received before the fulfillment of government specified performance obligations is recorded into deferred income. When the performance obligations are satisfied, the Company records the grants into other income, net. The Company had \$0.7 million and \$2.1 million of deferred income related to government grants as of December 31, 2024 and 2023, respectively.

(u) Share-Based Compensation

The Company grants share options and non-vested restricted shares to eligible employees, non-employees, and directors and accounts for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation* ("ASC 718").

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The grant-date fair value of non-vested restricted shares is the market value of the underlying stock on the award's grant date.

The Company has elected to use the straight-line method to recognize compensation expenses for share awards with graded vesting based on service conditions, provided that the minimum amount of cumulative compensation expense recognized is not less than the portion of the award vested to date. For share-based awards with service conditions only, the Company recognizes expenses (i) immediately at grant date if no vesting conditions are required; or (ii) using a straight-line method over the requisite service period, which is the vesting period, if vesting conditions are required. For share-based awards containing performance conditions, the Company recognizes expenses based on the estimated number of performance-based awards expected to vest using the graded vesting attribution method. The Company accounts for the effect of forfeitures as they occur.

(v) Income Taxes

Income tax expense includes (i) deferred tax expense, which generally represents the net change in the deferred tax asset or liability balance during the year plus any change in valuation allowances; (ii) current tax expense, which represents the amount of tax currently payable to or receivable from a taxing authority; and (iii) non-current tax expense, which represents the increases and decreases in amounts related to uncertain tax positions from prior periods and not settled with cash or other tax attributes.

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial statement and income tax bases of assets and liabilities, which are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant

information and applying current conventions. It is the Company's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

(w) Loss Per Share

Basic loss per ordinary share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

Diluted loss per ordinary share reflects the potential dilution that could occur if securities were exercised or converted into ordinary shares. The Company had stock options and non-vested restricted shares, which could potentially dilute basic loss per share in the future. To calculate the number of shares for diluted loss per share, the effect of the stock options and non-vested restricted shares is computed using the treasury stock method. The computation of diluted loss per share does not assume exercise or conversion of securities that would have an anti-dilutive effect.

(x) Comprehensive Loss

Comprehensive loss is defined as the changes in equity of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. For each of the periods presented, the Company's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

(y) Concentration of Risks

Concentration of Customers

In 2024, 2023, and 2022, the Company's five largest customers accounted for approximately \$128.7 million (32.4%), \$104.7 million (35.0%), and \$88.2 million (37.7%) of the product revenue, respectively. One customer accounted for approximately \$67.3 million (16.9%), \$59.4 million (19.9%), and \$52.5 million (22.4%) of the product revenue, respectively for the same periods.

Concentration of Credit Risk

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

As of December 31, 2024 and 2023, all of the Company's cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which management believes are of high credit quality and continually monitors the credit worthiness of these financial institutions.

Accounts receivable are typically unsecured and are derived from product sales. The Company manages credit risk of accounts receivable through ongoing monitoring of outstanding balances and limits the amount of credit extended based upon payment history and credit worthiness. Historically, the Company has collected receivables from customers within the credit terms with no significant credit losses incurred. One customer accounted for 10% or more of accounts receivable, with \$16.7 million and \$7.8 million as of December 31, 2024 and 2023, respectively.

Certain accounts receivable balances may be settled in the form of notes receivable. As of December 31, 2024, notes receivable represented bank acceptance promissory notes that are non-interest bearing and due within six months. Notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to be known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance

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promissory notes to settle the receivables is at the Company's discretion, and this selection does not impact the agreed contractual purchase prices.

The Company's other receivables were primarily due from its partners, which have good credit ratings. The credit risk for other receivables was generally very low.

Foreign Currency Risk

RMB is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts denominated in RMB of \$19.0 million and \$25.1 million, as of December 31, 2024 and 2023, respectively, representing 4% and 3% of the cash and cash equivalents as of December 31, 2024 and 2023, respectively.

(z) Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements Not Yet Adopted

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

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU requires disclosure, in the notes to financial statements, of specified information about certain costs and expenses. This ASU will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. This ASU will result in the required additional disclosures being included in the notes to consolidated financial statements, once adopted. The Company is currently evaluating the impact of this ASU and expects to adopt it for the year ending December 31, 2027.

Recently Adopted Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures* (Topic 280). This ASU requires all public entities, including public entities with a single reportable segment, to disclose the title and position of the Chief Operating Decision Maker ("CODM") and the significant segment expenses and any additional measures of a segment's profit or loss used by the CODM to allocate resources and assess performance. This ASU is effective on a retrospective basis for fiscal years beginning after December 15, 2023 and for interim periods beginning after December 15, 2024. Early adoption is permitted. The Company adopted this ASU for the year ended December 31, 2024 and disclosed additional descriptive information as required under ASC 280 (*see Note 21*).

Zai Lab Limited**Notes to the Consolidated Financial Statements****For the Years Ended December 31, 2024, 2023, and 2022****3. Cash and Cash Equivalents**

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

	December 31,	
	2024	2023
Cash	448,508	789,051
Cash equivalents (i)	1,159	1,100
	<u>449,667</u>	<u>790,151</u>
Denominated in:		
US\$	429,887	762,436
RMB (ii)	18,979	25,093
Hong Kong dollar ("HK\$")	114	1,974
Australian dollar ("A\$")	522	587
Taiwan dollar ("TW\$")	165	61
	<u>449,667</u>	<u>790,151</u>

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

4. Short-Term Investments

Short-term investments are primarily comprised of time deposits with original maturities between three months and one year. The short-term investments balance was \$330.0 million and \$16.3 million as of December 31, 2024 and 2023, respectively. No allowance for credit loss was recorded as of December 31, 2024 and 2023.

5. Inventories, Net

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

	December 31,	
	2024	2023
Finished goods	24,063	22,702
Raw materials	13,268	17,655
Work in progress	2,544	4,470
Inventories, net	<u>39,875</u>	<u>44,827</u>

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. The Company recorded write-downs in inventory, which were included in cost of product revenue of \$0.8 million, \$1.0 million, and \$0.5 million in 2024, 2023, and 2022, respectively.

