



Incorporated in the Cayman Islands  
with limited liability

HKEX: 9688

NASDAQ: ZLAB

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# 2022

# Annual

# Report



# CONTENTS

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CORPORATE INFORMATION	2
FORWARD-LOOKING STATEMENTS	5
BUSINESS	7
RISK FACTORS	59
CHAIRPERSON'S STATEMENT	149
FINANCIAL SUMMARY	152
MANAGEMENT DISCUSSION AND ANALYSIS	153
DIRECTORS AND SENIOR MANAGEMENT	176
DIRECTORS' REPORT	189
CORPORATE GOVERNANCE REPORT	223
INDEPENDENT AUDITOR'S REPORT	242
CONSOLIDATED FINANCIAL STATEMENTS	244
FINANCIAL STATEMENTS SCHEDULE I	
— FINANCIAL INFORMATION OF PARENT COMPANY	296
DEFINITIONS	301
GLOSSARY OF TECHNICAL TERMS	306

# CORPORATE INFORMATION

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## **DIRECTORS**

### **Executive Director**

Dr. Samantha Du (*Director, Chairperson, and Chief Executive Officer*)

### **Independent Directors**

Dr. Kai-Xian Chen

Dr. John Diekman (*appointed as the Lead Independent Director on July 22, 2022*)

Ms. Nisa Leung

Mr. William Lis

Mr. Leon O. Moulder, Jr.

Mr. Peter Wirth

Mr. Scott W. Morrison

Richard Gaynor, M.D.

Mr. Michel Vounatsos (*appointed on January 7, 2023*)

## **HEAD OFFICE AND PRINCIPAL PLACE OF BUSINESS IN MAINLAND CHINA**

Building 1, 4/F

Jinchuang Plaza

4560 Jinke Road

Pudong, Shanghai, 201210

P.R. China

## **HEAD OFFICE AND PRINCIPAL PLACE OF BUSINESS IN THE UNITED STATES**

314 Main Street

4th Floor, Suite 100

Cambridge, MA 02142

USA

## **HEAD OFFICE AND PRINCIPAL PLACE OF BUSINESS IN HONG KONG**

Room 2301, 23/F

Island Place Tower

510 King's Road

North Point, Hong Kong

P.R. China

## **REGISTERED OFFICE**

Harbour Place, 2nd Floor

103 South Church Street

P.O. Box 472

George Town

Grand Cayman KY1-1106

Cayman Islands

## **PRINCIPAL SHARE REGISTRAR AND TRANSFER AGENT**

International Corporation Services Ltd.

Harbour Place, 2nd Floor

103 South Church Street

P.O. Box 472

George Town

Grand Cayman KY1-1106

Cayman Islands

## **HONG KONG SHARE REGISTRAR AND TRANSFER AGENT**

Computershare Hong Kong Investor Services Limited

Shops 1712–1716

17th Floor, Hopewell Centre

183 Queen's Road East

Wanchai, Hong Kong

## COMPLIANCE ADVISOR

Somerley Capital Limited  
20/F China Building  
29 Queen's Road Central  
Hong Kong  
P.R. China

## AUTHORISED REPRESENTATIVES

Dr. Samantha Du  
Building 1, 4/F  
Jinchuang Plaza  
4560 Jinke Road  
Pudong, Shanghai, 201210  
P.R. China

Ms. Nelly Au-Yeung  
5/F, Manulife Place  
348 Kwun Tong Road  
Kowloon, Hong Kong  
P.R. China

## AUDIT COMMITTEE

Mr. Scott Morrison (*appointed as Chairperson on July 22, 2022*)  
Dr. John Diekman (*ceased to be Chairperson on July 22, 2022*)  
Mr. Peter Wirth

## COMPENSATION COMMITTEE

Mr. Peter Wirth (*Chairperson*)  
Ms. Nisa Leung (*ceased to be a member on October 19, 2022*)  
Mr. Leon O. Moulder, Jr.  
Dr. John Diekman (*appointed as a member on October 19, 2022*)

## NOMINATING AND CORPORATE GOVERNANCE COMMITTEE

Mr. Leon O. Moulder, Jr. (*Chairperson*)  
Dr. John Diekman  
Mr. William Lis

## RESEARCH AND DEVELOPMENT COMMITTEE

Mr. Richard Gaynor, M.D. (*Chairperson*)  
Dr. Samantha Du  
Dr. Kai-Xian Chen  
Mr. William Lis  
Mr. Michel Vounatsos (*appointed as a member on January 7, 2023*)

## COMMERCIAL COMMITTEE<sup>(Note 1)</sup>

Mr. Michel Vounatsos (*appointed as Chairperson on January 7, 2023*)  
Mr. William Lis (*appointed as a member on January 13, 2023*)  
Mr. Leon O. Moulder, Jr. (*appointed as a member on January 13, 2023*)

## JOINT COMPANY SECRETARIES

Mr. F. Ty Edmondson  
314 Main Street  
4th Floor, Suite 100  
Cambridge, MA 02142 USA

Ms. Nelly Au-Yeung  
5/F, Manulife Place  
348 Kwun Tong Road  
Kowloon, Hong Kong  
P.R. China

Note:

(1) The Commercial Committee was established on January 7, 2023.

# CORPORATE INFORMATION

## AUDITORS

KPMG LLP

*Public Interest Entity Auditor recognised in accordance with the Accounting and Financial Reporting Council Ordinance*

## STOCK CODE

HKEX: 9688

NASDAQ: ZLAB

## CONTACT

**Investor Relations:** Lina Zhang

+86 136 8257 6943

[lina.zhang@zailaboratory.com](mailto:lina.zhang@zailaboratory.com)

**Media:** Shaun Maccoun/Xiaoyu Chen

+1 (415) 317-7255/+86 185 0015 5011

[Shaun.maccoun@zailaboratory.com/](mailto:Shaun.maccoun@zailaboratory.com/)

[xiaoyu.chen@zailaboratory.com](mailto:xiaoyu.chen@zailaboratory.com)

## WEBSITE

<http://www.zailaboratory.com/>

# FORWARD-LOOKING STATEMENTS

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This annual report contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information that are not statements of historical facts or guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions, and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the following:

- The effects of the COVID-19 pandemic, including increased infection rates and any government actions and lockdown measures taken in response, particularly in mainland China where our operations and product markets are primarily located;
- Changes in United States and China trade policies and relations, as well as relations with other countries, and/or changes in regulations and/or sanctions;
- 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 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;
- Approval, filing, or procedural requirements imposed by the China Securities Regulatory Commission (“CSRC”) or other Chinese regulatory authorities in connection with issuing securities to foreign investors under Chinese law;
- Any violation or liability under the U.S. Foreign Corrupt Practices Act (“FCPA”) or Chinese anti-corruption laws;
- Restrictions on currency exchange;
- Limitations on the ability of our Chinese subsidiaries to make payments to us;
- Chinese requirements on the ability of residents in mainland China to establish offshore special purpose companies by residents in mainland China;
- Chinese regulations regarding acquisitions of mainland China-based companies by foreign investors;

## FORWARD-LOOKING STATEMENTS

- Any issues that our Chinese manufacturing facilities may have with operating in conformity with established GMPs and international best practices, and with passing U.S. Food and Drug Administration (“FDA”), National Medical Products Administration (“NMPA”), and European Medicines Agency (“EMA”) inspections;
- Expiration of, or changes to, financial incentives or discretionary policies granted by local governments;
- Restrictions or limitations on the ability of overseas regulators to conduct investigations or collect evidence within mainland China;
- 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;
- Review by the Committee on Foreign Investment in the United States (“CFIUS”) in our investments or other delays or obstacles for closing transactions;
- Any inability to renew our current leases on desirable terms or otherwise locate desirable alternatives for our leased properties;
- Our ability to generate revenues from our approved commercial products;
- Any inability of third parties on whom we rely to conduct our pre-clinical and clinical trials to successfully carry out their contractual duties or meet expected deadlines; 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 annual 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 annual 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 Latest Practicable Date.



## 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, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house 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 in China and worldwide.

Since the Company's founding in 2013, we have taken steps to execute on our corporate strategy to become a fully integrated global biopharmaceutical company with substantial research and development, business development, and commercialization capabilities.

In 2023, our key corporate strategic goals for driving innovation in China and beyond include:

- **Accelerating Medicines to Patients:** We seek to advance our product pipeline by continuing to invest in research and development, including internal discovery activities;
- **Expanding Our Pipeline:** We seek the continued growth of our differentiated product pipeline through regional and global collaborations and corporate development activities; and
- **Continuing 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 continue preparations to launch eight additional products in Greater China in the next 2–3 years. Through our efforts, we seek to achieve overall corporate profitability by the end of 2025.

We also seek to build and maintain the trust of our stakeholders. In 2022, we established our environmental, social and governance (“ESG”) 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.

## 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,

## BUSINESS

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 Latest Practicable Date, 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 \$416.5 million in capital contributions via twenty-three separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2023 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 the Foreign Investment Law of the People's Republic of China and its implementing rules, which jointly established the legal framework for the administration of foreign-invested companies, a foreign investor may, in accordance with other applicable laws, freely transfer into or out of mainland China its contributions, profits, capital earnings, income from asset disposal, intellectual property rights, royalties acquired, compensation, or indemnity legally obtained, and income from liquidation, made or derived within the territory of mainland China in RMB or any foreign currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount, and frequency. According to the Company Law of the People's Republic of China and other Chinese laws and regulations, our Chinese subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with Chinese accounting standards and regulations. In addition, each of our Chinese subsidiaries is required to set aside at least 10% of its accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss the Chinese subsidiary incurred in the previous financial year, its current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. Such statutory reserve funds and the accumulated after-tax profits that are used for covering the loss cannot be distributed to us as dividends. At their discretion, our Chinese subsidiaries may allocate a portion of their after-tax profits based on Chinese accounting standards to a discretionary reserve fund.

Renminbi, 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 State Administration of Foreign Exchange of China (“SAFE”) by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. The Chinese government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in 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, 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 ADSs and ordinary shares to be subject to Chinese taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes.

## OUR COMMERCIAL PRODUCTS

The following table summarizes the status of our approved commercial products:

Product	Indications	Regulatory Status	Commercial Rights	Partner
 Zejula niraparib	1 <sup>st</sup> line ovarian cancer maintenance treatment  Platinum sensitive relapsed ovarian cancer maintenance treatment	Launched in mainland China, Hong Kong, and Macau	Mainland China, Hong Kong, and Macau	GSK
 OPTUNE Elevate Expectations	Newly diagnosed glioblastoma multiforme (“GBM”) Recurrent GBM	Launched in mainland China, Hong Kong, and Macau	Mainland China, Hong Kong, Macau, and Taiwan	NovoCure
 OPTUNE L.L.A.	Unresectable, locally advanced, or metastatic malignant pleural mesothelioma (“MPM”)	Launched in Hong Kong and Macau	Mainland China, Hong Kong, Macau, and Taiwan	
 QINLOCK piperitricin	4 <sup>th</sup> line gastrointestinal stromal tumors (“GIST”)	Launched in mainland China, Hong Kong, and Taiwan; approved in Macau	Mainland China, Hong Kong, Macau, and Taiwan	Deciphera
 NUZYRA (omadacycline)	Community-acquired bacterial pneumonia (“CABP”) Acute bacterial skin and skin structure infections (“ABSSSI”)	Launched in mainland China	Mainland China, Hong Kong, Macau, and Taiwan	Paratek

# BUSINESS

## **ZEJULA (Niraparib)**

ZEJULA is an oral, once-daily small-molecule poly (ADP-ribose) polymerase (“PARP”) 1/2 inhibitor. A PARP inhibitor blocks the ability of cancer cells to repair themselves after they have been damaged by radiation and certain chemotherapies. This inhibition of DNA damage repair can result in the inability of cancer cells to replicate themselves and in programmed cell death. Tumors that are deficient in key DNA damage repair pathways, such as BRCA1 mutant tumors, are particularly sensitive to ZEJULA. As 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 a 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.

Since 2016, we have had an exclusive license agreement with Tesaro Inc. (a company later acquired by GSK) to develop and commercialize ZEJULA in mainland China, Hong Kong, and Macau for all potential indications except prostate cancer. For more information on this collaboration and license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — GSK (Niraparib).

ZEJULA is currently marketed in the United States, Europe, Greater China, Canada, Australia, and certain other countries/regions. ZEJULA was first approved in 2017 by the FDA for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who exhibit a complete or partial response to platinum-based chemotherapy and by the EMA as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive, relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy. Subsequently, in 2019, the FDA approved ZEJULA for treatment of patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens whose cancer is associated with homologous recombination deficiency (“HRD”)-positive status. And, in 2020, the FDA approved it as a monotherapy in first-line maintenance treatment of women with advanced ovarian cancer who are in complete or partial response to first-line platinum-based chemotherapy regardless of biomarker status, and the EMA approved it as a first-line monotherapy maintenance treatment for adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response following platinum-based chemotherapy regardless of biomarker status.

The NMPA approved ZEJULA as a maintenance therapy for adult patients in mainland China with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy in December 2019 and as a maintenance therapy for adult patients in mainland China with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to first-line platinum-based chemotherapy in September 2020.

Throughout this year, the FDA has been reviewing data on PARP inhibitors, and other companies have issued Dear HCP Letters in the U.S. as a result of ongoing discussions with the FDA. In September 2022, GSK disclosed that it was in discussions with the FDA to discuss overall survival (“OS”) data from GSK’s ENGOT-OV16/NOVA Phase III clinical trial for adult patients with recurrent ovarian cancer irrespective of the gBRCA mutation. We do not expect the FDA’s discussions with GSK to impact our approval from the NMPA for ZEJULA in China. The NMPA’s full approval of ZEJULA for patients with recurrent ovarian cancer is based on a separate study, the NORA study, which is a Phase 3 randomized, double-blind, placebo-controlled study of ZEJULA that the Company independently

conducted in China. While the NORA study is not fully mature, to date, favorable trends have been observed in OS irrespective of gBRCA mutation status. In December 2022, we presented new interim OS data in Chinese patients with platinum-sensitive recurrent ovarian cancer from the Phase III NORA study for ZEJULA at the European Society for Medical Oncology Virtual Plenary. Median OS was numerically longer for patients receiving ZEJULA regardless of biomarker status, at 46.3 months compared to 43.4 months in the placebo group, and no new safety issues were identified. As a result, we do not anticipate that our second-line all-comer label in China will be affected by the FDA's discussions with GSK. We also do not expect a change in our first-line label for ZEJULA; the FDA's discussions with GSK do not apply to this indication. In February 2023, the NMPA approved ZEJULA as a first-line ovarian cancer maintenance treatment; this complete approval was based on data from the Phase III PRIME study in China.

### Market Opportunity for ZEJULA

We have completed several studies evaluating ZEJULA as a treatment for Chinese patients with ovarian cancer, which is one of the most common gynecological cancers in China, with over 55,000 newly diagnosed cases and 37,000 deaths in China annually.

We launched ZEJULA in mainland China in January 2020 after ZEJULA was approved by the NMPA in December 2019 as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. In September 2020, ZEJULA was approved by the NMPA as a maintenance treatment for adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. In December 2020, ZEJULA was included in the National Reimbursement Drug List ("NRDL") as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively, termed as ovarian cancer) who are in a complete or partial response to platinum-based chemotherapy, and in December 2021, ZEJULA was included in the NRDL as a first-line maintenance treatment of adult patients with advanced ovarian cancer following a response to platinum-based chemotherapy.

We also previously launched ZEJULA in Hong Kong in December 2018 for adult patients with platinum-sensitive, relapsed high-grade, serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy after approval by the Hong Kong Department of Health. In August 2021, the Hong Kong Department of Health approved our post-approval variation for ZEJULA as a maintenance treatment for adult patients with high-grade serous epithelial ovarian cancer who are in a complete response or partial response to first-line platinum-based chemotherapy. ZEJULA was approved and launched in Macau for the same indication.

For details about our clinical development of ZEJULA, see Business — Our Oncology Pipeline — Additional Indications for ZEJULA.