6. Long-Term Investments

In July 2021, the Company made an equity investment in 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 \$30.0 million and obtained 958,467 newly issued common shares of MacroGenics at \$31.30 per share. The Company recorded this investment at acquisition cost and subsequently measured it at fair value, with the changes in fair value recognized in other income, net in the consolidated statements of operations. The equity investments with readily determinable fair value are measured using level 1 inputs and were \$3.1 million and \$9.2 million as of December 31, 2024 and 2023, respectively. The Company recognized a loss of \$6.1 million, a gain of \$2.8 million, and a loss of \$9.0 million in 2024, 2023, and 2022, respectively.

7. Property and Equipment, Net

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

	December 31,	
	2024	2023
Office equipment	1,230	1,047
Electronic equipment	9,211	9,161
Vehicle	196	199
Laboratory equipment	20,516	20,140
Manufacturing equipment	17,493	17,680
Leasehold improvements	11,306	11,371
Construction in progress	25,129	24,272
	85,081	83,870
Less: accumulated depreciation	(37,120)	(30,136)
Property and equipment, net	47,961	53,734

Depreciation expense was \$8.6 million, \$8.4 million, and \$7.7 million for 2024, 2023, and 2022, respectively.

8. Leases

The Company leases facilities for its offices, research and development center, and manufacturing facilities in mainland China, Hong Kong, Taiwan, and the United States. Lease terms vary based on the nature of operations and market dynamics; however, all leased facilities are classified as operating leases with remaining lease terms between one and eight years.

The following table presents operating lease costs (\$ in thousands). Total lease expense related to short-term leases was insignificant for those periods presented.

	Year Ended December 31,		
	2024	2023	2022
Operating fixed lease cost	8,751	8,691	8,774

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The following table presents operating cash flows related to leases (\$ in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in measurement of lease liabilities	8,831	9,317	8,084
Non-cash operating lease liabilities arising from obtaining operating right-of-use assets	15,150	3,668	14,801

The maturities of lease liabilities in accordance with ASC 842, *Leases* in each of the next five years and thereafter were as follows (\$ in thousands):

	Year Ended December 31, 2024
2025	8,611
2026	4,994
2027	3,725
2028	2,908
2029	2,312
Thereafter	609
Total lease payments	23,159
Less: imputed interest	(1,399)
Present value of minimum operating lease payments	21,760

Weighted-average remaining lease terms and discount rates were as follows:

	December 31,	
	2024	2023
Weighted-average remaining lease term	3.7 years	2.5 years
Weighted-average discount rate	3.4 %	3.0 %

9. Intangible Assets, Net

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

	As of December 31,					
	2024			2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Finite-lived intangible assets						
Commercial products (i)	57,104	(2,637)	54,467	11,351	(186)	11,165
Software	4,360	(2,800)	1,560	4,340	(2,116)	2,224
Total	61,464	(5,437)	56,027	15,691	(2,302)	13,389

(i) The increase in the net carrying value is primarily driven by \$33.4 million of regulatory milestone fees for repotrectinib and SUL-DUR (see *Note 16*) and \$12.2 million of acquired commercial manufacturing know-how and related development costs.

Zai Lab Limited**Notes to the Consolidated Financial Statements****For the Years Ended December 31, 2024, 2023, and 2022**

Amortization expense was \$3.2 million, \$0.7 million, and \$0.5 million in 2024, 2023, and 2022, respectively. The weighted-average remaining amortization period for intangible assets for commercial products and software was 9.5 years and 3.0 years, respectively.

Expected future amortization expense for the five succeeding years and thereafter is as follows (\$ in thousands):

	Year Ended December 31
2025	5,834
2026	6,350
2027	6,859
2028	6,686
2029	4,336
Thereafter	25,962
	<u><u>56,027</u></u>

10. Revenues***Product Revenue, Net***

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

	Year Ended December 31,		
	2024	2023	2022
Product revenue - gross	423,855	298,911	234,009
Less: Rebates and sales returns	(26,241)	(32,192)	(21,337)
Product revenue - net	<u><u>397,614</u></u>	<u><u>266,719</u></u>	<u><u>212,672</u></u>

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

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

	Year Ended December 31,		
	2024	2023	2022
ZEJULA	187,082	168,843	145,194
VYVGART / VYVGART Hytrulo	93,639	10,011	—
NUZYRA	43,199	21,656	5,200
OPTUNE	40,475	46,969	47,321
QINLOCK	28,826	19,240	14,957
XACDURO	3,305	—	—
AUGTYRO	1,088	—	—
Product revenue - net	<u><u>397,614</u></u>	<u><u>266,719</u></u>	<u><u>212,672</u></u>

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11. Income Tax

Cayman Islands

Zai Lab Limited, ZLIP Holding Limited, Zai Auto Immune Limited, and Zai Anti Infectives Limited are incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, Zai Lab Limited, ZLIP Holding Limited, Zai Auto Immune Limited, and Zai Anti Infectives Limited are not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

British Virgin Islands Taxation

ZL Capital Limited is incorporated in the British Virgin Islands. Under the current laws of the British Virgin Islands, ZL Capital Limited is not subject to income tax.

Australia

Zai Lab (AUST) Pty. Ltd. is incorporated in Australia and is subject to corporate income tax at a rate of 30%. Zai Lab (AUST) Pty. Ltd. had no taxable income for the periods presented; therefore, no provision for income taxes is required.

United States

Zai Lab (US) LLC is incorporated in the United States and is subject to U.S. federal corporate income tax at a rate of 21%. Zai Lab (US) LLC is also subject to state income tax in Delaware. Zai Lab (US) LLC had no taxable income for the periods presented; therefore, no provision for income taxes is required.

Taiwan

Zai Lab (Taiwan) Limited is incorporated in Taiwan and is subject to corporate income tax at a rate of 20%. Zai Lab (Taiwan) Limited had no taxable income for the periods presented; therefore, no provision for income taxes is required.

Hong Kong

Zai Lab (Hong Kong) Limited, ZL China Holding Two Limited, Zai Auto Immune (Hong Kong) Limited, and Zai Anti Infectives (Hong Kong) Limited are incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. Under the two-tiered profits tax rates regime in Hong Kong, the first HK\$2.0 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK\$2.0 million will be taxed at 16.5%. In 2024, 2023, and 2022, Zai Lab (Hong Kong) Limited, ZL China Holding Two Limited, Zai Auto Immune (Hong Kong) Limited, and Zai Anti Infectives (Hong Kong) Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented. Under the Hong Kong tax law, Zai Lab (Hong Kong) Limited, ZL China Holding Two Limited, Zai Auto Immune (Hong Kong) Limited, and Zai Anti Infectives (Hong Kong) Limited are exempted from income tax on its foreign-derived income, and there are no withholding taxes in Hong Kong on remittance of dividends.