### Optune (Tumor Treating Fields)

Tumor Treating Fields (or "TTFields") is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth, causing cancer cell death, decreasing cell migration, and inhibiting DNA damage response. TTFields therapy is delivered through a portable medical device. The complete delivery system, called Optune or Optune Lua, includes a portable electric field generator, arrays, rechargeable batteries, and accessories. Sterile, single-use arrays are placed directly on the skin in the region surrounding the tumor and connected to the electric field generator to deliver therapy. Arrays are changed when hair growth or the

# BUSINESS

hydrogel reduces array adhesion to the skin. The therapy is designed to be delivered continuously throughout the day and night, and efficacy is strongly correlated to time on therapy. When the device is turned on, TTFIELDS are continuously generated within the specific region of the body covered by the arrays. Healthy tissues located outside of this region remain unaffected by the therapy.

Since 2018, we have had an exclusive license from NovoCure to develop and commercialize Optune in Greater China in all human therapeutic and preventive uses in the field of oncology. For more information on this license and collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements – NovoCure (Tumor Treating Fields).

TTFIELDS is currently marketed in the United States, Greater China, Europe, Japan, and certain other countries/regions. In 2015, Optune was approved by the FDA for the treatment of adult patients with newly diagnosed GBM in combination with temozolomide (“TMZ”), a chemotherapy drug, and for adult patients with GBM following confirmed recurrence after chemotherapy as monotherapy treatment. In May 2020, the NMPA approved the Marketing Authorization Application (“MAA”) for Optune in combination with TMZ for the treatment of patients with newly diagnosed GBM and also as a monotherapy for the treatment of patients with recurrent GBM. Optune is also approved or has a CE certificate for the treatment of GBM in the European Union, Japan, and certain other countries.

In May 2019, NovoCure received FDA approval for the use of Optune Lua as a Humanitarian Use Device in combination with chemotherapy for the first-line treatment of adult patients with unresectable, locally advanced, or metastatic MPM. MPM is a type of cancer that occurs in the thin layer of tissue in the torso covering internal organs. In November 2022, the MAA for MPM was accepted by the NMPA.

## Market Opportunity for Optune

GBM, a malignant form of astrocytoma, is the most aggressive form of brain cancer. In mainland China during 2019, GBM represented about 46% of all newly diagnosed cases of brain cancer, with an estimated annual incidence of 15,134 patients in 2020. GBM is treated mainly by surgery, radiotherapy, and TMZ. Despite these treatments, prospects for long-term survival remain poor. In mainland China, the five-year survival rate of GBM patients is less than 5%. Optune is the first treatment approved by the NMPA for GBM in mainland China since 2007.

We launched Optune in Hong Kong in 2018 and in mainland China in June 2020 after the NMPA approved Optune in May 2020 in combination with TMZ for the treatment of patients with newly diagnosed GBM and also as a monotherapy for the treatment of patients with recurrent GBM. As of December 31, 2022, Optune was listed in 87 regional customized commercial health insurance plans guided by provincial or municipal governments throughout mainland China, or supplemental insurance plans, up from 33 as of December 31, 2021. Enrollment into these regional reimbursement programs has improved, and we expect will continue to improve, access to Optune for patients in need across mainland China.

We launched Optune Lua, a portable medical device that delivers TTFIELDS for the treatment of unresectable, locally advanced, or metastatic MPM in Hong Kong in August 2020 and in Macau in October 2020.

For more information about our clinical development of TTFIELDS, see Business — Our Oncology Pipeline — Additional Indications for Tumor Treating Fields.

## **QINLOCK (Ripretinib)**

QINLOCK is an orally administered switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFR $\alpha$  mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop.

Since 2019, we have had an exclusive license from Deciphera to develop and commercialize QINLOCK in Greater China for the prevention, prophylaxis, treatment, cure, or amelioration of any disease or medical condition in humans. For more information on this license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Deciphera (Ripretinib).

QINLOCK is currently approved and marketed in the United States, Greater China, Canada, Australia, and certain other countries/regions for the treatment of fourth-line advanced GIST. In May 2020, the FDA approved QINLOCK for adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. QINLOCK was approved for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, by the NMPA, Hong Kong Department of Health, and Taiwan Food and Drug Administration in March 2021, February 2020, and September 2021, respectively. In January 2023, QINLOCK was approved for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib, in Macau.

In January 2023, Deciphera presented additional data from the planned exploratory analysis from the INTRIGUE Phase III clinical study of QINLOCK using circulating tumor DNA for second-line GIST patients. Patients with mutations in KIT exon 11 and exon 17/18 only derived substantially improved clinical benefit with QINLOCK versus sunitinib. Deciphera plans to initiate the INSIGHT pivotal Phase III clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only in the second half of 2023.

### **Market Opportunity for QINLOCK**

We launched QINLOCK in mainland China in May 2021, after receiving NMPA approval in March 2021, and we are focused on the commercialization of QINLOCK for the treatment of fourth-line GIST in Greater China, where we believe QINLOCK is the standard of care. GISTs are the most common mesenchymal tumors, accounting for about 1/20 of gastrointestinal tumors, with an estimated annual incidence of around 20,000 to 30,000 newly diagnosed patients per year in mainland China.

In January 2023, QINLOCK was included in the NRDL for the treatment of advanced GIST patients who have received prior treatment with three or more kinase inhibitors in the all-comer setting.



# BUSINESS

## **NUZYRA (Omadacycline)**

NUZYRA is a once-daily oral and intravenous antibiotic in a new class of tetracycline derivatives known as aminomethylcyclines. NUZYRA is primarily being developed by our partner Paratek Pharmaceuticals, Inc. (“Paratek”) for the treatment of adults with CABP and ABSSSI in both hospital and community settings.

Since 2017, we have had an exclusive license from Paratek to develop, manufacture, and commercialize NUZYRA in Greater China in all human therapeutic and preventive uses other than biodefense. For more information on this license and collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Paratek (Omadacycline).

NUZYRA is currently marketed in the United States and mainland China. In October 2018, NUZYRA was approved by the FDA for once-daily oral or intravenous administration for the treatment of adults with CABP and ABSSSI. In December 2021, the NMPA approved NUZYRA as a category 1 innovative drug for the treatment of patients with CABP and ABSSSI for both oral and intravenous formulation. NUZYRA is locally manufactured by CMOs in mainland China.

### **Market Opportunity for NUZYRA**

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 NUZYRA in mainland China in December 2021. In January 2023, NUZYRA was included in the NRDL for the treatment of adults with CABP and ABSSSI for intravenous formulation.



**Our Pipeline of Product Candidates**

The following table summarizes the status of our clinical pipeline assets as of February 28, 2023:

Product Candidates	Description	Phase I	Phase II	Pivotal		Commercial Rights
				Phase Ib / Phase II	Phase III	
<b>Oncology</b>						
<b>ZEJULA</b>	<b>PARP</b>	Other solid tumors* <sup>1</sup>				Mainland China, HK, Macau
<b>Tumor Treating Fields</b>		MPM — <i>Approved in the United States, MAA accepted in mainland China</i>				Greater China
		NSCLC				
		NSCLC brain metastases				
		Pancreatic cancer				
		Ovarian cancer*				
		Gastric cancer <sup>2</sup>				
	Liver cancer*					
<b>MARGENZA</b>	<b>HER2</b>	Breast cancer <sup>3</sup> — <i>Approved in the United States, NDA accepted in mainland China</i>				
<b>TIVDAK</b>	<b>ADC</b>	Cervical cancer <sup>4</sup> — <i>Approved in the United States</i>				
<b>KRAZATI</b>	<b>KRAS<sup>G12C</sup></b>	Other tumors (mono/combo)*				
		NSCLC (mono/combo) <sup>5</sup> — <i>Approved in the United States</i>				
<b>Bemarituzumab</b>	<b>FGFR2b</b>	Colorectal cancer (mono/combo)				
<b>Odonextamab</b>	<b>CD20xCD3</b>	Gastric cancer/GEJ* <sup>6</sup>				
<b>Repotrectinib</b>	<b>ROS1, TRK</b>	B-NHL				
<b>Zipalertinib</b>	<b>EGFR Ex20ins</b>	ROS1+ NSCLC, NTRK+ solid tumors				
<b>Elzovantinib</b>	<b>MET</b>	NSCLC* <sup>7</sup>				
<b>BLU-945</b>	<b>EGFR mutant</b>	Gastric cancer/NSCLC*				
<b>ZL-1211</b>	<b>Claudin18.2</b>	NSCLC*				
<b>ZL-1218</b>	<b>CCR8</b>	Gastric/pancreatic cancer				
		Solid tumors <sup>8</sup>				
<b>Autoimmune Diseases</b>						
<b>VYVGART</b>	<b>FcRn</b>	gMG — <i>Approved in the United States, European Union, and Japan; BLA accepted in mainland China</i>				Greater China
		ITP				
		PV				
		CIDP				
		Bullous pemphigoid*				
		Lupus nephritis*				
<b>ZL-1102</b>	<b>IL-17</b>	Membranous nephropathy*				
		Psoriasis <sup>9</sup>				
<b>Infectious Diseases</b>						
<b>Sulbactam-Durlobactam</b>		Carbapenem-resistant <i>Acinetobacter</i> infections <sup>10</sup> — <i>NDA accepted in the United States, NDA accepted in mainland China</i>				Asia Pacific <sup>11</sup>
<b>Neuroscience</b>						
<b>KarXT</b>		Schizophrenia*				Greater China
		Alzheimer's Disease with Psychosis*				

Notes:

\* Greater China trial in preparation or under planning; (1) Reflects ongoing trials run by GSK, including a Phase III trial in non-small cell lung cancer (“NSCLC”); (2) Phase II pilot trial conducted in China; (3) New Drug Application (“NDA”) acceptance in mainland China in January 2022; (4) FDA accelerated approval in September 2021; (5) FDA accelerated approval in December 2022; (6) Global Phase III trial initiated; (7) Global Phase I/IIa trial ongoing; (8) Zai Lab expects to launch a global Phase I trial in the first half of 2023; (9) Achieved proof of concept in Phase Ib study in October 2021; (10) NDA was granted Priority Review in China in January 2023; (11) Includes Greater China, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand, and Japan. Please read this table in conjunction with the remainder of this annual report.

Abbreviations: B-NHL = B-cell non-Hodgkin lymphoma; GEJ = gastroesophageal junction; gMG = generalized myasthenia gravis; ITP = immune thrombocytopenia; PV = pemphigus vulgaris; CIDP = chronic inflammatory demyelinating polyneuropathy.

# BUSINESS

## OUR ONCOLOGY PIPELINE

### Additional Indications for ZEJULA

ZEJULA is a once-daily small-molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor.

As discussed above, we have the exclusive right to develop and commercialize ZEJULA in our licensed territories for all potential indications except prostate cancer pursuant to an exclusive license agreement with GSK. For more information on this collaboration and license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — GSK (Niraparib).

Our partner GSK is building a niraparib clinical development program by assessing activity across multiple tumor types and by evaluating several potential combinations of niraparib with other therapeutics. For the treatment of ovarian cancer, two Phase III studies, PRIMA and NOVA, have been completed to evaluate ZEJULA (niraparib) as monotherapy maintenance treatment in patients with first-line and recurrent ovarian cancer, respectively.

We continue to explore the use of ZEJULA, including the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy, and chemotherapy in clinically relevant indications.

### Additional Indications for Tumor Treating Fields

TTFields therapy is a cancer treatment that uses electric fields tuned to specific frequencies to disrupt cancer cell division.

As discussed above, we have an exclusive license from NovoCure to develop and commercialize Optune in Greater China in all human therapeutic and preventive uses in the field of oncology. For more information on this license and collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — NovoCure (Tumor Treating Fields).

NovoCure continues to test TTFields against a broad range of solid tumor types, including NSCLC, gastric cancer, and pancreatic cancer. We have enrolled, or intend to enroll, patients in Greater China in the various global trials for TTFields. The studies currently underway affect over 1.8 million new patients a year in China.

We are participating in the Phase III pivotal LUNAR trial, which is intended for patients who have recently been diagnosed with progression of NSCLC during or after platinum-based therapy. 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 2020 was 815,563 cases, with 714,699 deaths. In mainland China, the five-year survival rate of lung cancer is estimated to be about 20%. Lung cancer consists of NSCLC in approximately 85% of cases and small cell lung cancer in approximately 15% of cases. In January 2023, Zai Lab and NovoCure announced that the pivotal LUNAR study for patients with stage 4 NSCLC who progressed during or after platinum-based therapy met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival

when patients were treated with TTFIELDS and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFIELDS and docetaxel versus docetaxel alone. TTFIELDS therapy was well tolerated by patients enrolled in the experimental arm of the study.

We are participating in the EF-31 Phase II pilot study evaluating the safety and efficacy of TTFIELDS together with standard-of-care treatment (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric cancer. In June 2022, we and NovoCure announced that this study met its primary endpoint of objective response rate with supportive signals across secondary endpoints. TTFIELDS therapy was well tolerated, with no increase in the systemic toxicity of the XELOX chemotherapy regimen or the combination regimen, and no high-grade skin toxicities were reported. Initial analysis was conducted with a median follow-up period of 8.6 months. The primary endpoint, confirmed objective response rate (“cORR”), was 50%. Median progression-free survival was 7.8 months. Duration of response was 10.3 months. Median overall survival has not yet been reached with a one-year survival rate of 72%. Gastric cancer is the third most-frequent cancer in China. According to the World Health Organization, more than one million new gastric cancer cases are diagnosed worldwide in 2020, and approximately half of all gastric cancer cases occur in China. Currently, the five-year survival rate of locally advanced or metastatic gastric cancer ranges from 5% to 20%, and the median overall survival is approximately one year.

In March 2022, NovoCure announced the results of a pre-specified interim analysis for the global Phase III pivotal INNOVATE-3 study evaluating the safety and efficacy of TTFIELDS together with paclitaxel for the treatment of patients with platinum-resistant ovarian cancer. An independent data monitoring committee reviewed the safety data for all platinum-resistant ovarian cancer patients enrolled in the trial. The pre-specified interim analysis concluded that the INNOVATE-3 study should proceed to the final analysis as planned. Data will be reviewed in 2023, following an 18-month follow-up period.

We are participating in the PANOVA-3 Phase III pivotal trial of TTFIELDS for pancreatic cancer. In February 2023, NovoCure announced that the last patient has been enrolled in this study. PANOVA-3 is a global, open-label, randomized Phase III trial evaluating the efficacy of TTFIELDS administered concomitantly with gemcitabine and nab-paclitaxel as front-line treatment for patients with unresectable, locally advanced pancreatic cancer. The primary endpoint is overall survival. Secondary endpoints include progression-free survival, local progression-free survival, objective response rate, one-year survival rate, quality of life, pain-free survival, respectability rate, and toxicity. According to the World Health Organization, pancreatic cancer was the eighth-leading cancer type in mainland China in 2020, with an estimated 124,994 newly diagnosed cases and 121,853 deaths. The current median survival of patients with metastatic pancreatic cancer is four to six months, and the five-year survival rate is 7.2%, making it the malignancy with the lowest survival rate in mainland China.

We are also participating in the pivotal METIS study evaluating the efficacy of TTFIELDS therapy following stereotactic radiosurgery for treatment of patients with brain metastases resulting from NSCLC. In March 2023, NovoCure announced that the last patient has been enrolled in this study.

In September 2021, NovoCure announced that the FDA had granted breakthrough designation to the NovoTTF-200T System, a TTFIELDS delivery system, for use with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer. We expect to participate in the global Phase III study for liver cancer.

# BUSINESS

## **MARGENZA™ (margetuximab)**

Margetuximab is an investigational, immune-enhancing monoclonal antibody that targets HER2-expressing tumors, including certain types of breast and gastroesophageal cancers.

Since 2018, we have had an exclusive license from MacroGenics to develop and commercialize MARGENZA in Greater China in all human fields of use. For more information on the collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — MacroGenics (including Margetuximab and Tebotelimab).

In December 2020, the FDA approved MARGENZA for use in the United States, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

In January 2022, the NMPA accepted the NDA for review of margetuximab for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease, in combination with chemotherapy.

## **TIVDAK (tisotumab vedotin)**

TIVDAK is an antibody drug conjugate (“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 the microtubule-disrupting agent monomethyl auristatin E (“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 (“ADCP”) and antibody-dependent cellular cytotoxicity (“ADCC”).

Since September 2022, we have had an exclusive license from Seagen to develop and commercialize TIVDAK in Greater China. For more information on this collaboration and license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Seagen (TIVDAK).

In 2021, TIVDAK was approved in the United States for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy and is an important addition to our oncology portfolio. We are participating in the global Phase III confirmatory innovaTV 301 study in second- or third-line recurrent or metastatic cervical cancer, and we treated the first patient in China in February 2023.