People's Republic of China

Under EIT Law, the statutory income tax rate is 25%, and the EIT rate will be reduced to 15% for state-encouraged High and New Technology Enterprises ("HNTE"). Zai Lab (Shanghai) Co., Ltd., first obtained an HNTE certificate in 2018 and began to enjoy the preferential tax rate of 15% from 2018 to 2020 and further extended the certificate effective

Zai Lab Limited**Notes to the Consolidated Financial Statements****For the Years Ended December 31, 2024, 2023, and 2022**

for 2021 to 2026. Zai Lab International Trading (Shanghai) Co., Ltd., Zai Lab (Suzhou) Co., Ltd., Zai Biopharmaceutical (Suzhou) Co., Ltd., and Zai Lab Trading (Suzhou) Co., Ltd. are subject to the statutory rate of 25%.

No provision for income taxes has been required to be accrued because the Company is in a cumulative loss position for the periods presented.

The following table presents loss (income) before income taxes (\$ in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cayman Islands	(2,453)	(16,792)	19,454
British Virgin Islands	—	—	2
Mainland China	146,725	253,274	290,056
Hong Kong	1,808	4,483	53,425
United States	110,422	92,869	79,620
Australia	19	14	(260)
Taiwan	582	772	989
	<u>257,103</u>	<u>334,620</u>	<u>443,286</u>

Reconciliations of the differences between the Chinese statutory income tax rate and the Company's effective income tax rate were as follows:

	Year Ended December 31,		
	2024	2023	2022
Statutory income tax rate	25%	25%	25%
Tax-exempted income	0.42%	0.19%	—%
Share-based compensation	(3.52%)	(2.08%)	(1.40%)
Research and development super deduction	5.28%	7.11%	2.51%
Non-deductible expenses	(0.77%)	(2.83%)	(2.31%)
Prior year tax filing adjustment	(3.05%)	1.32%	6.33%
Effect of different tax rate of subsidiary operation in other jurisdictions	(0.73%)	0.02%	(2.85%)
Preferential tax rate	(5.05%)	(7.12%)	(6.26%)
Expiration of tax loss	(2.72%)	—%	—%
Expiration of deductible qualified donation	(0.78%)	2.28%	—%
Changes in valuation allowance	(14.08%)	(23.89%)	(21.02%)
Effective income tax rate	<u>—%</u>	<u>—%</u>	<u>—%</u>

Zai Lab Limited
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The following table presents the principal components of deferred tax assets and liabilities (\$ in thousands):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Depreciation of property and equipment	171	131
Research and experimental capitalization	38,215	30,429
Share-based compensation	3,797	3,422
Accrued expenses	1,038	707
Government grants	98	467
Deferred revenue	3,442	4,354
Qualified donation	26,832	22,992
Lease liability	3,885	2,967
Net operating loss carry forwards	321,068	295,313
Less: valuation allowance	(394,778)	(357,956)
Total Deferred tax assets	3,768	2,826
Deferred tax liabilities:		
Right-of-use assets	(3,768)	(2,826)
Deferred tax assets, net	—	—

ASC 740, *Income Taxes*, provides for the recognition of deferred tax assets if realization of such assets is more likely than not. The Company's ability to realize deferred tax assets depends on its ability to generate sufficient taxable income within the carry forward periods provided for in the tax law. In assessing the need for any additional valuation allowance for 2024, the Company considered all available evidence both positive and negative, including potential for prudent and feasible tax planning strategies, recent losses, and forecasts of future profitability. As of December 31, 2024 and 2023, the Company determined that the deferred tax assets on temporary differences and net operating loss carry forwards related to certain subsidiaries will not be realized, and as such it has fully provided the corresponding valuation allowance.

The following table presents that movement of the valuation allowance on deferred tax assets (\$ in thousands):

	2024	2023
Balance as of January 1,	(357,956)	(284,072)
Additions	(36,822)	(73,884)
Balance as of December 31,	(394,778)	(357,956)

As of December 31, 2024 and 2023, the Company had net operating loss carry forwards of \$1,951.5 million and \$1,804.9 million, respectively. As of December 31, 2024, net operating losses were primarily comprised of: \$1,497.0 million derived from a certain entity in mainland China which expires in years 2025 through 2034; \$83.6 million derived from other entities in mainland China which expire in years 2025 through 2029; \$2.5 million derived from Taiwan which expires in years 2025 through 2034; and \$57.7 million, \$306.9 million, and \$3.8 million derived from Hong Kong, the United States, and Australia, respectively, that have indefinite carryforwards. Net operating loss carryforwards in mainland China and Taiwan expire through 2034 and those in Hong Kong, the United States, and Australia do not expire.

Uncertainties exist with respect to how the current income tax law in mainland China applies to the Company's overall operations, and more specifically, with regard to tax residency status. The EIT Law includes a provision specifying

that legal entities organized outside of mainland China will be considered residents for Chinese income tax purposes if the place of effective management or control is within mainland China. The implementation rules to the EIT Law provide that non-resident legal entities will be considered Chinese residents if substantial and overall management and control over the manufacturing and business operations, personnel, accounting, and properties occurs within mainland China. Despite the present uncertainties resulting from the limited Chinese tax guidance on the issue, the Company does not believe that the legal entities organized outside of mainland China within the Company should be treated as residents for EIT Law purposes. If the Chinese tax authorities subsequently determine that the Company and its subsidiaries registered outside of mainland China should be deemed resident enterprises, the Company and its subsidiaries registered outside of mainland China will be subject to Chinese income taxes, at a rate of 25%. The Company is not subject to any other uncertain tax position.

According to the PRC Tax Administration and Collection Law, the statute of limitation is three years if the underpayment of taxes is due to computational errors made by the taxpayer or the withholding agent. The statute of limitation is extended to five years under special circumstances where the underpayment of taxes is more than RMB0.1 million. In the case of transfer pricing issues, the statute of limitation is 10 years. There is no statute of limitation in the case of tax evasion. The income tax returns of the Company's PRC subsidiary for the years from 2015 to 2024 are open to examination by the PRC tax authorities.