## **KRAZATI™ (adagrasib)**

Adagrasib is a highly selective and potent oral small-molecule inhibitor of KRAS<sup>G12C</sup> for treating KRAS-G12C-mutated NSCLC, colorectal cancer (“CRC”), pancreatic cancer, and other solid tumors.

Since May 2021, we have had an exclusive license from Mirati to develop and commercialize adagrasib in Greater China. For more information on the collaboration and license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Mirati (Adagrasib).

Mirati is conducting several studies of adagrasib for the treatment of KRAS<sup>G12C</sup>-mutated NSCLC, CRC, pancreatic cancer, and other solid tumors. We have enrolled, or intend to enroll, patients in Greater China in various global trials for adagrasib.

In December 2022, the FDA approved adagrasib for the treatment of patients with NSCLC who harbor the KRAS<sup>G12C</sup> mutation who have received at least one prior systemic therapy.

Adagrasib was also granted accelerated approval by the FDA in December 2022 for adult patients with KRAS<sup>G12C</sup>-mutated locally advanced or metastatic NSCLC who have received at least one prior systemic therapy. We seek to leverage the global data package for the FDA approval, the ongoing PK study in China, and the global confirmatory KRYSTAL-12 study to obtain regulatory approval in China. We are participating in the global Phase III KRYSTAL-12 study and treated the first patients in Greater China in July 2022.

In December 2022, the FDA granted Breakthrough Therapy Designation to adagrasib in combination with cetuximab for the treatment of patients with KRAS<sup>G12C</sup>-mutated, advanced CRC whose cancer has progressed following prior treatment with chemotherapy and an anti-VEGF therapy. This designation is supported by results from the Phase Ib cohort of the KRYSTAL-1 trial. The FDA also granted accelerated approval for KRAZATI as a targeted treatment option for adult patients with KRAS<sup>G12C</sup>-mutated locally advanced or metastatic NSCLC who have received at least one prior systemic therapy. We will continue to participate in the global Phase III KRYSTAL-10 study, which we joined in June 2022.

For first-line NSCLC, we are participating in the global Phase II KRYSTAL-7 study of adagrasib in combination with pembrolizumab in first-line KRAS<sup>G12C</sup>-mutated NSCLC patients, and we treated the first patient in Greater China in August 2022. In December 2022, Mirati reported results from the KRYSTAL-7 Phase II trial and KRYSTAL-1 Phase Ib cohort evaluating adagrasib concurrent combined with pembrolizumab in patients for the treatment of first-line NSCLC harboring a KRAS<sup>G12C</sup> mutation across all PD-L1 subgroups. These results are the first to demonstrate the tolerability and feasibility of a concurrent combination regimen of a KRAS<sup>G12C</sup> inhibitor and a PD-1/L1 checkpoint inhibitor.

In September 2022, Mirati presented results from KRYSTAL-1, a multicohort Phase I/II study evaluating adagrasib with or without cetuximab in patients with advanced CRC harboring a KRAS<sup>G12C</sup> mutation. Of the evaluable patients in the adagrasib monotherapy cohort (n=43), the investigator assessed cORR was 19% (8/43), and the disease control rate (“DCR”) was 86% (37/43). The median duration of response (“mDOR”) was 4.3 months (95% CI, 2.3–8.3), and median progression-free survival (“mPFS”) was 5.6 months (95% CI, 4.1–8.3). Of the evaluable patients in the adagrasib plus cetuximab combination cohort (n=28), the investigator assessed cORR was 46% (13/28), and the DCR was 100% (28/28). The mDOR was 7.6 months (95% CI 5.7–NE), and mPFS was 6.9 months (95% CI, 5.4–8.1). The prognosis for patients with CRC has historically been poor in later lines of therapy with response rates of approximately 1–2% and mPFS of approximately 2 months in patients with late-line CRC; patients with KRAS<sup>G12C</sup>-mutated CRC tend to have even worse outcomes than the broader CRC patient population. In the overall subset of patients with KRAS<sup>G12C</sup>-mutated CRC evaluated in this study, adagrasib was found to be well-tolerated as a monotherapy and in combination with cetuximab. The majority of observed treatment-related adverse events (“TRAEs”) were grade 1-2 (59%); no grade 5 TRAEs were observed.

## BUSINESS

In June 2022, Mirati presented full results from the registration-enabling Phase II cohort of the KRYSTAL-1 study evaluating adagrasib in patients with previously treated NSCLC harboring a KRAS<sup>G12C</sup> mutation. This presentation included results from a retrospective subgroup analysis from the Phase II NSCLC cohort of the KRYSTAL-1 study evaluating adagrasib in patients with KRAS<sup>G12C</sup>-mutated NSCLC and stable, previously treated central nervous system (“CNS”) metastases. The initial clinical results from the Phase II registration-enabling study (n=112) showed that the objective response rate (“ORR”) was 43%, the DCR was 80%, the mDOR was 8.5 months (95% confidence interval (“CI”): 6.2–13.8), and the mPFS was 6.5 months (95% CI: 4.7–8.4). With a January 15, 2022 data cutoff, the median overall survival (“mOS”) was 12.6 months (95% CI: 9.2–19.2). With respect to CNS-specific activity in a subset analysis of stable, previously treated CNS metastases (n=33), results revealed an intracranial (“IC”) ORR of 33% (11/33). Mirati also reported updated findings from a pooled analysis from the KRYSTAL-1 study, including the registrational Phase II and Phase I/Ib NSCLC cohorts. The initial results of the pooled analysis of KRYSTAL-1 NSCLC cohorts (n=132) showed that the ORR was 44%, the DCR was 81%, the mDOR was 12.5 months, and the mPFS was 6.9 months. With a January 15, 2022 data cutoff, the mOS was 14.1 months.

In June 2022, Mirati also announced the results of a prospective analysis from the Phase Ib cohort of the KRYSTAL-1 study evaluating IC responses of adagrasib in patients with KRAS<sup>G12C</sup>-mutated advanced NSCLC with active and untreated CNS metastases. The results of the CNS-specific activity in active and untreated CNS metastases (n=19) showed an IC ORR of 32% (6/19).

In January 2022, Mirati announced positive results from a Phase II cohort of the KRYSTAL-1 study evaluating adagrasib at the 600mg BID dose in patients with pretreated pancreatic ductal adenocarcinoma and other gastrointestinal (“GI”) tumors harboring a KRAS<sup>G12C</sup> mutation, including cancers of the biliary tract, appendix, small bowel, gastro-esophageal junction, and esophagus. Results showed that adagrasib demonstrated significant clinical activity and broad disease control. Of the evaluable patients (n=27), the ORR was 41% and the DCR was 100%. In the overall subset of patients with KRAS<sup>G12C</sup>-mutated GI cancers evaluated in this cohort, adagrasib was well-tolerated, with a manageable safety profile.

### **Bemarituzumab**

Bemarituzumab is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor that is in clinical development as a targeted therapy for gastric and GEJ cancer patients whose tumors overexpress FGFR2b.

Since 2017, we have had an exclusive license from Five Prime Therapeutics, Inc. (“Five Prime”) (a company later acquired by Amgen) to develop and commercialize bemarituzumab in Greater China for the treatment or prevention of any disease or condition in humans. For more information on this license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Amgen (Bemarituzumab).

In September 2021, the Center for Drug Evaluation of the NMPA (“CDE”) granted Breakthrough Therapy Designation for bemarituzumab (FPA144) for first-line treatment for patients with FGFR2b-overexpressing and human epidermal growth factor receptor 2 (“HER2”)-negative metastatic and locally advanced gastric and GEJ cancers in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).

Amgen is conducting a registrational Phase III program for bezarituzumab in first-line advanced gastric and GEJ cancer. This program is evaluating bezarituzumab in combination with either backbone chemotherapy or chemotherapy plus a checkpoint inhibitor. We plan to join the global Phase 3 FORTITUDE-101 study in first-line gastric cancer in China in mid-2023.

Amgen continues to enroll patients in several studies of bezarituzumab, including: FORTITUDE-101, a Phase III study of bezarituzumab plus chemotherapy, versus placebo plus chemotherapy in first-line gastric cancer with FGFR2b overexpression, and FORTITUDE-102, the Phase III portion of the Ib/III study of bezarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer with FGFR2b overexpression. We expect to join the global Phase III FORTITUDE-101 study in China around mid-2023.

In the second quarter of 2022, Amgen reported that the final analysis of the FIGHT study, a Phase II randomized, double-blind, controlled study evaluating bezarituzumab and modified FOLFOX6 (“mFOLFOX6”) in patients with previously untreated advanced gastric and gastroesophageal junction cancer was completed, with results continuing to demonstrate that bezarituzumab + mFOLFOX6 improves the clinical outcome of patients with FGFR2b expressing tumors with no new safety concerns and noting that a greater survival benefit was observed with increasing FGFR2b expression levels. In addition, Amgen initiated a Phase Ib/II FORTITUDE-310 study evaluating the safety and efficacy of bezarituzumab monotherapy in solid tumors with FGFR2b overexpression.

## **Odronextamab**

Odronextamab is an investigational bispecific monoclonal antibody designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20). Odronextamab has demonstrated clinical activity in heavily pre-treated patients with late stages of follicular lymphoma (“FL”), diffuse large B-cell lymphoma (“DLBCL”), and other B-cell lymphomas in a Phase I trial and is currently being investigated in a potentially registrational Phase II program.

Since April 2020, we have had an exclusive license from Regeneron Ireland Designated Activity Company, an affiliate of Regeneron, to develop and commercialize odronextamab for oncology in Greater China. For more information on the collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Regeneron (Odronextamab).

We have received Clinical Trial Application (“CTA”) approval in mainland China for, and have joined, the open-label, multi-center, global, registrational Phase II program evaluating the efficacy and safety of odronextamab in several disease-specific cohorts, including patients with relapsed/refractory (“R/R”) FL and DLBCL. In December 2022, Regeneron announced positive first interim data from the ELM-2 Phase II trial in patients with heavily pre-treated, R/R FL and DLBCL. The data were presented at the 64th American Society of Hematology Annual Meeting. In the FL cohort, odronextamab showed the highest CR rates observed in this late-stage setting to date. In the DLBCL cohort, the ORRs are comparable in patients regardless of CAR-T experience. The modified step-up dosing regimen appears to demonstrate an improved safety profile with consistent efficacy resulting in lower rates of treatment discontinuations, interruptions, dose reductions, and dose delay. There is zero Gr3+ CRS event for both the FL and DLBCL cohorts.



# BUSINESS

## Repotrectinib

Repotrectinib is an investigational next-generation tyrosine kinase inhibitor (“TKI”) designed to effectively target ROS1 and TRK A/B/C in TKI-naïve or TKI-pretreated cancer patients.

Since July 2020, we have had an exclusive license from Turning Point Therapeutics (a company later acquired by BMS) to develop and commercialize repotrectinib in Greater China in all human therapeutic indications. For more information on this license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — BMS (Repotrectinib).

The FDA has granted two Breakthrough Therapy Designations for repotrectinib for:

- Patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with one or two prior TRK TKIs, with or without prior chemotherapy, and have no satisfactory alternative treatments;
- Patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI.

The FDA has also granted four Fast-Track designations for repotrectinib for:

- Patients with ROS1-positive advanced NSCLC who have not been previously treated with a ROS1 TKI;
- Patients with ROS1-positive advanced NSCLC who have been previously treated with one prior line of platinum-based chemotherapy and one prior ROS1 TKI;
- Patients with ROS1-positive advanced NSCLC pretreated with one prior ROS1 TKI without prior platinum-based chemotherapy; and
- Patients with advanced solid tumors who have an NTRK gene fusion and who have progressed following treatment with at least one prior line of chemotherapy and one or two prior TRK TKIs and have no satisfactory alternative treatments.

Repotrectinib was also granted Orphan Drug Designation by the FDA in 2017.

We are participating in the global TRIDENT-I study for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI. In April 2022, we announced topline data for repotrectinib within the China region from the previously disclosed Phase I/II TRIDENT-1 study dataset.

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



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

In October 2022, Turning Point provided a clinical data update from the global, registrational Phase I/II TRIDENT-1 study of repotrectinib. Repotrectinib continued to demonstrate meaningful clinical activity in patients with ROS1+ advanced NSCLC, who were TKI-naïve or TKI-pretreated, including with ROS1 G2032R resistance mutation. Durable responses and intracranial efficacy were observed in both TKI-naïve and TKI-pretreated patients. Repotrectinib also continued to show clinical activity in patients with NTRK+ advanced solid tumors who were TKI-naïve or TKI-pretreated, and responses were seen across diverse tumor types. Safety is well characterized, manageable with known protocols, and signals potential compatibility with long-term use. Also in October 2022, we completed enrollment in China in all cohorts of the registrational Phase I/II TRIDENT-1 study.

In February 2022, the CDE of the NMPA granted Breakthrough Therapy Designation for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI. The breakthrough therapy designation was supported by the initial data from both global and Chinese TKI-naïve ROS1-positive NSCLC patients enrolled in the Phase I/II TRIDENT-1 study. In June 2022, the CDE of the NMPA granted two additional Breakthrough Therapy Designations for investigational repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and one prior line of platinum-based chemotherapy and for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and no chemotherapy or immunotherapy. These Breakthrough Therapy Designations were supported by the data from both global and Chinese TKI-pretreated ROS1-positive NSCLC patients enrolled in the Phase I/II TRIDENT-1 study. We discussed with the NMPA the regulatory pathway at a pre-NDA meeting in March 2023 and expect to submit an NDA to the NMPA for ROS1+ advanced NSCLC in 2023.

### **Zipalertinib (previously CLN-081)**

Zipalertinib (previously CLN-081) is an orally available small molecule designed as a next-generation, irreversible epidermal growth factor receptor (“EGFR”) inhibitor in development by Cullinan Pearl, a subsidiary of Cullinan Oncology, Inc., for the treatment of patients with EGFR exon 20 insertion NSCLC.

## BUSINESS

Since December 2020, we have had an exclusive license from Cullinan Pearl (a company later acquired by Taiho) for the research, development, manufacturing, and commercialization of Ziplertinib in Greater China in all uses in humans and animals. For more information on this license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Taiho (Ziplertinib).

In January 2022, Cullinan Oncology announced that the FDA had granted Breakthrough Therapy Designation for CLN-081 for the treatment of patients with locally advanced or metastatic NSCLC harboring EGFR exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy.

Cullinan Pearl is conducting a Phase I/IIa dose escalation and expansion trial evaluating oral, twice-daily administration of various doses of CLN-081 in patients with NSCLC harboring EGFR exon 20 insertion mutations who have had at least one prior treatment with platinum-based chemotherapy or another approved standard therapy. In June 2022, Cullinan Oncology presented updated data from this study. Of the 39 patients in the 100 mg BID dose group: 16 (41%) had a confirmed PR; the estimated mDOR was greater than 21 months; mPFS was 12 months; and the safety profile of CLN-081 was amenable for long-term treatment.

Taiho initiated a pivotal study of ziplertinib in patients with EGFR exon 20 insertion NSCLC progressing after prior systemic therapy in the fourth quarter of 2022.

### **Elzovantinib (TPX-0022)**

Elzovantinib is an orally bioavailable multi-targeted kinase inhibitor with a novel three-dimensional macrocyclic structure that inhibits the MET, CSF1R (colony stimulating factor 1 receptor), and SRC kinases.

In January 2021, we entered into an exclusive license agreement with Turning Point to develop and commercialize elzovantinib in Greater China. For further details of the exclusive license, see Business — Overview of Significant License and Strategic Collaboration Agreements — BMS (TPX-0022).

### **ZL-2313 (BLU-945)**

BLU-945 is a selective and potent investigational oral EGFR inhibitor designed to selectively target the EGFR L858R activating mutation as well as C797X and T790M on-target resistance mutations, while being highly selective against wild-type EGFR. BLU-945 is in development for the potential treatment of EGFR-mutant NSCLC.

Since November 2021, we have had an exclusive license from Blueprint to develop and commercialize BLU-945 and BLU-701 and certain other forms thereof, including backup compounds, in mainland China. For more information on this license and collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Blueprint (BLU-945 and BLU-701).

In April 2022, Blueprint announced the proof-of-concept data from the Phase I/II SYMPHONY clinical trial of BLU-945 in advanced EGFR-driven NSCLC patients at the 2022 American Association for Cancer Research (“AACR”) Annual Meeting. The preliminary trial results showed early evidence of safety and clinical activity consistent with preclinical data, supporting plans to expand development of BLU-945 in combination with multiple agents including Osimertinib. Blueprint Medicines is initiating a cohort in the ongoing Phase I/II SYMPHONY trial assessing BLU-945 in combination with osimertinib in patients with second-line or later EGFR-mutant NSCLC. In November 2022, Blueprint presented an update on the Phase I/II SYMPHONY trial data supporting plans to develop BLU-945 in combination with osimertinib in first-line EGFR L858R mutation-positive NSCLC. We expect an initial clinical data update on the SYMPHONY trial expansion of BLU-945 in combination with osimertinib in first-line EGFR L858R-positive NSCLC in the second half of 2023.

## **ZL-1211 (Claudin18.2)**

ZL-1211 is a humanized, IgG1 monoclonal antibody engineered to promote enhanced ADCC that specifically targets CLDN18.2. In preclinical models, ZL-1211 has achieved more potent activity in a wider spectrum of high- and low-CLDN18.2 expressing tumors than other agents in the class. CLDN18.2 has recently emerged as a novel target for gastric cancer and a promising target for therapeutic intervention.

In January 2022, we initiated dosing of a Phase I clinical trial for ZL-1211 in patients with advanced solid tumors. Depending on the results of this trial, we may proceed with a Phase II clinical trial.

## **ZL-1218 (CCR8)**

ZL-1218 is humanized, IgG1 monoclonal antibody that binds to human CCR8 with high affinity and specificity to induce potent ADCC activity enabling strong NK cell-mediated killing of CCR8-expressing T-regs. In preclinical models, we show that in human CCR8 knock-in mouse models bearing syngeneic tumors, ZL-1218 reduces intra-tumoral T-reg cells and thus elicits significant tumor growth inhibition in a dose dependent manner. Preclinical studies also suggest the potential of ZL-1218 in combination immunotherapy, with enhanced anti-tumor activity when ZL-1218 is combined with an anti-PD-1 agent.

We expect to initiate a global Phase I clinical trial for ZL-1218 as monotherapy and in combination with an anti-PD1 mAb in the first half of 2023.

## **OUR AUTOIMMUNE DISORDER PIPELINE**

### **VYVGART® (Efgartigimod)**

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (“IgG”) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (“FcRn”), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation.

# BUSINESS

Since January 2021, we have had an exclusive license from argenx to develop and commercialize efgartigimod in Greater China. For more information on this collaboration and license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — argenx (Efgartigimod).

In December 2021, the FDA approved efgartigimod for the treatment of generalized myasthenia gravis (“gMG”) in adult patients who are anti-acetylcholine receptor (“anti-AchR”) antibody positive, and it was approved for the same indication in Europe in August 2022. These patients represent approximately 85% of the total gMG population. In January 2022, efgartigimod was approved for intravenous use for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies by Japan’s Ministry of Health, Labour, and Welfare.

In November 2022, the FDA accepted for priority review a Biologics License Application (“BLA”) for subcutaneous (“SC”) efgartigimod for the treatment of adult patients with gMG who are anti-AchR antibody positive. The Prescription Drug User Fee Act date is June 20, 2023.

In June 2022, efgartigimod was introduced to the Hainan Bo’ao Lecheng International Medical Tourism Pilot Zone (“BMTMZ”), and the first Chinese patient was treated with efgartigimod. In July 2022, the NMPA accepted our NDA for efgartigimod alfa injection for the treatment of adult patients with gMG in mainland China. This NDA was supported by two pharmacokinetic studies we conducted in Greater China.

As of December 31, 2022, VYVGART had been listed in 15 supplemental insurance plans in China.

We are participating in the Greater China portion of several studies evaluating efgartigimod, including the registrational ADHERE study of SC efgartigimod in adult patients with chronic inflammatory demyelinating polyneuropathy (“CIDP”), Phase III ADDRESS study of efgartigimod in patients with pemphigus vulgaris or pemphigus foliaceus, and Phase III ADVANCE-SC study of SC efgartigimod in patients with primary immune thrombocytopenia (“ITP”). In addition, in February 2023, we initiated enrollment of two proof-of-concept trials in autoimmune renal diseases.

## **ZL-1102 (IL-17)**

ZL-1102 is a human Humabody® targeting the interleukin-17A, or IL-17A, cytokine with high affinity and avidity. It is a Vh fragment of the human IgG and about 1/10th of the molecular weight of a full IgG. This feature may enable enhanced penetration of the psoriatic skin barrier compared to the current marketed anti-IL17 antibodies, thereby potentially avoiding the toxicities observed by systemic exposure. In May 2018, we entered into an exclusive worldwide license agreement with Crescendo Biologics Limited to develop, manufacture and commercialize CB001 Humabody®, an antibody VH domain therapeutic.

The accepted approach to treatment for mild to moderate chronic plaque psoriasis is different from that for moderate to severe psoriasis. For mild to moderate psoriasis patients, topical treatment is often the first-line choice, and dermatologists tend to avoid systemic treatment. For patients with moderate to severe disease, the use of systemic treatments is usually preferred, and dermatologists often choose IL-17 monoclonal antibodies because they result in excellent response rates. However, therapy with systemic IL-17 antibodies can result in safety issues due to immunosuppression; therefore, labeling is restricted to more severely affected patient populations. As with other full-size monoclonal antibodies, current IL-17-directed antibodies must be administered by intravenous or SC injection. It is conventionally assumed that antibodies and other macromolecules do not penetrate skin.

We are conducting a randomized, double-blind, placebo-controlled Phase Ib proof-of-concept patient study showing that our formulation of ZL-1102, topically applied to lesions, can penetrate psoriatic plaques. Despite a short treatment course (1 month), these changes affected the lesional PASI score which may be indicative of early clinical benefit. In September 2022, we presented results of the Phase 1 proof-of-concept study for ZL-1102 at the 2022 European Academy of Dermatology and Venereology Congress in Milan, Italy. We plan to move ZL-1102 into full global development and initiate a global Phase II study for chronic plaque psoriasis. Our initial plans to initiate the global Phase II study were delayed as manufacturing issues resulted in a program delay. We now anticipate starting this study in 2023.

## OUR INFECTIOUS DISEASE PIPELINE

### Sulbactam/Durlobactam (SUL-DUR)

Sulbactam/durlobactam (“SUL-DUR”) is a combination of a beta-lactam antibiotic (“sulbactam”) and a beta-lactamase inhibitor (“durlobactam”) for the treatment of serious infections caused by *Acinetobacter*, including multidrug-resistant (“MDR”) and carbapenem-resistant strains. *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, *A. baumannii* has become multi-drug resistant, including resistant to the penem class of antibiotics. There are few non-toxic and effective antibiotics left for clinicians. In China, *Acinetobacter baumannii* infections are often seen in the hospital setting, and approximately 54% of such infections are the result of *Acinetobacter baumannii* MDR isolates and carbapenemase-producing isolates (“carbapenem-resistant *Acinetobacter baumannii*” or “CRAB”).

Since April 2018, we have had an exclusive license from Entasis to develop and commercialize durlobactam with sulbactam (the combination, SUL-DUR) 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. For more information on this license and collaboration agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Entasis (SUL-DUR).

In September 2017, the FDA granted SUL-DUR Qualified Infectious Disease Product, Fast-Track and Priority Review status for the treatment of hospital-acquired and ventilator-acquired bacterial pneumonia and bloodstream infections due to *Acinetobacter*. We completed a pharmacokinetic study in the fall of 2020 for SUL-DUR in mainland China in normal healthy volunteers.

## BUSINESS

Entasis submitted an NDA to the FDA in September 2022, which was accepted for priority review with an action date of May 29, 2023. We submitted an NDA to the NMPA in December 2022 for the treatment of infections caused by *Acinetobacter baumannii*, including multidrug-resistant and CRAB strains, which was granted priority review status in January 2023 and accepted in February 2023.

We are participating in the global Phase III registrational ATTACK trial evaluating the safety and efficacy of SUL-DUR versus colistin in patients with infections caused by *Acinetobacter baumannii*. In April 2022, Entasis announced topline results from the ATTACK trial at the 32nd European Congress of Clinical Microbiology and Infectious Diseases Annual Conference in Lisbon, Portugal. The primary efficacy endpoint was met, and the study showed a reduced mortality rate with SUL-DUR versus colistin in the CRAB population. The primary efficacy endpoint, 28-day all-cause mortality in the CRAB-calcoaceticus (“CRABC”) m-MITT cohort (those in the ITT population who received any study drug and had a CRABC organism isolated at baseline) (n=125) was 19.0% (12/63) and 32.3% (20/62) for SUL-DUR versus colistin, respectively (difference -13.2% [95% CI: -30.0%, 3.5%]). At Test of Cure, there was a statistically significant difference in clinical response favoring SUL-DUR over colistin. The clinical cure rates at test-of-cure were 61.9% (39/63) and 40.3% (25/62) for SUL-DUR versus colistin (difference 21.6% [95% CI: 2.9%, 40.3%]). SUL-DUR also met the primary safety objective of the study achieving statistically significant reduction in nephrotoxicity. A statistically significant reduction in nephrotoxicity was observed with SUL-DUR compared to colistin: 13.2% (12/91) versus 37.6% (32/85) (difference -24.4% [p=0.0002]). Treatment-related TEAEs were 12.1% (11/91) and 30.2% (26/86) in the SUL-DUR and colistin groups, respectively. In October 2022, Entasis presented additional safety and efficacy data at the annual meeting of the Infectious Disease Society of America that reinforced the positive safety and efficacy data Entasis had previously disclosed from its topline data analysis.

## OUR NEUROSCIENCE PIPELINE

### KarXT (xanomeline-trospium)

KarXT (xanomeline-trospium) is an oral, investigational M1/M4-preferring muscarinic acetylcholine receptor agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia and dementia-related psychosis. KarXT preferentially stimulates muscarinic receptors in the central nervous system 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 dementia-related psychosis based on its differentiated mechanism of action.

Since November 2021, we have had an exclusive license from Karuna to develop, manufacture, and commercialize KarXT in Greater China. For more information on this license agreement, see Business — Overview of Significant License and Strategic Collaboration Agreements — Karuna (KarXT).

In the third quarter of 2022, Karuna initiated the Phase 3 ADEPT-1 study evaluating KarXT as a treatment for psychosis in Alzheimer’s disease. In the fourth quarter of 2022, Karuna completed enrollment in the Phase 3 EMERGENT-3 trial in schizophrenia and presented data from the Phase 3 EMERGENT-2 trial of KarXT in schizophrenia at the 35th European College of Neuropsychopharmacology Congress in Vienna, Austria. A poster presentation and symposium included previously reported efficacy and safety data, as well as new additional safety data from the trial.

In the fourth quarter of 2022, we initiated a bridging study for KarXT, and we obtained agreement from the NMPA on the development plan for a clinical trial in China to start in mid-2023.

### **Internally Discovered and Internally Developed Product Candidates**

We have assembled an integrated drug discovery and development team with extensive experience in discovery, translational medicine, and pre-clinical and clinical development and who have been directly involved in the discovery and development of several innovative product candidates. We identify pre-clinical assets through both internal-discovery efforts and co-development collaboration with our business partners. Through these efforts, we have advanced our internally developed pipeline, which includes three product candidates that are currently in global Phase I development. In addition to the internally developed and internally discovered product candidates in clinical development mentioned above (ZL-1211, ZL-1218, and ZL-1102), Zai has internally discovered and developed compounds in preclinical development, including ZL-2201, a potent selective inhibitor of DNA-PK involved in DNA damage repair in tumor cells; and multiple other undisclosed compounds.

## **OVERVIEW OF SIGNIFICANT LICENSE AND STRATEGIC COLLABORATION AGREEMENTS**

### **GSK (Niraparib)**

In September 2016, we entered into a collaboration, development, and license agreement with Tesaro, Inc., 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, 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.

To date, we have made an upfront payment of \$15.0 million and have paid \$16.5 million in development, regulatory, and sales-based milestones, including a \$1.0 million development milestone payment accrued in 2020 and made in 2021, a \$4.0 million milestone payment made in 2022, and a \$3.5 million development milestone and \$8.0 million sales-based milestone paid in 2022, which were accrued in 2019 and 2021, respectively. We may be required to pay an additional aggregate amount of up to \$28.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid- to high-teens on annual net sales of the licensed products in the licensed territory.



## BUSINESS

We are not obligated to purchase ZEJULA or other licensed products from GSK. We have entered into a separate supply agreement pursuant to which GSK manufactures and supplies ZEJULA to us for commercial use in Hong Kong. Unless terminated earlier pursuant to its terms, the agreement with GSK will remain in effect until the expiration of the royalty term for ZEJULA, where the royalty term for ZEJULA in a region continues until the latest of (i) the expiration of the last-to-expire valid claim within the licensed patent rights that covers the licensed product in such region; (ii) the expiration of market or data exclusivity for such licensed product in such region; or (iii) ten (10) years after the date of the first commercial sale of such licensed product in such region. The agreement may be terminated for customary reasons, including upon the other party's uncured material breach, bankruptcy, insolvency, or similar event. In addition, we have the right to terminate the agreement for convenience at any time, subject to a certain notice period.

### **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 Tumor Treating Fields products in all human therapeutic and preventative uses in the field of oncology in Greater China.

To date, we have made an upfront payment of \$15.0 million and two milestone payments totaling \$10.0 million in 2020. We may be required to pay an additional aggregate amount of up to \$68.0 million in development, 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.

We will purchase licensed products exclusively from NovoCure. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of the last royalty term and payment by us of all of our royalty payment obligations applicable to such licensed product and such region, where the royalty term for a licensed product in a region continues until the latest of (i) the expiration of the last-to-expire valid claim within licensed patent rights covering such licensed products (including composition, method of use or making) in such region, (ii) the expiration of regulatory exclusivity of such licensed product, and (iii) the tenth (10th) anniversary of the first commercial sale of such licensed product in such region. In addition, either party may terminate the agreement upon the material breach of the agreement by the other party, subject to a certain cure period, or for the other party's bankruptcy or insolvency. We may terminate the agreement for convenience, subject to a certain notice period, and NovoCure may terminate the agreement under specified circumstances if we or our affiliates or sublicensees challenge its patent rights or due to our certain development or commercialization diligence failures, subject to a certain cure period and dispute resolution mechanisms if disputes arise with respect to such failures.

### **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 in the field of prevention, prophylaxis, treatment, cure, or amelioration of any disease or medical condition in humans in Greater China.



To date, we have made an upfront payment of \$20.0 million and three milestone payments totaling \$12.0 million. We 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.

We will purchase the licensed products exclusively from Deciphera. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such licensed product and such region, where the royalty term for a licensed product in a region continues until the latest of (i) the abandonment, expiry, or final determination of invalidity of the last valid claim within the licensed patents rights that covers the composition of matter, formulations or a method of making or use of such licensed product in such region, (ii) the expiration of regulatory exclusivity for such licensed product in such region, or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of such licensed product in such region. Subject to the terms of the agreement, we may terminate the agreement for convenience by providing written notice to Deciphera, which termination will be effective following a prescribed notice period. In addition, Deciphera may terminate the agreement under specified circumstances if we or certain other parties challenge Deciphera's patent rights, or if we or our affiliates do not conduct certain development activities with respect to one or more licensed products for a specified period of time, subject to specified exceptions. Either party may terminate the agreement for the other party's uncured material breach of a material term of the agreement, with a customary notice and cure period, or insolvency. After termination (but not natural expiration), Deciphera is entitled to retain a worldwide and perpetual license from us to develop, manufacture, and commercialize the licensed products. On a region-by-region and a licensed product-by-licensed product basis, upon the natural expiration of the agreement as described above, the licenses granted by Deciphera to us under the agreement in such region with respect to the licensed product become fully paid-up, perpetual, and irrevocable. In January 2020, we entered into an amendment with Deciphera to clarify several operational matters.

### **Paratek (Omadacycline)**

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda Ltd., a subsidiary of Paratek, pursuant to which we obtained both an exclusive license under certain patents and know-how of Paratek Bermuda Ltd. and an exclusive sub-license under certain intellectual property that Paratek Bermuda Ltd. licensed from Tufts University to develop, manufacture, and commercialize products containing omadacycline (ZL-2401) as an active ingredient in Greater China in the field of all human therapeutic and preventative uses other than biodefense. Under certain circumstances, our exclusive sub-license to certain intellectual property Paratek Bermuda Ltd. licensed from Tufts University may be converted to a non-exclusive license if Paratek Bermuda Ltd.'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 Bermuda Ltd.'s partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek Bermuda Ltd. retains the right to manufacture the licensed product in our licensed territory to support development and commercialization of the same outside our licensed territory. We also granted to Paratek Bermuda Ltd. 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.