For Hong Kong income tax purposes, the statute of limitations is six years after the relevant year of assessment. This can be extended to 10 years in the case of fraud or willful evasion of taxes. There are no provisions that govern the time limit for tax collection.

For U.S. federal income tax purposes, the statute of limitations is generally 3 years after the due date of the return, or 3 years after the date the return was actually filed, whichever is later. The statute of limitations does not apply to fraud or tax evasion. Also, the statute of limitations is indefinite if no tax return is filed. For state income tax purposes, the statute of limitations is generally 4 years from the return filing date or due date in states including California, Kentucky, and New Jersey, subject to certain exceptions (e.g., fraud, failure to file).

12. Borrowings

The Company has debt arrangements with the Bank of China, SPD Bank, CMB, and Ningbo Bank to support its working capital needs in mainland China. The following table presents the Company's short-term debt as of December 31, 2024 (\$ in thousands):

	Weighted average interest rate per annum	December 31, 2024
Bank of China Working Capital Loans	2.77 %	69,138
SPD Bank Working Capital Loans	3.13 %	27,823
China Merchant Bank Working Capital Loans	2.91 %	34,750
Total short-term debt	2.88 %	131,711

Bank of China Working Capital Loan Facility

On February 5, 2024, the Company entered into an uncommitted facility letter with the Bank of China (Hong Kong) Limited ("BOC HK") pursuant to which BOC HK will provide standby letters of credit for loans of up to \$100.0 million for a term of one year. In connection with this agreement, the Company paid a one-time, non-refundable fee of \$0.7 million in the first quarter of 2024. In accordance with this agreement, the Company also maintained restricted deposits of \$100.0 million, which are presented as restricted cash-current on the consolidated balance sheet, to secure the standby

letters of credit. On February 6, 2024 and June 20, 2024, upon the Company's application, BOC HK provided standby letters of credit in favor of the Bank of China Pudong Development Zone Branch ("BOC Pudong Branch") for \$50.0 million and \$23.0 million, respectively, which are or may become payable by the Company's wholly-owned subsidiary, Zai Lab (Shanghai) Co., Ltd. ("Zai Lab Shanghai"). BOC HK and BOC Pudong Branch are collectively referred to as Bank of China. Zai Lab Shanghai entered into working capital loans with BOC Pudong Branch under this facility in the first half of 2024, and the aggregate principal amount outstanding was RMB497.0 million (approximately \$69.1 million) as of December 31, 2024. Each working capital loan has a one-year term and is subject to a floating interest rate, which is subject to adjustment every six months.

SPD Bank Working Capital Loan Facility

On February 6, 2024, the Company entered into a maximum-amount guarantee contract with the Shanghai Pudong Development Bank Co., Ltd. Zhangjiang Hi-Tech Park Sub-Branch ("SPD Bank"), pursuant to which the Company will guarantee working capital loans of up to RMB300.0 million (approximately \$42.0 million) from SPD Bank to Zai Lab Shanghai over a three-year period. Zai Lab Shanghai entered into working capital loan contracts with SPD Bank under this debt facility in 2024, and the aggregate principal amount outstanding was RMB200.0 million (approximately \$27.8 million) as of December 31, 2024. Each working capital loan has a one-year term and is subject to a fixed interest rate.

Ningbo Bank Working Capital Loan Facility

On February 6, 2024, the Company's wholly-owned subsidiary, Zai Lab (Suzhou) Co., Ltd. ("Zai Lab Suzhou"), entered into a maximum credit contract with Bank of Ningbo Co., Ltd. Suzhou Sub-branch ("Ningbo Bank") as well as an Electronic Commercial Draft Discounting Master Agreement and Online Working Capital Loan Master Agreement (collectively, the "Ningbo Bank Agreements"). The Ningbo Bank Agreements permit Zai Lab Suzhou to utilize, including through discounting or working capital loan agreements and subject to the terms and conditions in related master agreements, up to RMB230.3 million (approximately \$32.4 million), of which Zai Lab Suzhou is authorized to utilize up to RMB160.0 million (approximately \$22.5 million). In connection with the arrangements described in the Ningbo Bank Agreements, Zai Lab Suzhou agreed to pledge certain real property it owns in Suzhou. As of December 31, 2024, Zai Lab Suzhou had not entered into any discounting arrangements or working capital loans under this Ningbo Bank working capital loan facility.

China Merchants Bank Working Capital Loan Facility

On July 5, 2024, the Company issued a maximum-amount irrevocable letter of guarantee to China Merchants Bank Co., Ltd. Shanghai Branch ("CMB"), pursuant to which the Company will guarantee working capital loans of up to RMB250.0 million (approximately \$34.4 million) from CMB to Zai Lab Shanghai, and Zai Lab Shanghai entered into a Credit Agreement with CMB with respect to the RMB250.0 million facility. The credit facility will be available for one year. As of December 31, 2024, Zai Lab Shanghai has an aggregate principal amount outstanding of RMB249.8 million (approximately \$34.8 million) under this debt facility. Each working capital loan has a one-year term and is subject to a floating interest rate, which is subject to adjustment every three months.

13. Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued payroll	30,198	33,711
Accrued professional service fee	5,728	7,520
Payables for purchase of property and equipment	449	2,474
Accrued rebate to distributors	10,839	16,926
Tax payables	5,154	16,988
Other (i)	6,352	5,353
Total	58,720	82,972

(i) Other primarily includes accrued travel, business-related expenses, other payables to employees, and advance payments from partners.

14. Loss Per Share

The following table presents the computation of the basic and diluted net loss per share (\$ in thousands, except share and per share data):

	Year Ended December 31,		
	2024	2023	2022
Numerator:			
Net loss attributable to ordinary shareholders	(257,103)	(334,620)	(443,286)
Denominator:			
Weighted average number of ordinary shares - basic and diluted	989,477,730	966,394,130	958,067,140
Net loss per share-basic and diluted	(0.26)	(0.35)	(0.46)

As a result of the Company's net loss for 2024, 2023, and 2022, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	December 31,		
	2024	2023	2022
Share options	101,015,470	104,584,050	91,181,420
Non-vested restricted shares	31,951,710	31,279,600	33,433,890

15. Share-Based Compensation

The Company has adopted equity incentive plans, pursuant to which the Company grants share options, SARs, restricted and unrestricted shares, and share units, performance awards, and other awards that are convertible into or otherwise based on ordinary shares to employees and directors of the Company as well as to certain advisors and service providers. In March 2015, the Board of Directors of the Company approved such an Equity Incentive Plan (the "2015 Plan"). In August 2017, in connection with the completion of the Company's initial public offering on Nasdaq (the "IPO"),

the Board of Directors approved the 2017 Equity Incentive Plan (the “2017 Plan”). No new equity-based awards would be granted under the 2015 Plan subsequent to the IPO; new equity-based awards would be granted under the 2017 Plan.

The Company adopted the 2022 Equity Incentive Plan (the “2022 Plan”), which became effective in June 2022 following required approvals from the Company’s shareholders and Board of Directors. No new equity-based awards will be made under the 2017 Plan as of the effective date of the 2022 Plan. The initial aggregate number of shares available for issuance under the 2022 Plan was 97,908,743 ordinary shares.

The Company adopted the 2024 Equity Incentive Plan (the “2024 Plan”), which became effective in June 2024 following required approvals from the Company’s shareholders and Board of Directors. No new equity-based awards will be made under the 2022 Plan as of the effective date of the 2024 Plan. The initial aggregate number of shares available for issuance under the 2024 Plan was 99,208,743 ordinary shares.

The share options granted under the equity incentive plans described above have a contractual term of ten years. Share options granted since April 2023 generally vest ratably over a four-year period, and share options granted prior to April 2023 generally vest ratably over a five-year period, with 25% or 20% of the awards vesting on each anniversary of the grant date, respectively, subject to continued employment/service with the Company on the vesting date. The restricted shares granted generally vest ratably over a specified period on the anniversary of the grant date, subject to continued employment/service with the Company on the vesting date. The shares underlying restricted share grants represent shares not yet vested until they have met related consideration or vesting requirements, which are generally continued employment/service to the Company or satisfaction of specified performance conditions. The restricted shares will be released from the restrictions once they vest. Upon termination of the award holders’ service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited unless otherwise determined by the administrator or set forth in an agreement between the Company and the award holder.

Before November 2023, upon each settlement date of the share awards, shares were generally withheld to cover the required withholding tax, which was based on the value of a share on the settlement date as determined by the closing price of the ADSs on the trading day of the applicable settlement date. The remaining shares after the withholding were delivered to the recipient. The amount remitted to the tax authorities for employee tax obligations was reflected as a financing activity on the consolidated statements of cash flows. These shares withheld by the Company as a result of the net settlement were accounted for as treasury stock and considered issued but not outstanding.

Stock Option Activity

The following table presents a summary of option activity and related information in 2024:

	Number of options	Weighted average exercise price (\$)	Weighted average remaining contractual term (years)	Aggregate intrinsic value (\$ in thousands)
Outstanding at December 31, 2023	104,584,050	3.14	5.97	83,424
Granted	20,947,480	1.69		
Exercised	(5,147,140)	0.64		
Forfeited	(19,368,920)	3.93		
Outstanding at December 31, 2024	101,015,470	2.82	5.81	83,381
Vested and exercisable as of December 31, 2024	55,805,360	2.50	3.73	65,797

Zai Lab Limited**Notes to the Consolidated Financial Statements****For the Years Ended December 31, 2024, 2023, and 2022**

The aggregate intrinsic value of stock options exercised during 2024, 2023, and 2022 was \$9.4 million, \$20.3 million, and \$14.3 million, respectively.

Stock Option Valuation Assumptions

The following table presents the assumptions used to estimate the fair values of the share options granted:

	2024	2023	2022
Risk-free rate of return	3.5%-4.5%	3.5%-4.7%	1.4%-4.0%
Expected term (in years)	6.25	6, 6.25 or 6.5	6.5
Estimated volatility rate	70%	70%	65%
Expected dividend rate	0%	0%	0%

Options granted are measured based on grant-date fair value using the Black-Scholes option pricing model. The weighted-average grant-date fair value per share for options granted during 2024, 2023, and 2022 were \$1.12, \$2.21, and \$2.74 per share, respectively.

Non-Vested Restricted Shares Activity

The following table summarized the Company's non-vested restricted share activity in 2024:

	Numbers of non-vested restricted shares	Aggregate intrinsic value (\$ in thousands)
Non-vested as of December 31, 2023	31,279,600	85,487
Granted	17,687,410	
Vested	(10,120,260)	
Forfeited	(6,895,040)	
Non-vested as of December 31, 2024	31,951,710	83,682

The grant-date fair value of restricted shares is the fair value of the underlying stock on the award's grant date. The weighted-average grant-date fair value per share for restricted shares granted in 2024, 2023, and 2022 were \$1.73, \$3.18, and \$3.71 per share, respectively.

Stock-Based Compensation Expenses

The following table presents the share-based compensation expense which has been reported in the Company's consolidated statements of operations (\$ in thousands):

	Year Ended December 31,		
	2024	2023	2022
Selling, general and administrative	42,532	48,017	38,118
Research and development	28,119	31,617	23,184
Total	70,651	79,634	61,302

As of December 31, 2024, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of \$70.3 million and \$73.3 million, respectively, which the Company expects to recognize over a weighted-average period of 2.63 years and 2.45 years, respectively.

16. License and Collaboration Agreements

The Company may enter into collaboration agreements with third parties to license intellectual property. These agreements may require the Company to make upfront payments and payments related to certain future development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual sales of the licensed products in the licensed territory. These agreements generally remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The royalty terms generally continue until the latest of: (i) the expiration of the last-to-expire valid claim with respect to licensed patent rights; (ii) the expiration of market or regulatory exclusivity; or (iii) a specified period of time, generally around ten years, after the date of the first commercial sale of the licensed product. These agreements also contain customary provisions for termination by either party, including in the event of a material breach by the other party that remains uncured; by the Company for convenience upon a specified notice period; for certain bankruptcy, insolvency, or other similar events; and by its partners upon challenge of their licensed patent rights.