## BUSINESS

To date, we have made an upfront payment of \$7.5 million and three milestone payments totaling \$14.0 million. We may be required to pay an additional aggregate amount of up to \$40.5 million in 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.

We have the right to manufacture the licensed products for commercialization in the licensed territory. The agreement with Paratek Bermuda Ltd. will remain in effect until, on a region-by-region basis, the expiration of the royalty term and payment by us of all of our royalty payment obligations in such region, where the royalty term for a licensed product in a region continues until the later of (i) the abandonment, expiration or invalidation of the last-to-expire valid claim within the licensed patents covering the licensed product, or (ii) the close of business of the eleventh (11th) anniversary of the first commercial sale of the licensed product in such region. In addition, either party may terminate this agreement for the other party's uncured material breach, subject to a certain cure period, or for the other party's bankruptcy or insolvency. We have the right to terminate the agreement for convenience at any time, subject to a certain notice period. Paratek Bermuda Ltd. has the right to terminate the agreement if we or our affiliates or sublicensees challenge its patents. Upon termination of the agreement, our license of certain intellectual property to Paratek Bermuda Ltd. will continue for Paratek Bermuda Ltd. to develop, manufacture, and commercialize licensed products worldwide.

### **MacroGenics (including Margetuximab and Tebotelimab)**

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

To date, we have made an upfront payment of \$25.0 million and three milestone payments totaling \$9.0 million, including \$4.0 million paid in 2020 and \$5.0 million accrued in 2021 but paid in 2022. We may be required to pay an additional aggregate amount of up to \$84.0 million in development and regulatory milestones as well as certain royalties at tiered percentage rates ranging from mid-teens to twenty for margetuximab, mid-teens for tebotelimab, and low-teens for the TRIDENT molecule on annual net sales of the licensed products in the licensed territory. The tebotelimab program was terminated in 2022, but we continue to collaborate with respect to the other licensed products.

We will purchase licensed products exclusively from MacroGenics. The collaboration agreement continues in effect until the expiration of the last royalty term under the collaboration agreement, where the royalty term for a licensed product in a region continues until the latest of (i) the expiration of the last-to-expire valid claim within licensed patent rights covering the composition, manufacture, use, sale, or importation of such licensed products in such region, (ii) the expiration of data exclusivity for such licensed product in such region, or (iii) the twelfth (12th) anniversary of the first commercial sale of such licensed product in such region. In addition, either party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party, subject to certain cure periods. At any time after November 29, 2020, we may terminate the collaboration agreement for convenience, subject to a certain notice period. MacroGenics may terminate the collaboration agreement in its entirety or on a licensed

product-by-licensed product or region by region basis with a certain notice period if one or more major safety issues have occurred with respect to such licensed product prior to the first commercial sale of such licensed product in the territory and MacroGenics has discontinued the global development, manufacturing, and commercialization activities with respect to such licensed product and publicly announced it.

On June 15, 2021, we entered into another collaboration and license agreement with MacroGenics, pursuant to which we and MacroGenics agreed to collaboratively develop and commercialize up to four bispecific antibody-based molecules based on the MacroGenics' proprietary DART® and TRIDENT® multi-specific technology platforms. Under the agreement, each party agrees to contribute specified intellectual property to enable the research, development, manufacture, and commercialization of up to four future CD3 or CD47-based bispecific molecules. We were granted exclusive rights in Greater China, Japan, and Korea for two programs and exclusive global rights for two other programs.

To date, for all four programs, we have made an upfront payment of \$25.0 million in 2021. Further, on June 15, 2021, as partial consideration for the rights granted to us under this agreement, we entered into a stock purchase agreement with MacroGenics, pursuant to which we purchased from MacroGenics in a private placement an aggregate of 958,467 newly issued shares of common stock, par value \$0.01 per share, of MacroGenics, with a per share purchase price of \$31.30, for aggregate gross proceeds of approximately \$30.0 million. We may be required to pay an additional aggregate amount of up to \$1,386.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual net sales of specified products, subject to reduction under specified circumstances. We also have an option to convert the royalty arrangement for the lead research molecule to a global 50/50 profit and loss sharing arrangement by making a payment of approximately \$85.0 million.

This agreement will generally terminate on a program-by-program and country-by-country or region-by-region basis, with certain exceptions, upon the later to occur of (i) the date that is 12 years after the date of the first commercial sale of the product in the applicable country or region, (ii) the date of expiration of the last valid claim covering such product with a licensed patent in the applicable country or region, and (iii) the expiration date of any data exclusivity period for such product in the applicable country or region. For certain programs, we may terminate the agreement, in whole or in part, after the second or fourth anniversary of the date of the agreement by providing 90 days' written notice to MacroGenics and, upon other conditions, after the second anniversary of the date of the agreement with 180 days' written notice to MacroGenics. MacroGenics may terminate the agreement on a collaboration product-by-collaboration product upon 90 days' written notice if a major safety issue has occurred with respect to a collaboration product. Either party may terminate the agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, MacroGenics may terminate the agreement if we challenge the licensed patent rights.

### **Seagen (TIVDAK)**

On September 23, 2022, we entered into a collaboration and license agreement with Seagen, pursuant to which we and Seagen agreed to collaboratively develop and commercialize TIVDAK (tisotumab vedotin). Under the agreement, we obtained an exclusive license to develop and commercialize TIVDAK in Greater China.

## BUSINESS

To date, we have made an upfront payment of \$30.0 million in 2022. We may be required to pay an additional aggregate amount of up to \$263.0 million in development, regulatory, and sales-based milestones 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 the licensed territory. The agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The agreement contains 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, for certain bankruptcy events, and by Seagen upon a challenge of the licensed patent rights.

### **Mirati (Adagrasib)**

In May 2021, we entered into a collaboration and license agreement with Mirati pursuant to which we and Mirati agreed to collaboratively develop MRTX849 (adagrasib) in Greater China. Under the agreement, we received from Mirati the right to research, develop, manufacture, and exclusively commercialize adagrasib in all indications in Greater China, with Mirati retaining exclusive rights for the development, manufacturing, and commercialization of adagrasib outside Greater China and certain co-commercialization, manufacture, and development rights in Greater China.

To date, we have made an upfront payment of \$65.0 million in 2021 and two development milestone payments totaling \$10.0 million in 2022. We may be required to pay an additional aggregate amount of up to \$263.0 million in clinical, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from the high-teens to low-twenties on annual net sales of the licensed products in the licensed territory.

The agreement will terminate on a licensed product-by-licensed product basis and on a region-by-region basis in Greater China, upon the later to occur of (i) the date of expiration of the last valid claim covering such licensed product in such region, (ii) the date that is 10 years after the date of the first commercial sale in such region, and (iii) the expiration date of any regulatory exclusivity for such licensed product in such region, or for a co-commercialized product on the date the parties agree to terminate such co-commercialization, or in its entirety upon the expiration of all payment obligations under this agreement. We may terminate the agreement at any time by providing 12 months' prior notice to Mirati. Either party may terminate the agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Mirati may terminate the agreement if we challenge the licensed patent rights.

### **Amgen (Bemarituzumab)**

In December 2017, we entered into a license and collaboration agreement with Five Prime (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.

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 Five Prime's global development and registration of licensed products, including Five Prime's global Phase III registrational trial of bemarituzumab (FPA144) in combination with FOLFOX in front-line gastric and gastroesophageal cancer (the "bemarituzumab FPA144-004 Study") in the licensed territory under a global development plan.

To date, we have made an upfront payment of \$5.0 million and a milestone payment of \$2.0 million in 2020. We 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 ranging from high-teens to low twenties on annual net sales of the licensed product in the licensed territory.

Pursuant to the terms of the agreement, provided that we enroll and treat a specified number of patients in the bemarituzumab FPA144-004 Study in mainland China, we are eligible to receive a low single-digit percentage quarterly royalty, on a licensed product-by-licensed product basis on net sales of all licensed product outside the licensed territory until the tenth (10th) anniversary of the first commercial sale of each such licensed product outside the licensed territory.

We will purchase licensed products exclusively from Five Prime. The agreement will expire on a region-by-region basis upon the expiration of the royalty term and payment by us of all of our payment obligations with respect to each licensed product and region under the agreement, where the royalty term for a licensed product in a region continues until the latest of (i) the eleventh (11th) anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of the last valid claim within the Five Prime patents covering such licensed product in such region, and (iii) the expiration of regulatory exclusivity with respect to such licensed product in such region. In addition, we may terminate the agreement in its entirety at any time, subject to a certain notice period. Either party may terminate the agreement in its entirety with written notice for the other party's material breach, subject to a certain cure period, or for the other party's bankruptcy or insolvency. Five Prime may terminate the agreement in its entirety with written notice for the material breach of our diligence obligations with respect to development and obtaining marketing approval in mainland China and may terminate the agreement on a region-by-region basis for the breach of our diligence obligations with respect to timely initiation of commercialization of a licensed product in a region following the marketing approval of such licensed product. Five Prime may also terminate the agreement in its entirety if we or one of our affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of Five Prime's patents.

In April 2021, Five Prime was acquired by Amgen.

### **Regeneron (Odronexamab)**

In April 2020, we entered into a collaboration agreement with Regeneron Ireland Designated Activity Company, an affiliate of Regeneron, pursuant to which we obtained oncology development and exclusive commercialization rights for products containing odronexamab as the sole active ingredient in Greater China.

## BUSINESS

To date, we have made a \$30.0 million upfront payment in 2020. We may be required to pay an additional aggregate amount of up to \$160.0 million in regulatory and sales-based milestones. Additionally, we will make payments to Regeneron based on annual net sales, such that Regeneron shares in a significant portion of any potential profits. We are also responsible for contributing to the global development costs of odronextamab for certain trials.

We will purchase odronextamab exclusively from Regeneron. The agreement continues in effect after the date of the agreement and until such time when we have ceased development and commercialization activities on odronextamab for six consecutive months, subject to certain exceptions. In addition, subject to certain conditions, we and Regeneron each may terminate the collaboration agreement for convenience, subject to a certain notice period, or for violation of anti-corruption law, subject to a certain cure period. Regeneron may terminate the agreement under specified circumstances if we or our affiliates or subcontractors challenge its patent rights, or upon a change of control of us, if Regeneron reasonably determines the acquirer of us does not have the resources or expertise to perform the obligations under this agreement. Either party may terminate the agreement for the other party's uncured material breach of the agreement, subject to a certain cure period, or for the other party's bankruptcy or insolvency.

### **BMS (Repotrectinib)**

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

To date, we have made an upfront payment of \$25.0 million in 2020 and three milestone payments totaling \$5.0 million in 2021. We may be required to pay an additional aggregate amount of up to \$146.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid-to-high teens on annual net sales of licensed products in the licensed territory. Under the exclusive license agreement, we are responsible for funding all development and commercialization activities related to the products in our licensed territory, subject to certain exceptions pursuant to which Turning Point may be responsible for the cost. Turning Point will be responsible for funding global clinical studies of the licensed products subject to certain exceptions pursuant to which we may bear the costs of certain studies.

We will purchase licensed products exclusively from Turning Point. Unless terminated earlier pursuant to its terms, the license agreement will continue in effect until expiration of the last royalty term set forth in the agreement with respect to any licensed product in any region in the Territory, where the royalty term for a licensed product in a region continues until the latest of (i) the expiration of the last-to-expire valid claim within the licensed patent rights that covers the licensed product in such region; (ii) the expiry of the regulatory exclusivity for such licensed product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of such licensed product in such region. In addition, we may terminate the agreement for convenience, subject to a certain notice period. Turning Point may terminate the agreement under specified circumstances if we or our affiliates or sublicensees challenge its patent rights, subject to a certain cure period. Either party may terminate the agreement for the other party's uncured material breach of the agreement, subject to a certain cure period, for the other party's bankruptcy or insolvency or if the other party or its affiliates merges with or acquires a third party engaged in activities with a competing product, which is not divested or discontinued within a specified period.

**Taiho (Zipalertinib)**

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

To date, we have made an upfront payment of \$20.0 million in 2021, which was accrued in 2020. We may be required to pay an additional aggregate amount of up to \$211.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentages ranging from high-single-digit to low-teens on annual net sales of the licensed products in the licensed territory. Cullinan Pearl received worldwide rights for CLN-081, excluding Japan, from Taiho Pharmaceutical, Co., Ltd. in 2018. In June 2022, Taiho acquired Cullinan Pearl and obtained exclusive global rights to CLN-081 outside of the United States. In December 2022, we agreed with Taiho on the assignment of our license agreement with Cullinan Pearl to Taiho.

We have the sole right to manufacture the licensed products for commercialization in the licensed territory. The agreement continues in effect until the expiration of the last royalty term for a licensed product in any region in the licensed territory, where the royalty term for a licensed product in a jurisdiction continues until the later of (i) the expiration of the last-to-expire valid claim within the licensed patent rights that covers the licensed product in such region, or (ii) the close of business of the tenth (10th) anniversary of the date of the first commercial sale of such licensed product in such region.

Either party may terminate the agreement on a region-by-region basis or in its entirety upon a material breach by the other party or bankruptcy of the other party. We may terminate the agreement in its entirety or on a product-by-product basis at any time and for any or no reason, provided, however, that we will terminate the agreement upon prior written notice to Taiho if we determine that we shall discontinue all development and commercialization activities with respect to the licensed products. Furthermore, Taiho may terminate the agreement in its entirety, if we or our affiliates commence a legal, administrative, or other action challenging the validity, enforceability, or scope of any licensed patent or patent (other than the licensed patent) owned or controlled by Taiho and its affiliates. In addition, if no active development activities have been conducted by us and our affiliates or a permitted sublicensee within ten (10) months of the execution of the agreement and such inactivity is not caused by a serious adverse event or serious adverse drug reaction, a force majeure event, or Taiho's failure to supply sufficient quantities of clinical supply product, then we will be deemed to have abandoned development for the product and Taiho shall have the right to terminate the agreement upon written notice, unless we have cured such abandonment within sixty (60) days of such written notice. The agreement may also be terminated by mutual written agreement. Unless earlier terminated, the agreement continues in effect on a product-by-product basis until the expiration of all applicable royalty terms with respect to all products in any region in the territory.

**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 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 will be responsible for recruiting patients in mainland China to argenx's global registrational trials for the development of efgartigimod.



## BUSINESS

To date, we have made an upfront payment, valued at \$62.3 million at the time of issuance, in the form of 568,182 newly issued ordinary shares of Zai Lab Limited (which became 5,681,820 ordinary shares after the Share Subdivision in March 2022); a \$75.0 million cash payment as a guarantee for non-creditable, non-refundable development cost-sharing in 2021; and a \$25.0 million development milestone payment in 2022 which was accrued in 2021. We may be required to pay certain royalties at tiered percentages ranging from mid-teen to low-twenties on annual net sales of the licensed products in the licensed territory. For additional information on the Share Subdivision, see Note 2(a) to the consolidated financial statements below.

We will purchase licensed products exclusively from argenx. The agreement continues in effect until, on a jurisdiction-by-jurisdiction and licensed product-by-licensed product basis, the date of expiration of the applicable royalty term set forth in the agreement, where the royalty term for a licensed product in a jurisdiction continues until the latest of (i) the expiration of the last-to-expire valid claim within the licensed patent rights that covers the licensed product, its manufacture or use in such jurisdiction; (ii) the expiration of regulatory exclusivity in such jurisdiction for such licensed product; or (iii) twelve (12) years after the date of the first commercial sale of such licensed product in such jurisdiction. In addition, we may terminate the license agreement for convenience, subject to a certain notice period. Argenx may terminate the agreement under specified circumstances if we or our affiliates or sublicensees challenge its patent rights, subject to a certain cure period. Either party may terminate the agreement for the other party's uncured material breach of the agreement, subject to a certain cure period, or for the other party's bankruptcy or insolvency.

### **Crescendo (ZL-1102)**

In May 2018, we entered into an agreement with Crescendo Biologics Ltd. ("Crescendo"), pursuant to which we obtained an exclusive, worldwide license to develop, commercialize, and manufacture ZL-1102 for all indications. Pursuant to the terms of the agreement, we are responsible for conducting all regulatory filings, clinical studies, and commercialization activities, with both companies participating in a Joint Development Committee.

In October 2020, the Company and Crescendo entered into a supplemental license agreement, under which Crescendo granted to the Company a non-exclusive, worldwide license to use the Crescendo VH HLEs in connection with the development, commercialization, manufacture, and other exploitation of VH HLE licensed products.

To date, we have made two upfront payments totaling \$4.5 million, including a \$2.5 million payment in 2020, and three milestone payments totaling \$6.0 million, including a \$2.0 million payment in 2020 and a \$4.0 million payment in 2021. We may be required to pay an additional aggregate amount of up to \$298.1 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual global sales.

We have the right to terminate this agreement at any time by providing written notice of termination to Crescendo.



## **Entasis (SUL-DUR)**

In April 2018, we entered into a license and collaboration agreement with Entasis, 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) 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. Our rights to develop and commercialize the licensed products are limited to the lead product (SUL-DUR) until such lead product receives initial FDA approval in the United States.

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.

To date, we have made an upfront payment of \$5.0 million and two development milestone payments totaling \$7.0 million. We may be required to pay an additional aggregate amount of up to \$91.6 million in development and commercial 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. 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.

We will purchase the licensed products exclusively from Entasis. The agreement will expire on a country-by-country basis upon the expiration of the royalty term and payment by us of our payment obligations applicable to such country, where the royalty term for a licensed product in a country continues until the latest of (i) the tenth (10th) anniversary of the first commercial sale of such licensed product in such country, (ii) the expiration or abandonment of the last-to-expire valid claim within certain Entasis patents covering such licensed product in such country, and (iii) the expiration of regulatory exclusivity with respect to such licensed product in such country. We may terminate the agreement upon written notice to Entasis at any time and for any reason. Either party may terminate the agreement if the other party is in material breach after a permitted cure period, or with immediate effect upon the occurrence of specified events of insolvency. Further, Entasis can terminate the agreement if we cease to commercialize the licensed products or challenge any of the patents we licensed. If we have the right to terminate the agreement due to Entasis's uncured material breach, we may elect to continue the agreement and Entasis would be obligated to pay us a premium on the amount of damages arising from such breach. In the event of any termination of the agreement, we will assign or grant a right of reference to any regulatory documentation related to the licensed products to Entasis, all rights and licenses to us will terminate and we will grant Entasis a license under our technology to make and commercialize licensed products in the territory.

## **Karuna (KarXT)**

On November 8, 2021, we entered into a license agreement with Karuna, pursuant to which we and Karuna agreed to collaboratively develop KarXT in Greater China. Under the agreement, we obtained from Karuna an exclusive license to develop, manufacture, and commercialize KarXT in Greater China.

# BUSINESS

To date, we have made an upfront payment of \$35.0 million in 2021 and two development milestone payments totaling \$10.0 million in 2022. We may be required to pay an additional aggregate amount of up to \$142.0 million in clinical, 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.

The agreement will terminate on a region-by-region basis and on a licensed product-by-licensed product basis in the Licensed Territory, upon the later to occur of (i) the date the last-to-expire valid claim in such region expires, (ii) the close of business of the day that is exactly 12 years after the date of the first commercial sale in such region, and (iii) the expiration date of any regulatory exclusivity in such region, or in its entirety upon the expiration of all payment obligations under the agreement. We may terminate the agreement at any time by providing 180 days' prior notice to Karuna. Either party may terminate the agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Karuna may terminate the agreement if we challenge the licensed patent rights.

## **Blueprint (BLU-945 and BLU-701)**

On November 8, 2021, we entered into a license and collaboration agreement with Blueprint, pursuant to which we obtained rights to develop and exclusively commercialize BLU-945 and BLU-701 and certain other forms thereof, including backup compounds, for the treatment of patients with EGFR-driven NSCLC in Greater China.

To date, we have made an upfront payment of \$25.0 million in 2021. We may be required to pay an additional aggregate amount of up to \$590.0 million in clinical, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from the low- to mid-teens on annual net sales of the licensed products in the licensed territory. Blueprint deprioritized BLU-701 in 2022, but we continue to collaborate with respect to BLU-945.

The agreement will terminate on a licensed product-by-licensed product basis and on a region-by-region basis in Greater China, upon the later to occur of (i) 12th anniversary of the date of the first commercial sale in such region, (ii) the expiration of the last valid claim within the royalty patent rights that covers the licensed product in such region, and (iii) the expiration of the last regulatory exclusivity for such licensed product in such country or region, or in its entirety upon the expiration of all payment obligations under the agreement. We may terminate the agreement at any time after November 8, 2023, by providing 12 months' prior notice to Blueprint after the first commercial sale or nine months' prior notice prior to the first commercial sale. Either party may terminate the agreement upon a material breach by the other party that remains uncured or upon certain bankruptcy events. In addition, Blueprint may terminate the agreement if we challenge the licensed patent rights.

## **BMS (TPX-0022)**

In January 2021, we entered into a license agreement with Turning Point (a company later acquired by BMS) pursuant to which we received an exclusive license under certain patents and know-how to develop and commercialize products containing Turning Point's product candidate, TPX-0022, as an active ingredient in all human therapeutic indications in Greater China. We may, at our election and expense, subject to specified exceptions, participate in future global clinical studies of the licensed products through clinical trial sites in the licensed territory. In addition, we granted Turning Point a first right to negotiate a license outside the original licensed territory to a potential product candidate from one of our pipeline programs if we file an investigational new product application for the product candidate.

To date, we have made an upfront payment of \$25.0 million in 2021. We may be required to pay an additional aggregate amount of up to \$336.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from mid-teen to low twenties on annual net sales of the licensed products in the licensed territory.

We will purchase licensed products exclusively from Turning Point. Unless terminated earlier pursuant to its terms, the license agreement will continue in effect until expiration of the last royalty term set forth in the agreement with respect to any licensed product in any region in the Territory, where the royalty term for a licensed product in a region continues until the latest of (i) the expiration of the last-to-expire valid claim within the licensed patent rights that cover the licensed product in such region, (ii) the expiry of the regulatory exclusivity for the licensed product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the first commercial sale of the licensed product in such region. In addition, we may terminate the license agreement for convenience, subject to a certain notice period. Turning Point may terminate the agreement under specified circumstances if we or our affiliates or sublicensees challenge its patent rights, subject to a certain cure period. Either party may terminate the agreement for the other party's uncured material breach of the agreement, subject to a certain cure period, for the other party's bankruptcy or insolvency or if the other party or its affiliates merges with or acquires a third party engaged in activities with a competing product, which is not divested or discontinued within a specified period.

## **Incyte (Retifanlimab)**

In July 2019, we entered into a collaboration and license agreement with Incyte, pursuant to which we obtained an exclusive license under certain patents and know-how of Incyte to develop and commercialize products containing retifanlimab (INCMGA012) as an active ingredient in the treatment, palliation, diagnosis, or prevention of diseases in the fields of hematology or oncology in humans in Greater China. We terminated this license agreement, in accordance with its terms, effective January 11, 2023, but we will support the transition of on-going clinical trials, such as the China portion of the Phase 3 global study for NSCLC and the Phase 1 global study for endometrial cancer.

# BUSINESS

## **Takeda Pharmaceutical Company Limited (“Takeda”) (Simurosertib)**

In December 2020, the Company entered into an exclusive license agreement with Takeda. Under the terms of the license agreement, Takeda exclusively licensed to the Company the right to research, develop, and commercialize the licensed products in the licensed field during the term. To date, the Company has made an upfront payment of \$6.0 million to Takeda, which was accrued in 2020 and paid in 2021. This program was terminated in 2022.

## **INTELLECTUAL PROPERTY**

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our product candidates and our core technologies and other know-how 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 or intellectual property rights. We expect that we will seek to protect our proprietary and intellectual property position by, among other methods, licensing or filing our own U.S., international, and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

### **Patents**

Patents, patent applications and other intellectual property rights are important in the sector in which we operate. We consider on a case-by-case basis filing patent applications with a view to protecting certain innovative products, processes, and methods of treatment. We may also license or acquire rights to patents, patent applications or other intellectual property rights owned by third parties, academic partners or commercial companies which are of interest to us. For the internally developed product candidates, we identify patents through both self-development effort and joint development through collaboration with business partners such as academic institutions.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our drug candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive or license in the future may be challenged, invalidated, or circumvented. For example, we cannot be certain of the priority of our patents and patent applications over third-party patents and patent applications. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide. 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. Under the current China Patent Law (Revised in 2020), the term of patent protection starts from the date of application. Patents relating to inventions are effective for twenty years, and utility models and designs are effective for ten years and fifteen years, respectively, from the date of application. However, with regard to the design patent applications filed and the design patents granted prior to the effectiveness of the current China Patent Law (Revised in 2020), the term of patent protection is ten years from the date of 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 own or license patents.

The following describes representative patents and/or pending applications related to our approved products and product candidates.

## **ZEJULA**

As of December 31, 2022, we exclusively licensed three issued patents in mainland China directed to ZEJULA's free base compound, salts thereof, or analog of ZEJULA. These issued patents are projected to expire in 2027, 2028, and 2029, respectively. We also exclusively licensed one pending patent application in mainland China directed to methods of treating ovarian cancer. If this patent application issues as a patent, such patent will be projected to expire in 2037. Additionally, we have obtained patents in each of mainland China, the United States, the European Union, Israel, Japan, Korea, and India that cover intermediate synthesis process. We own this family of patents/applications.

## **Tumor Treating Fields**

As of December 31, 2022, we licensed nine issued patents in mainland China and five issued patents in Hong Kong that relate to Tumor Treating Fields. Additional patent applications that relate to Tumor Treating Fields are pending, including nine in mainland China and three in Hong Kong. We are pursuing patent rights to protect our rights in these technologies and have continued our efforts to secure patent rights in mainland China for our devices and technologies for applying electric fields to a patient for treating a disease or condition, especially diseases that promote tumor growth.

## **QINLOCK**

As of December 31, 2022, we exclusively licensed one issued patent and two pending patent applications in mainland China as well as two issued patents in Hong Kong and one issued patent in Macau directed to dihydronaphthyridines, the API of ripretinib. These issued patents and pending patent applications are projected to expire by 2032. We also exclusively licensed patent applications pending in mainland China, Hong Kong, and Taiwan that are directed to the uses/combo uses involving the API, which are projected to expire between 2037 and 2040. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of Greater China.

# BUSINESS

## **Omadacycline**

As of December 31, 2022, we exclusively licensed issued patents in mainland China, Hong Kong, Macau, and Taiwan directed to omadacycline's crystalline forms. These patents are projected to expire in 2029. We have also exclusively licensed four pending patent applications in mainland China, three pending patent applications in Hong Kong and three pending patent applications in Taiwan, that relate to different methods of treatment related to omadacycline. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of Greater China.

## **Margetuximab**

As of December 31, 2022, we exclusively licensed one issued patent in mainland China, Macau, and Hong Kong. These patents cover antibody sequences and therapeutic uses of margetuximab, which are projected to expire in 2029. Additional licensed patents/applications include those related to methods, combo uses, or bi-specific binding molecules, which are projected to expire between 2030 and 2038.

## **TIVDAK**

As of December 31, 2022, we exclusively licensed a TIVDAK-related patent portfolio that includes patents or pending applications related to composition of matter, formulations, and/or their uses. The patents or applications (if issued as patents) are projected to expire between 2029 and 2040. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

## **Adagrasib**

As of December 31, 2022, we exclusively licensed one pending patent application in each of mainland China, Hong Kong, and Taiwan that covers the drug substance and is projected to expire in 2038. Additional patents/applications licensed from Mirati also include those related to combination therapy, method of use, or solid forms, which are projected to expire in 2039 or thereafter.

## **Bemarituzumab**

As of December 31, 2022, we exclusively licensed one issued patent in mainland China and three issued patents and one pending patent application in Hong Kong. These issued patents/application are directed to certain anti-FGFR2 antibodies and are projected to expire in 2029. We have also exclusively licensed one issued patent and one pending patent application in mainland China, two issued patents in Taiwan, one issued patent in Macau, and one issued patent and two pending patent applications in Hong Kong, which are related to afucosylated anti-FGFR2IIIB antibodies and projected to expire in 2034. Additional licensed patents/applications include those related to combo therapy, method of use, or formulations, which are projected to expire between 2036 and 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of Greater China.

## **Odronextamab**

As of December 31, 2022, Regeneron has three issued patents and four pending patent applications in mainland China, two issued patents and four pending patent applications in Hong Kong, two issued patents in Macau, and six issued patents and one pending patent application in Taiwan. These issued patents relate to CD3/CD20 bispecific antibody odronextamab/uses thereof and are projected to expire between 2030 and 2035. Regeneron also has additional patent applications pending in Greater China including those related to combination therapy using CD3/CD20 bispecific antibody or related to a dosing strategy. If issued, claims of these patent applications are projected to expire between 2036 and 2039.

## **Repotrectinib**

As of December 31, 2022, we exclusively licensed three issued patents in mainland China, one issued patent and three pending patent applications in Hong Kong, one issued patent in Macau, and two issued patents in Taiwan. These issued patents or pending applications are directed to repotrectinib and are projected to expire in 2035. We have also exclusively licensed two issued patents and two pending patent applications in mainland China, two issued patents and one pending patent application in Hong Kong, two issued patents in Macau, and one pending patent application in Taiwan, that relate to chiral diaryl macrocycles, diaryl macrocycles polymorph, the use thereof, and combination therapy involving diaryl macrocyclic compounds. If issued, claims of these patent applications are projected to expire between 2036 and 2038. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of Greater China.

## **CLN-081**

As of December 31, 2022, we exclusively licensed one issued patent in each of mainland China, Hong Kong, Macau, and Taiwan. These four patents are composition-of-matter patents, which are projected to expire in 2034. We have also exclusively licensed patents and applications pending in mainland China, Hong Kong, and Taiwan related to inhibition of mutant EGFR. Patents issued from these applications are projected to expire between 2037 and 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

## **BLU-945**

As of December 31, 2022, we exclusively licensed a patent portfolio related to BLU-945. The patents or applications (if issued as patents) are projected to expire in 2040 or thereafter. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

## **ZL-1211**

As of December 31, 2022, we have filed applications in fourteen countries, including the United States, mainland China, Australia, Europe, Canada, South Korea, and Singapore, which are directed to anti-claudin antibodies and uses thereof. These patent applications, after maturing into patents, are projected to expire in 2039. We own these patent applications.

# BUSINESS

## **Efgartigimod**

As of December 31, 2022, we exclusively licensed one issued patent in mainland China, one issued patent in Macau, and one pending patent application in each of mainland China and Hong Kong. These patent and pending patent applications are directed to an isolated FcRn antagonist or uses thereof. They are projected to expire in 2034. We have also exclusively licensed four pending patent applications in mainland China, six pending patent applications in Hong Kong, and two pending patent application in Taiwan. These applications are directed to uses of FcRn antagonists or compositions. Any patents issued from these applications are projected to expire between 2036 and 2041. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

## **ZL-1102**

As of December 31, 2022, we have exclusively licensed one issued patent in each of the United States, Japan, Macau, and mainland China and one pending patent application in each of the United States, Europe, mainland China, Hong Kong, and Japan. These patent and patent applications are directed to composition of matter with a patent term projected to expire in 2036. We have also exclusively licensed one issued patent in the United States and Japan and one pending application in each of the United States, mainland China, Japan, and Europe. These patent/applications are directed to formulations. Any patents issued from these applications are projected to expire in 2037.

## **Durlobactam**

As of December 31, 2022, we exclusively licensed one issued patent in mainland China, one issued patent in Japan, and one corresponding patent issued in each of several additional jurisdictions in the territory covered by our agreement with Entasis, including Australia, New Zealand, Hong Kong, Singapore, Taiwan, and Korea. These issued patents are directed to certain beta-lactamase inhibitor compounds and are projected to expire in 2033. We have also exclusively licensed a second family of patent applications with patents issued in mainland China, Hong Kong, Japan, Taiwan, Singapore, and Australia. The patents/applications of the second family are projected to expire in 2035. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the licensed territory in the license and collaboration agreement with Entasis.

## **KarXT**

As of December 31, 2022, we exclusively licensed an issued patent in Hong Kong directed to the use of KarXT, which is projected to expire in 2030. Additional licensed patents/applications are related to a composition which are projected to expire in 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

## **ZL-2201**

As of December 31, 2022, we have licensed a world-wide patent portfolio related to ZL-2201. The patents or applications (if issued as patents) are projected to expire in 2040 or thereafter.