Payments under these agreements generally become due and payable upon the achievement of such milestones or sales. These commitments are not recorded as liabilities on the consolidated balance sheet because the achievement and timing of these milestones are not fixed and determinable. The following is a description of the Company's significant license and collaboration agreements as of December 31, 2024, including milestone fees incurred in 2024, 2023, and 2022.

Significant License and Collaboration Arrangements

License and Collaboration Agreement with GSK (Niraparib)

In September 2016, the Company entered into a collaboration, development, and license agreement with Tesaro, a company later acquired by GSK, pursuant to which the Company obtained an exclusive sublicense under certain patents and know-how of GSK to develop, manufacture, and commercialize GSK's proprietary PARP inhibitor, niraparib, for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer) in mainland China, Hong Kong, and Macau. The Company will purchase ZEJULA from GSK for commercial use in Hong Kong. The Company is not otherwise obligated to purchase ZEJULA or other licensed products from GSK.

The Company recorded development milestone fees into research and development expenses of \$4.0 million in 2022. The Company recorded a sales-based milestone fee into an intangible asset of \$12.0 million in 2023. The Company may be required to pay an additional aggregate amount of up to \$16.0 million in sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid- to high-teens on annual net sales of the licensed products in the licensed territories.

Collaboration and License Agreement with argenx (Efgartigimod)

In January 2021, the Company entered into a collaboration and license agreement with argenx, pursuant to which the Company obtained an exclusive license under certain patents and know-how of argenx to develop and commercialize products containing efgartigimod as an active ingredient in all human and animal uses for any preventative or therapeutic indications in Greater China. The Company will purchase the licensed products exclusively from argenx.

Pursuant to the collaboration and license agreement, the Company and argenx entered into a share issuance agreement. The Company issued as an upfront payment to argenx of 5,681,820 ordinary shares of the Company. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares were subject to certain restrictions. The fair value of the shares on the closing date was determined to be \$62.3 million in the aggregate.

The Company may be required to pay an additional aggregate amount of up to \$42.5 million in sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid-teens to low-twenties on annual net sales of licensed products in the licensed territory.

License and Collaboration Agreement with Novo Holdings (Omadacycline)

In April 2017, the Company entered into a license and collaboration agreement with Paratek Bermuda Ltd. (“Paratek”), a subsidiary of Paratek Pharmaceuticals, Inc. (which was subsequently acquired by Gurnet Point Capital and Novo Holdings A/S), pursuant to which the Company obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, and commercialize products containing omadacycline as an active ingredient in the field of all human therapeutic and preventative uses other than biodefense in Greater China.

The Company may be required to pay an additional aggregate amount of up to \$40.5 million in sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to mid-teens on annual net sales of licensed products in the licensed territory.

License and Collaboration Agreement with NovoCure (Tumor Treating Fields)

In September 2018, the Company entered into a license and collaboration agreement with NovoCure, pursuant to which it obtained an exclusive license under certain patents and know-how of NovoCure to develop and commercialize any Tumor Treating Fields treatment or delivery system, including the device branded as OPTUNE, in all human therapeutic and preventative uses in the field of oncology in Greater China. The Company will purchase the licensed products exclusively from NovoCure.

The Company may be required to pay an additional aggregate amount of up to \$68.0 million in regulatory and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to mid-teens on annual net sales of the licensed products in the licensed territory.

License and Collaboration Agreement with Deciphera (Ripretinib)

In June 2019, the Company 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. The Company will purchase the licensed products exclusively from Deciphera.

The Company may be required to pay an additional aggregate amount of up to \$173.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of the licensed products in the licensed territory.

License and Collaboration Agreement with Innoviva (SUL-DUR)

In April 2018, the Company entered into a license and collaboration agreement with Entasis (now a wholly owned subsidiary of Innoviva), pursuant to which it obtained an exclusive license under certain patents and know-how of Entasis to develop and commercialize products containing Entasis’s proprietary compounds known as durlobactam with Sulbactam (the combination, SUL-DUR) with the possibility of developing and commercializing a combination of such compounds with Imipenem in all human diagnostic, prophylactic, and therapeutic uses in Greater China, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand, and Japan. The Company will purchase the licensed products exclusively from Innoviva.

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For the Years Ended December 31, 2024, 2023, and 2022

The Company recorded a regulatory milestone fee of \$8.0 million as an intangible asset in 2024. The Company recorded development milestone fees into research and development expenses of \$3.0 million in 2023. The Company may be required to pay an additional aggregate amount of up to \$78.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from high single digits to low-teens on annual net sales of the licensed products in the licensed territory. The Company is also responsible for a portion of the costs of the global pivotal Phase III ATTACK clinical trial of SUL-DUR outside of the licensed territory.

License Agreement with BMS (Repotrectinib)

In July 2020, the Company entered into an exclusive license agreement with Turning Point (now a wholly-owned subsidiary of BMS), pursuant to which the Company received an exclusive license to develop and commercialize products containing repotrectinib as an active ingredient in all human therapeutic indications in Greater China. The Company will purchase the licensed products exclusively from BMS.

The Company recorded regulatory milestone fees of \$25.0 million as an intangible asset in 2024. The Company recorded development milestone fees into research and development expenses of \$5.0 million in 2023. The Company may be required to pay an additional aggregate amount of up to \$116.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of the licensed products in the licensed territory.

License and Collaboration Agreement with Amgen (Bemarituzumab)

In December 2017, the Company entered into a license and collaboration agreement with Five Prime (a company later acquired by Amgen), 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. The Company will purchase the licensed products exclusively from Amgen.

The Company may be required to pay an additional aggregate amount of up to \$37.0 million in development and regulatory milestones as well as certain royalties at tiered percentage rates in high-teens on annual net sales of the licensed products in the licensed territory.

Under the terms of the agreement, provided that the Company enrolls and treats a specified number of patients in the bemarituzumab FPA144-004 study in mainland China, the Company is eligible to receive a low single-digit percentage quarterly royalty, on a licensed product-by-licensed product basis on net sales of all licensed products outside of the licensed territory until the tenth (10th) anniversary of the first commercial sale of each such licensed product outside of the licensed territory.