## Trade Secrets

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, 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 and invention assignment agreements with our consultants and employees. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information, and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. If any of the partners, collaborators, scientific advisors, employees, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. 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.

## RESEARCH AND DEVELOPMENT

We believe research and development is important to our future growth and our ability to remain competitive. We are dedicated to discovering or licensing and developing and commercializing proprietary therapeutics that address areas of significant unmet medical need in Greater China and worldwide, including in the fields of oncology, autoimmune disorders, infectious diseases, and neuroscience.

We have built an integrated product discovery and development platform that aims to bring both in-licensed and internally discovered medicines to patients in Greater China and globally. We have assembled an in-house research and development team with over 400 dedicated personnel who have extensive experience in discovery, translational medicine, and late-stage development. Our in-house research and development team had previously been directly involved in the discovery and development of several innovative product candidates. Our in-house research and development team focuses on the development of innovative therapeutics for the treatment of oncology and autoimmune disorders. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new product candidates for patients around the world. This effort has resulted in the identification of a number of proprietary candidates against targets in our focus areas that include immuno-oncology, DNA damage response/repair and oncogenic signaling that we are moving into pre-clinical development. The Company has a leadership team with extensive pharmaceutical research, development, and commercialization track records in both global and Chinese biopharmaceutical

## BUSINESS

companies. We believe this team and our in-house discovery and development capabilities will enable us to achieve our long-term goal of commercializing our internally discovered innovative medicine for patients worldwide. In addition, we collaborate with external research partners, such as leading CROs, academic institutions, and commercial partners. We contract with these parties for execution of our pre-clinical and clinical trials. For details, see Business — Suppliers.

For 2022 and 2021, our research and development expenses were \$286.4 million and \$573.3 million, respectively. Our expenditures incurred on research and development activities include the following: (i) expenses incurred for payments to CROs, investigators, and clinical trial sites that conduct our clinical studies; (ii) employee compensation related expenses, including salaries, benefits and equity compensation expense; (iii) expenses for licensors; (iv) the cost of acquiring, developing, and manufacturing clinical study materials; (v) facilities, depreciation, and other expenses, which include office leases and other overhead expenses; (vi) costs associated with pre-clinical activities and regulatory operations; and (vii) expenses associated with the construction and maintenance of our manufacturing facilities.

## MATERIAL DEVELOPMENTS OF GOVERNMENT REGULATION

### Chinese Regulation of Pharmaceutical Product Development and Approval

#### *Marketing Authorization Holder System*

In December 2022, the NMPA issued the Provisions on Supervision and Administration of Marketing Authorization Holders Concerning the Implementation of Primary Responsibilities for Drug Quality and Safety. This regulation requires marketing authorization holders to establish and improve the drug quality management system, and assume primary responsibility for the safety, effectiveness, and quality of drugs during the total product life cycle. Marketing authorization holders need to build an information-based traceability system and establish a sound drug recall system, among other things.

#### *Data Privacy and Data Protection*

The current Cybersecurity Review Measures, which were released by the Cyberspace Administration of China (“CAC”) together with 12 other Chinese regulatory authorities on January 4, 2022, came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

#### *Data Privacy and Data Protection (Cross-Border Data Transfer)*

On September 1, 2022, the Measures on Security Assessment of Cross-Border Data Transfer (the “Security Assessment Measures”) issued by the CAC came into effect. The Security Assessment Measures set out a security assessment framework for cross-border data transfers out of mainland China as well as ground rules for a security assessment filing for cross-border data transfers which is stipulated in the Cyber Security Law and the PIPL.

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

Prior to applying for a security assessment with the CAC, data processors are required to carry out a self-risk assessment, which needs to be presented to the CAC along with an application filing and other required materials for a security assessment. During a security assessment, the CAC will primarily focus on risks to national security, public interests, and the legitimate rights and interests of individuals or organizations that such cross-border data transfer may cause. A cross-border data transfer of relevant data will not be allowed if the CAC does not approve the security assessment filing. Once the CAC approves the security assessment filing, such approval will remain valid for two years and may be renewed. An application for security assessment needs to be re-submitted if there is a change in the cross-border data transfer that may affect the security of the exported data, such as changes in the purpose, method, scope, and type of the exported data and changes in the purpose and method of the processing of the exported data by overseas recipients.

The Security Assessment Measures have retroactive effect for relevant data transfers out of mainland China conducted prior to September 1, 2022, and data processors have until February 28, 2023 to undergo mandatory security assessment for such prior data transfers. If a data processor fails to complete a security assessment for relevant data transfers out of mainland China conducted prior to September 1, 2022, it needs to rectify the failure by February 28, 2023. We continue to assess our obligations under these laws and are working with the CAC to ensure our compliance with respect to any mandatory security assessments.

#### *Good Laboratories Practice Certification for Nonclinical Research*

In January 2023, the NMPA issued a revised version of the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, which will come into effect on July 1, 2023. Under the new rule, a GLP certification issued by the NMPA will be valid for five years. GLP certified institutions shall submit a GLP annual report to the provincial medical products administration, covering the institution's basic information, Quality Management System operation status, research progress, etc.

#### **Rest of the World Regulation of Pharmaceutical Product Development and Approval**

For other countries outside of mainland China, such as the United States, countries in Europe, Latin America, or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing, and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with applicable GCP requirements and the applicable regulatory requirements and ethical principles.

# BUSINESS

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

## **Other Significant Chinese Regulation Affecting Our Business Activities in China**

### *PRC Anti-Monopoly Law*

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

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

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

Penalties for violation of the Amended AML have been substantially increased by the Amended AML. For example, according to the Amended AML, if a company completes a concentration of business in violation of the Amended AML that will have or is likely to have the effect of eliminating or restricting competition, in addition to other remedial measures, a fine of up to 10% of the last year’s sales revenue may be imposed. If the concentration of business in violation of the Amended AML completed by the company does not have the effect of eliminating or restricting competition, a fine of up to RMB5 million may be imposed. In the case that the aforementioned violation has particularly serious circumstances, bad impact, or consequences, the fine imposed may be further increased to between two and five times the aforementioned fine amount.

*Regulations on Securities Offering and Listing Outside of China*

On February 17, 2023, the CSRC, promulgated a new set of regulations that consist of the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (the “Trial Measures”) and five supporting guidelines, which became effective on March 31, 2023, to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

The Trial Measures and supporting guidelines apply to overseas offerings by domestic companies of equity shares, depository receipts, convertible corporate bonds, or other equity-like securities, and overseas listing of the securities for trading. Both direct and indirect overseas securities offering and listing by domestic companies would be regulated, of which the former refers to securities offering and listing in an overseas market made by a joint-stock company incorporated domestically, and the latter refers to securities offering and listing in an overseas market made in the name of an offshore entity, while based on the underlying equity, assets, earnings or other similar rights of a domestic company which operates its main business domestically. According to the Trial Measures, if an issuer meets the following conditions, the offering and listing shall be determined as an indirect overseas offering and listing by a domestic company: (i) the total assets, net assets, revenues or gross profits of the domestic company(ies) of the issuer in the most recent financial year account for more than 50% of the corresponding figure in the issuer’s audited consolidated financial statements over the same period; (ii) the majority of the senior management in charge of business operation and management of the issuer are Chinese citizens or habitually reside in mainland China, or its main places of business operation are located in China or main parts of its business activities are conducted in China.

Under the Trial Measures and supporting guidelines, a filing-based regulatory system would be implemented covering both direct and indirect overseas offering and listing. For an indirect initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to submit the filing documents to the CSRC, including but not limited to the prospectus within three working days after such application of overseas offering and listing is submitted. The CSRC would, within 20 working days if filing documents are complete and in compliance with the stipulated requirements, complete the filing notice, and publish the filing information on the CSRC’s official website. While for confidential filings of overseas offering and listing application documents, the designated filing entity may apply for an extension of the publication of such filing. The issuer shall report to the CSRC within three working days after the overseas offering and listing application documents become public. In addition, subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after the offering is completed.

Meanwhile, overseas offering and listing would be prohibited under certain circumstances, including but not limited to that (i) the offering and listing are expressly forbidden by the Chinese laws, regulations and relevant rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws 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 a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the domestic company shall postpone or terminate the intended overseas offering and listing and report to the CSRC and competent authorities under the State Council in a timely manner.

## BUSINESS

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. The controlling shareholders and actual controllers of such domestic companies that organize or instruct the aforementioned violations may be fined up to RMB10 million and directly liable persons-in-charge and other directly liable persons may be fined up to RMB5 million.

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

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

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

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

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

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

- Good Practices for Medical Device Clinical Trials

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

## SALES AND MARKETING

### Commercialization

We believe that the scale and sophistication of our commercial operation is crucial to our business. We have invested, and will continue to invest, substantial financial and management resources to build-out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales, and other personnel in support of the sales of our commercialized products.

As of January 31, 2023, our commercialization team consisted of 965 sales and marketing staff, covering major medical centers across Greater China. Our commercialization team has a proven track record and experience from leading oncology multinational pharmaceutical companies including AstraZeneca, Roche, Novartis, and BMS in Greater China. Our commercial team has capabilities that cover the product sales cycle, including medical affairs, market access, and distributor management. We tailor our commercialization strategies according to our individual products and their different market potential to drive product launch. For ZEJULA, we plan to increase market penetration in mainland China, accelerate sales in the growing 1L maintenance market in part through ZEJULA's inclusion on NRDL effective in January 2022, which we anticipate will allow us to make ZEJULA available to more hospitals and patients during 2022. For Optune, we plan to increase brand perception and adoption in mainland China and provide more post-launch product support services for patients. For NUZYRA, in March 2020, we entered an exclusive promotion agreement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd. ("Huizheng"), a direct wholly owned subsidiary of Hanhui Pharmaceutical Co., Ltd. ("Hanhui"), one of the leading pharmaceutical companies for antibiotics in mainland China. The agreement allows us to use Hanhui's existing infrastructure for the potential future commercial launch of NUZYRA in mainland China. For QINLOCK, we plan to continuously enhance physicians' education to attempt to establish QINLOCK as standard of care in 4L GIST in mainland China.

### Our Distribution Channel

We rely on independent third-party distributors in Greater China to sell our commercialized products, which is consistent with the pharmaceutical industry norm. We believe that distributors help us effectively execute our marketing strategies specifically tailored to each geographical location and the hospitals located within their distribution territories across mainland China. During 2020, after we launched ZEJULA and Optune in mainland China, we started to engage distributors. Our commercial relationship with the distributors we use is a seller and buyer relationship. Accordingly, we recognize product revenue when our products are delivered to and accepted by the distributors. During 2022 and 2021, the aggregate amount of product revenue generated from our five largest customers accounted for approximately 37.7% and 39.9%, 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, and past performance, and their 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 the distributors upon delivery to and acceptance by the distributors.



# BUSINESS

## MANUFACTURING AND SUPPLY

### Our Manufacturing Facilities

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

Since 2018, we have had a large molecule facility in Suzhou that uses Cytiva FlexFactory platform technology and is capable of supporting the clinical production of our product candidates. The annual production capacity of our large molecule manufacturing capacity is up to 12 to 18 200L or 1,000L clinical batches, respectively. In 2022, we added an additional 1,000L drug substance (“DS”) production line at this facility from Cytiva and a self-clean/autoclave automatic drug product (“DP”) production line from Tofflon Science. The annual production capacity of this facility is up to 22 of either 200L or 1,000L clinical DS batches and 40 clinical DP batches (up to 10,000 vials), respectively.

Since 2017, we have also had a cGMP-compliant small molecule facility in Suzhou with capacity to produce up to 50 million units per year for oral solid dosage form. In 2021, we added an early clinical manufacturing workshop for oral solids at this facility with additional capacity to produce approximately 30,000 units/batch. We also enabled additional R&D capability for small molecule Chemistry, Manufacturing and Controls that supported technology transfer, process development, and method validation. We have successfully manufactured supplies for multiple projects at this facility. For example, in December 2021, we updated our Pharmaceutical Manufacturing Permit to cover the manufacturing of internal product ZL-1218 for injection, and in November 2022, we successfully passed a ZL-1218 related European Union Qualified Person audit with only 2 minor observations.

Our two manufacturing facilities feature an oral solid dosage and a biological processing/formulation production line designed to comply with both the PRC and PIC/S drug manufacturing standards. The oral solids manufacturing facility 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. We procure our manufacturing equipment from leading domestic and international suppliers. We have acquired manufacturing licenses for both oral solid dosage and biological facilities. We have passed an onsite inspection by the NMPA for ZEJULA. Additionally, we have obtained the Marketing Authorization Holder manufacturing license for ZEJULA and NUZYRA. As of January 31, 2023, our manufacturing team consisted of 84 employees.

Although we expect our two manufacturing facilities to be able to satisfy the commercial as well as clinical needs and support the growth of our business in the near future, we are investing in the expansion of our large molecule manufacturing facility in anticipation of increased activities for our internally developed pipeline. In addition, we acquired land use rights in Suzhou that can be used to expand our manufacturing and research needs in the future. We believe that possessing manufacturing and commercialization capabilities presents benefits, which include maintaining better control over the quality and compliance of our operations with increasingly stringent industry regulations.



We are or will be dependent on third party partners for the manufacture and supply of certain of our products and product candidates. For example, we source Optune from NovoCure, QINLOCK from Deciphera, TIVDAK from Seagen, adagrasib from Mirati, efgartigimod from argenx, SUL-DUR from Entasis, odronextamab from Regeneron, repotrectinib from Turning Point, margetuximab from MacroGenics, and BLU-945 from Blueprint. We also are or will be dependent on third parties for our supply chain. If any of these third parties fail to provide us with sufficient quantities of product or materials, or fail to do so at acceptable quality levels or prices, our business could be harmed.

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

## **Contract Manufacturing Organizations**

We outsource to a limited number of external CMOs the production of some drug substances and products, and we expect to continue to do so to meet the pre-clinical, clinical, and commercial requirements of our products and product candidates. For example, we have engaged CMOs to locally manufacture NUZYRA and ZL-1102 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 in meeting delivery schedules, and proposed terms for the production arrangement. The CMOs with which we contract provide services to us on a short-term and project-by-project basis. Our agreements with the CMOs typically specify requirements, including, but not limited to, product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. The CMOs procure the necessary raw materials themselves.

## **Suppliers**

Our suppliers consist primarily of (i) third party licensors from which we obtained license rights in respect of our in-licensed products and drug candidates; (ii) selected CROs; and (iii) suppliers of other raw materials for our clinical trial activities.

We obtain raw materials for our clinical trial activities from multiple suppliers who we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, if there was an interruption to supplies, this could harm our business, perhaps materially. 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 do experience price fluctuations associated with our raw materials, we have not experienced any material disruptions in the supply of these raw materials in the past. In addition, we have suppliers across the world and do not rely exclusively on the imports from the suppliers in the United States.

# BUSINESS

## COMPETITION

Competition in the biopharmaceutical industry is intense. There are many companies, including biotechnology and pharmaceutical companies, engaged in developing products for the indications our approved products are approved to treat 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 establishing 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 and retaining leading scientists and technicians to conduct our research activities and advance our development programs, including with the commercial expertise to effectively market our products.

Competition among products approved for sale 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 will 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 our marketed products and pricing pressure on our marketed products. The development of new or improved treatment options or standards of care or cures for the diseases our products treat reduces and could 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.

Additional information about the competition that our marketed products face is set forth below in 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 director and officer insurance. We do not maintain insurance to cover intellectual property infringement or misappropriation.

## QUALITY CONTROL AND ASSURANCE

We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing, and testing of our drug candidates. 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.

## 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 a three lines of defense risk management framework to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an on-going basis, and a risk governance structure that includes oversight by the Audit Committee of the Board of Directors. The risk governance structure also 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. We conduct an annual enterprise risk assessment to identify our top tier risks and, based on that assessment, will complete enterprise risk management plans to manage those risks. Management discusses with the Audit Committee the results of its annual enterprise risk assessments as well as its enterprise risk management policies and guidelines.

The following provides additional information on our three lines of defense and risk governance structure:

- **First Line of Defense:** Our business functions are primarily responsible for implementing our risk management program in their areas. This includes identifying, measuring, monitoring, controlling, and reporting risk in adherence to our risk policies, controls, and guidelines established by management and the Board of Directors or Audit Committee.
- **Second Line of Defense:** Our Legal and Ethics and Compliance functions oversee implementation of our enterprise risk management program. For example, our Chief Legal Officer, supported by our Chief Compliance Officer, is responsible for: developing and updating our enterprise risk management program and targets; reviewing and approving major risk management issues; promulgating and supervising 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.