Collaboration and License Agreement with Pfizer (Tisotumab Vedotin)

In September 2022, the Company entered into a collaboration and license agreement with Seagen (a company later acquired by Pfizer), pursuant to which the Company and Seagen agreed to collaboratively develop and commercialize tisotumab vedotin (TIVDAK). Under the agreement, the Company obtained an exclusive license to develop and commercialize TIVDAK in Greater China. The Company will purchase the licensed products exclusively from Pfizer.

The Company recorded an upfront payment of \$30.0 million into research and development expenses in 2022. The Company may be required to pay an additional aggregate amount of up to \$258.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from mid-teens to low-twenties on annual net sales of the licensed products in Greater China.

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License Agreement with BMS (Xanomeline and Trospium Chloride)

In November 2021, the Company entered into a license agreement with Karuna (a company later acquired by BMS), pursuant to which the Company obtained an exclusive license to develop, manufacture, and commercialize xanomeline-trospium (KarXT) in Greater China.

The Company recorded development milestone fees into research and development expenses of \$10.0 million in each of 2024 and 2022, respectively. The Company may be required to pay an additional aggregate amount of up to \$132.0 million in regulatory and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of the licensed products in Greater China.

Collaboration and License Agreement with MediLink Therapeutics (DLL3 ADC)

In April 2023, the Company entered into a collaboration and license agreement with MediLink, pursuant to which the Company obtained an exclusive global license to research, develop, manufacture, and commercialize MediLink's proprietary ADC compound targeting DLL3.

The Company recorded an upfront payment into research and development expenses of \$10.0 million in 2023. The Company may be required to pay an additional aggregate amount of up to \$592.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from high single digits to low double digits on annual net sales of the licensed products.

Other License and Collaboration Arrangements That Are Not Individually Significant

The Company may be required to pay an additional aggregate amount of up to \$2,045.4 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual net sales under such agreements.

17. Other Income, Net

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

	Year Ended December 31,		
	2024	2023	2022
Government grants	8,170	2,433	11,471
(Loss) Gain on equity investments with readily determinable fair value	(6,105)	2,789	(8,952)
Other miscellaneous gain	3,235	1,784	594
Total	<u>5,300</u>	<u>7,006</u>	<u>3,113</u>

18. Restricted Net Assets

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

In accordance with the Company Law of the People's Republic of China, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective

registered capital based on the enterprise's Chinese statutory accounts. A domestic enterprise may provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's Chinese statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's Chinese subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

No appropriation to statutory reserves was made in 2024, 2023, and 2022 because the Chinese subsidiaries had substantial losses during such periods.

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

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

19. Employee Defined Contribution Plans

Full-time employees of the Company in mainland China participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund, and other welfare benefits are provided to employees. Chinese labor regulations require that the Company's subsidiaries in mainland China make contributions to the government for these benefits primarily based on certain percentages of the employees' salaries subject to certain caps and other government requirements. The total amounts for such employee benefits, which were expensed as incurred, were \$26.0 million, \$25.8 million, and \$23.6 million for 2024, 2023, and 2022, respectively.

The Company's employees who are U.S. taxpayers and who meet certain age and service requirements are eligible to participate in a broad-based, defined contribution retirement plan which is qualified under Section 401 of the Internal Revenue Code (the "401(k) plan"). The Company makes a matching contribution equal to 100% in 2024 and 2023 and 50% in 2022 of the first 5% of the employee's elective contributions under the plan, up to 5.0% of an employee's eligible compensation. Contributions made by the Company vest 100% upon contribution. The total amounts for such employee benefits, which were expensed as incurred, were \$1.1 million, \$1.0 million, and \$0.5 million in 2024, 2023, and 2022, respectively.

The Company also provides required Mandatory Provident Fund contribution for its full-time employees located in Hong Kong and provides social benefits contribution for its full-time employees located in Taiwan. The total amounts for these contributions, which were expensed as incurred, was \$0.2 million in each of 2024, 2023, and 2022.

There is no forfeiture of contribution related to any of the Company's employee defined contribution plans as described above.

20. Commitments and Contingencies**(a) Purchase Commitments**

As of December 31, 2024, the Company's commitments related to commercial manufacturing development and facilities construction and improvement activities that are contracted but not yet reflected in the consolidated financial statements were \$6.8 million and were expected to be incurred within one year.

(b) Legal Proceedings

The Company is not currently a party to any material legal proceedings. Each quarter, the Company evaluates whether there have been any developments in legal proceedings that would require an accrual. In accordance with the accounting guidance for contingencies, the Company will accrue for losses that are both probable and reasonably estimable. The Company will record any legal and other third-party costs related to its legal contingencies as incurred.

(c) Indemnifications

In the normal course of business, the Company enters into agreements that indemnify others for certain liabilities that may arise in connection with a transaction or certain events and activities. If the indemnified party were to make a successful claim pursuant to the terms of the indemnification, the Company may be required to reimburse the loss. These indemnifications are generally subject to various restrictions and limitations. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

21. Segment Information

The Company operates as a single operating segment engaged in discovering, developing, and commercializing products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. A global research and development organization and a supply chain organization discover, develop, manufacture, and supply our products. A global commercial organization markets, distributes, and sells the products. The business is also supported by global corporate staff functions. The Company's CODM is the Chief Executive Officer, who assesses performance and allocates resources based on the significant expenses and net income on a consolidated basis. The significant expenses that are regularly provided to the CODM include those amounts that are also reported on the consolidated statement of operations as well as below additional disaggregated measures. The CODM also reviews cash position (which are cash and cash equivalents, current restricted cash, and short-term investments) that are also reported on the consolidated balance sheets when making operating decisions. In accordance with ASC 280, the Company has only one reportable segment.

The following tables present disaggregated expenses that are regularly provided to the CODM:

	Year Ended December 31,		
	2024	2023	2022
Selling and marketing expenses	190,367	169,555	159,136
General and administrative expenses	108,374	112,053	99,835
Total selling, general, and administrative expenses	298,741	281,608	258,971

Zai Lab Limited**Notes to the consolidated financial statements****For the years ended December 31, 2022, 2023 and 2024**

	Year Ended December 31,		
	2024	2023	2022
Personnel compensation and related costs	106,154	115,749	105,561
Licensing fees	30,997	19,291	53,441
CROs/CMOs/Investigators expenses	69,870	103,333	100,544
Other costs	27,483	27,495	26,862
Total research and development expenses	234,504	265,868	286,408

	Year Ended December 31,		
	2024	2023	2022
Clinical programs	86,126	112,158	155,792
Pre-clinical programs	31,913	17,356	6,644
Unallocated research and development expenses	116,465	136,354	123,972
Total research and development expenses	234,504	265,868	286,408

	Year Ended December 31,		
	2024	2023	2022
Personnel compensation and related costs	174,958	173,389	162,045
Other costs	123,783	108,219	96,926
Total selling, general, and administrative expenses	298,741	281,608	258,971

22. Subsequent Events

In January 2025, the Company identified an additional opportunity to access capital denominated in RMB through a debt facility with Bank of Communications on favorable commercial terms to support its working capital needs in mainland China. As a result, on January 2, 2025, the Company entered into a guarantee contract with Bank of Communications Co., Ltd. Shanghai Zhangjiang Sub-Branch (“BOCOM”) pursuant to which the Company will guarantee working capital loans from BOCOM to Zai Lab Shanghai, and Zai Lab Shanghai entered into a working capital loan contract with BOCOM with respect to a revolving credit facility of up to RMB300.0 million (approximately \$41.1 million), of which the full amount was subsequently withdrawn by Zai Lab Shanghai in February 2025. The working capital loan has a one-year term and is subject to a floating interest rate, which is subject to adjustment every three months.

In February 2025, upon the maturity of a portion of the short-term debt with BOC Pudong Branch (*see Note 12*), Zai Lab Shanghai repaid RMB340.0 million (approximately \$46.9 million) of the loan balance.

Schedule I — Condensed Financial Information of Registrant

Zai Lab Limited

Financial Information of Parent Company

Condensed Balance Sheets

(in thousands of \$, except for number of shares and per share data)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	98,755	565,981
Restricted Cash, current	100,000	—
Short-term investments	330,000	—
Prepayments and other current assets	5,227	7,423
Total current assets	533,982	573,404
Investment in subsidiaries	309,901	224,954
Total assets	843,883	798,358
Liabilities and shareholders' equity		
Liabilities		
Current liabilities:		
Other current liabilities	2,985	2,240
Total current liabilities	2,985	2,240
Total liabilities	2,985	2,240
Shareholders' equity		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized, 1,082,614,740 and 977,151,270 shares issued as of December 31, 2024 and 2023, respectively; 1,077,702,540 and 972,239,070 shares issued and outstanding as of December 31, 2024 and 2023, respectively)	7	6
Additional paid-in capital	3,264,295	2,975,302
Accumulated deficit	(2,453,083)	(2,195,980)
Accumulated other comprehensive income	50,515	37,626
Treasury stock	(20,836)	(20,836)
Total shareholders' equity	840,898	796,118
Total liabilities and shareholders' equity	843,883	798,358

Schedule I — Condensed Financial Information of Registrant

Zai Lab Limited

Financial Information of Parent Company

Condensed Statements of Operations and Comprehensive Loss

(in thousands of \$)

	Year Ended December 31,		
	2024	2023	2022
Operating Expenses:			
Research and development	(8)	(82)	(178)
General and administrative	(20,275)	(16,958)	(19,773)
Loss from operations	(20,283)	(17,040)	(19,951)
Interest income	28,176	30,840	12,857
Other (expense) income, net	(5,438)	4,029	(8,678)
Profit (Loss) before income tax and equity in loss of subsidiaries	2,455	17,829	(15,772)
Equity in loss of subsidiaries	(259,558)	(352,449)	(427,514)
Income tax expense	—	—	—
Net loss	(257,103)	(334,620)	(443,286)
Other comprehensive income (loss), net of tax of nil:			
Foreign currency translation adjustment	12,889	11,941	49,330
Comprehensive loss	(244,214)	(322,679)	(393,956)

Schedule I — Condensed Financial Information of Registrant

Zai Lab Limited

Financial Information of Parent Company

Condensed Statements of Cash Flows

(in thousands of \$)

	Year Ended December 31,		
	2024	2023	2022
Cash flows from operating activities:			
Net loss	(257,103)	(334,620)	(443,286)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Amortization of deferred income	—	—	(234)
Share based compensation	4,759	3,217	3,724
Equity in loss of subsidiaries	259,558	352,449	427,514
Loss from fair value changes of equity investment of readily determinable fair value	6,105	(2,789)	8,952
Changes in operating assets and liabilities:			
Prepayments and other current assets	2,266	2,780	(7,839)
Other current liabilities	(248)	(379)	1,648
Net cash provided by (used in) operating activities	15,337	20,658	(9,521)
Cash flows from investing activities:			
Purchases of short-term investments	(330,000)	—	(260,274)
Proceeds from maturity of short-term investments	—	—	705,274
Investment in subsidiaries	(271,830)	(392,893)	(80,942)
Net cash (used in) provided by investing activities	(601,830)	(392,893)	364,058
Cash flows from financing activities:			
Proceeds from exercises of stock options	3,200	2,369	5,870
Proceeds from issuance of ordinary shares upon public offerings	217,350	—	—
Payment of public offering costs	(1,283)	—	—
Employee taxes paid related to settlement of equity awards	—	(8,802)	(7,600)
Net cash provided by (used in) financing activities	219,267	(6,433)	(1,730)
Effect of foreign exchange rate changes on cash and cash equivalent	—	—	—
Net (decrease) increase in cash and cash equivalents	(367,226)	(378,668)	352,807
Cash, cash equivalents and restricted cash — beginning of the year	565,981	944,649	591,842
Cash, cash equivalents and restricted cash — end of the year	198,755	565,981	944,649

Schedule I — Condensed Financial Information of Registrant

Zai Lab Limited

Financial Information of Parent Company

Notes

1. Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.
2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. For the parent company, Zai Lab Limited records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, *Investments-Equity Method and Joint Ventures*. Such investments are presented on the Condensed Balance Sheets as “Investment in subsidiaries”. Ordinarily under the equity, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.
3. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The footnote disclosures provide certain supplemental information relating to the operations of the Company and, as such, these statements should be read in conjunction with the notes to the accompanying consolidated financial statements.
4. As of December 31, 2024 and 2023, there were no material contingencies, significant provisions of long-term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of Zai Lab Limited.