# BUSINESS

- **Third Line of Defense:** Our Internal Audit Division is responsible for evaluating the design, adequacy, operational effectiveness, and efficiency of our governance, risk management, and control processes.
- **Risk Coordination Council:** The Risk Coordination Council, which is co-chaired by the Chief Compliance Officer and another rotating member and 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 both at the functional line level and through the Chief Compliance Officer 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 is responsible for establishing our enterprise risk management and internal control system and reviewing its effectiveness. For more information on the Board of Director's oversight of risk management, including through its committees, see Corporate Governance — Board Leadership Structure and Role in Risk Oversight.

## 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.

## Available Information

We file reports and other information with the U.S. Securities and Exchange Commission ("SEC") and The Stock Exchange of Hong Kong Limited ("Hong Kong Stock Exchange"). We make available on our website our annual reports on Form 10-K (and previously on Form 20-F), our quarterly reports on Form 10-Q, and our current reports on Form 8-K (and previously on Form 6-K), and all other SEC reports and amendments to those reports. We also make our ESG Report available on the website of the Hong Kong Stock Exchange and our website. 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.

We use our website as a means of disclosing material non-public information — including information on our products; business activities and partnerships; research; ESG strategy, commitments, and reports; and other events and developments. Our website address is [www.zailaboratory.com](http://www.zailaboratory.com). We do not incorporate the information on or accessible through our website into this annual report, and you should not consider any information on, or that can be accessed through, our website as part of this annual report.

*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 annual report and our other filings with the SEC before deciding to invest in our ADSs or ordinary shares. The risks described below are not the only ones we face. For example, 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.*

## **RISKS RELATED TO DOING BUSINESS IN CHINA**

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

In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in mainland China. However, 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 rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the 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 sometime after the violation. 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 July 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities markets and promote the high-quality development of 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. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation-making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us. It is especially difficult for us to accurately predict the potential impact on the Company of new legal requirements in mainland China because the Chinese legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

## RISK FACTORS

**Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.**

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

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated, if the U.S. or Chinese government take retaliatory actions due to the recent U.S.-China tension or if the Chinese government exerts more oversight and control over securities offering that is conducted in the United States, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

**The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs or ordinary shares, including potentially making those ADSs or ordinary shares worthless.**

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 recently published new policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will 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, which may adversely affect our business, financial condition, and results of operations. Furthermore, recent statements made by the Chinese government have indicated an intent to increase the government's oversight and control over offerings of companies with significant operations in mainland China that are to be conducted in foreign markets, as well as foreign investment in China-based issuers like us. Any such action, if taken by the Chinese government, could significantly limit or completely hinder our ability to offer or continue to offer ADSs or ordinary shares to our investors and could cause the value of our ADSs or ordinary shares to significantly decline or become worthless.

**Because the majority of our operations are in mainland China and our auditor for prior fiscal years was located in mainland China, there have been concerns regarding oversight of the audits of our financial statements filed with the SEC. Further, as a result of the enactment of the Holding Foreign Companies Accountable Act, as amended (the “HFCAA”), which requires the SEC to prohibit trading on a national securities exchange or over-the-counter market in the United States of securities for a company that has been conclusively identified by the SEC as a Commission-Identified Issuer for two consecutive years, there have been concerns regarding the continued listing of our securities on Nasdaq. Although in May 2022 the Company engaged KPMG LLP, an auditor located in the United States and subject to inspection by the PCAOB, as our independent registered public accounting firm and in December 2022 the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB-registered public accounting firms in mainland China, if for any reason we were to fail to meet the audit requirements of the HFCAA for two consecutive years, we may be prohibited from listing our securities on a national securities exchange, including Nasdaq, or on over-the-counter markets in the United States, which could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital.**

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, PCAOB inspections 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, which could adversely affect the ability of companies using such auditors to access U.S. capital markets.

As part of the continued focus on access to audit and other information for companies with substantial operations in China, in December 2020, the United States enacted 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 a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor’s local jurisdiction (a “Commission-Identified Issuer”). Under the HFCAA, as amended in December 2022, if the SEC conclusively identifies an issuer as a Commission-Identified Issuer for two consecutive years, the SEC is required to prohibit the trading of the issuer’s securities on a national securities exchange or through any other method that is within the jurisdiction of the SEC to regulate, including over-the-counter markets in the United States.

In 2021, the PCAOB issued a Determination Report, which found that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by Chinese authorities in those jurisdictions, and in March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer because our predecessor auditor, which filed an audit report with our annual report for the fiscal year ended December 31, 2021, was located in mainland China.



## RISK FACTORS

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 for the fiscal year ended December 31, 2022. In addition, in December 2022, the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB-registered public accounting firms in mainland China. As a result, until such time as the PCAOB issues a new determination, the SEC has determined that there are no issuers currently at risk of having their securities subject to a trading prohibition under the HFCAA. Although we are not currently at risk of delisting pursuant to the HFCAA, if the PCAOB were to issue a new determination regarding limitations on its ability to inspect or investigate our independent auditor and we were to fail to meet the audit requirements of the HFCAA for two consecutive years, our securities may be prohibited from trading on a national securities exchange or over-the-counter market in the United States, and this could result in our ADSs being delisted from Nasdaq. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital. The market price of our ordinary shares and/or ADSs also could be adversely affected as a result of anticipated negative impacts of such legislative or executive actions upon, as well as negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States, regardless of whether such actions are implemented and regardless of our actual operating performance.

**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 February 2023, the CSRC released the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (the “Archives Rules”), which will become effective on March 31, 2023. 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.

**Compliance with China’s Data Security Law, Cyber Security Law, Cybersecurity Review Measures, the PIPL, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, and any other future laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, materially and adversely impacting our operating results.**

China has implemented extensive data protection, privacy, and information security rules and is considering a number of additional proposals relating to these subject areas. Based on our understanding of these laws, regulations, and policies — some of which were only recently enacted — and the government regulators’ interpretation of those legal requirements as applied to life sciences companies like us, we believe we are compliant with all of our material legal obligations. Nevertheless, we face significant uncertainties and risks which, as explained below, may materially and adversely affect our operations.



## RISK FACTORS

We maintain personally identifiable information of persons located within mainland China and at times transfer some of this personal information outside of China for legitimate business reasons. We also collect and maintain de-identified or anonymized health data for clinical trials in compliance with local regulations, and we transfer outside of mainland China de-identified or anonymized health data for clinical trials. This data could be deemed by government regulators to be “personal information” or “important data.” With mainland China’s growing emphasis on its sovereignty over personal information of persons within mainland China and data derived from mainland China, the outbound transmission of personal information or de-identified or anonymized health data for clinical trials may be subject to the new national security legal regime, including the Cyber Security Law, the Data Security Law, the PIPL, the Regulation on the Administration of Human Genetic Resource, and various implementing regulations and standards.

The Cyber Security Law, which became effective in 2017, requires companies to take certain organizational, technical, and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt a multi-level protection scheme (“MLPS”), under which network operators are required to perform obligations of security protection to ensure that their networks are free from interference, disruption, or unauthorized access, and prevent network data on their networks from being disclosed, stolen, or tampered. Under the MLPS, entities’ operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which their information and network systems belong — from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We are obligated to notify affected individuals and appropriate Chinese regulators of, and respond to, any data security and network security incidents.

Furthermore, under the Cyber Security Law and Data Security Law, data categorized as “core data” and “important data,” the latter of which will be determined by governmental authorities in the form of catalogs which have not yet been published, is to be processed and handled with a higher level of protection, but what data constitutes core data or important data is currently not clearly defined except for certain industry sections. Therefore, to comply with the statutory requirements, we will need to determine whether we possess core data or important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments, and comply with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of core data or important data.

Establishing and maintaining such systems and complying with such requirements takes substantial time, effort, and cost, and we may not be able to establish and maintain such systems or comply with such requirements as fully as needed for compliance with our legal obligations. Despite our investment, such systems and compliance efforts may not adequately protect us or enable us to appropriately respond to or mitigate all data compliance risks or data security and network security risks or incidents we face.

## RISK FACTORS

The Data Security Law and the PIPL prohibit entities in mainland China from transferring data (including personal information) stored in mainland China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. We may need to pass a government security review or obtain government approval in order to share data (including personal information) stored in mainland China with judicial and law enforcement authorities outside of mainland China. Therefore, if judicial and law enforcement authorities outside mainland China require us to provide data stored in mainland China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impacts on our operations in and outside of mainland China.

Recently, the CAC has taken action against several Chinese internet companies listed on U.S. securities exchanges for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law, the Cyber Security Law, and the Cybersecurity Review Measures, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests."

Pursuant to the current Cybersecurity Review Measures, which came into effect on February 15, 2022, critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, are required to conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review.

The Regulations on Network Data Security Management (Draft for Comment) (the "Draft Management Regulations"), which was published by the CAC in November 2021, proposed that data processors – defined as individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion – are subject to cybersecurity review if either they process personal information of more than one million individuals and aim to list on foreign stock markets, or their data processing activities influence or may influence national security. The Draft Management Regulations also propose requiring data processors seeking to list on foreign stock markets to annually assess their data security themselves or through data security service organizations and submit the assessment reports to relevant competent authorities. As the Draft Management Regulations was released only for public comment, the final version and the effective date thereof may be subject to change with substantial uncertainty.

We have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator" or "online platform operator" or requiring us to go through cybersecurity review procedures by the CAC pursuant to the Cybersecurity Review Measures. Based on our understanding of the Cybersecurity Review Measures, and the Draft Management Regulations if enacted as currently proposed, we do not expect ourselves to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over mainland China's national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information of more than one million users or individuals. However, there remains uncertainty as to how the Cybersecurity Review Measures, and the Draft Management Regulations if enacted as currently proposed, will be interpreted or implemented and whether Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Cybersecurity Review Measures and

## RISK FACTORS

the proposed Draft Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Cybersecurity Review Measures, the Draft Management Regulations if enacted, or other laws and regulations related to privacy, data protection, and information security.

It is also unclear at the present time how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. Mainland China's regulators may impose penalties for non-compliance ranging from fines to suspension of operations, and this could lead to us delisting from the U.S. stock market. Currently, we have not been involved in any investigations on cybersecurity review initiated by the CAC or related governmental regulatory authorities, and we have not received any inquiry, notice, warning, or sanction in such respect.

China continues to strengthen its regulation of cross-border transfers out of mainland China of data, including important data and personal information.

The Cyber Security Law, which has been in effect since June 2017, requires "critical information infrastructure operators" to store within mainland China important data collected and generated during their operations in mainland China and to undergo a security assessment prior to transferring any such important data outside of mainland China. The Data Security Law reiterated this requirement when it went into effect in September 2021, and additionally provided that the requirements for cross-border transfers out of mainland China of important data by other data processors are to be formulated by various Chinese cyberspace regulators.

In August 2021, the SCNPC passed the PIPL, which became effective in November 2021. The PIPL provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in mainland China, and the processing of personal information of persons in mainland China outside of mainland China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in mainland China. The PIPL requires all personal information processors that need to transfer out of mainland China personal information to either: (i) pass a security assessment organized by Chinese cyberspace regulators, (ii) undergo certification by specialized certification agencies in accordance with relevant regulations, (iii) conclude a standard contract designated by China cyberspace regulators with the overseas recipient of the personal information, or (iv) satisfy other conditions contemplated by laws, administrative regulations, or Chinese cybersecurity regulators. The PIPL also provides that critical information infrastructure operators and personal information processors who process personal information meeting a volume threshold to be set by Chinese cyberspace regulators are also required to store in mainland China personal information generated or collected in mainland China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the PIPL provides for significant fines for serious violations of up to RMB50 million or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities.

To implement the security assessment mechanisms for cross-border transfers out of China of data under the Cyber Security Law, the Data Security Law, and the PIPL, the CAC promulgated the Security Assessment Measures, which took effect on September 1, 2022, and published the Security Assessment Guide on August 31, 2022. Under the Security Assessment Measures, a mandatory security

## RISK FACTORS

assessment is required for data transfers out of mainland China under any of the following circumstances: (i) transfer of important data by data processors; (ii) transfer of personal information by critical information infrastructure operators and data processors that process personal information of more than one million individuals; (iii) transfer of personal information by data processors that have transferred either personal information of over 100,000 individuals or sensitive personal information of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. We understand that the Security Assessment Measures cover (1) overseas transmission and storage by data processors of data generated during PRC domestic operations, and (2) access to or use of the data collected and generated by data processors and stored in the PRC by overseas institutions, organizations, or individuals. The Security Assessment Measures have retroactive effect for relevant cross-border data transfers out of mainland China conducted prior to September 1, 2022, and data processors have until February 28, 2023, to undergo mandatory security assessment for such prior relevant cross-border data transfers. We continue to assess our obligations under these laws and are working with the CAC to ensure our compliance with respect to any mandatory security assessments.

To implement the standard contract mechanism for cross-border transfers out of China of personal information under the PIPL, on February 22, 2023, the CAC published the Measures for the Standard Contract for Outbound Cross-Border Transfer of Personal Information, along with the final version of the PRC standard contract, which will be effective on June 1, 2023. Going forward, personal information processors may conclude a PRC standard contract with overseas recipients of personal information to comply with PIPL requirements for cross-border transfers out of mainland China of personal information that do not need to undergo a security assessment.

To implement the personal information protection certification mechanism for cross-border transfers out of China of personal information under the PIPL, on November 4, 2022, the CAC and SAMR jointly issued the Notification on the Implementation of Personal Information Protection Certification. In parallel, on December 16, 2022, the National Information Security Standardization Technical Committee released an updated version of the Certification Specification which provides the general principles and detailed requirements for personal information processors engaging in the cross-border transfer out of mainland China of personal information to meet in order to obtain a personal information protection certification from qualified certification institutions for cross-border transfers out of China of personal information governed by the PIPL. However, the list of qualified certification institutions has not been released to date.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in mainland China. For example, the HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR outside of China. Chinese parties are required to seek an advance approval for the collection and biobanking of all China-Sourced HGR. Approval for any export or cross-border transfer of China-Sourced HGR in the form of biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the Human Genetic Resources Administration Office of China (“HGRAC”) for record purposes and to obtain a notification filing number in order to transfer the data. The HGR Regulation also requires that foreign parties or entities established or actually controlled by them ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

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

So far, the HGRAC has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant human genetic materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any CTAs until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in mainland China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multinational pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAC approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of 6 to 12 months, respectively.

Interpretation, application, and enforcement of these laws, rules, and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation, or changes in enforcement. Compliance with the Cyber Security Law, the Data Security Law, the PIPL, and other related laws and regulations could significantly increase the cost to us of providing our products, require significant changes to our operations, or even prevent us from providing certain products in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations, and other obligations relating to privacy, data protection, and information security, it is possible that our practices, products, or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law, the PIPL, and/or related laws and regulations. Any failure on our part to comply with such laws or regulations or any other obligations relating to privacy, data protection, or information security, or any compromise of security that results in unauthorized access, use, or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us, or 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, and results of operations. If the Chinese parties fail to comply with data privacy and cybersecurity laws, regulations, and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately, or destroyed, we may lose our

## RISK FACTORS

confidential information and be subject to litigation and government enforcement actions. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, delays in sharing or an inability to share or receive clinical trial data with or from our collaborators, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in mainland China. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure, and reputational damage that could potentially have a material adverse effect on our business and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition, and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the Cyber Security Law, the Cybersecurity Review Measures, and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital in the U.S. market in the future.

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

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

A substantial portion of our operations (including our commercial operations) are conducted in mainland China. Accordingly, our business, results of operations, financial condition, and prospects may be influenced to a significant degree by economic, political, legal, and social conditions in mainland China as well as mainland China's economic, political, legal, and social conditions in relation to



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

**If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our ADSs or ordinary shares may decline in value or become worthless.**

In July 2021, the Chinese government provided new guidance on Chinese companies raising capital outside of mainland China, including through arrangements called variable interest entities, or VIEs. Currently, our corporate structure contains no variable interest entities and we are not in an industry that is subject to foreign ownership limitations in mainland China. However, there are uncertainties with respect to the Chinese legal system and there may be changes in laws, regulations and policies, including how those laws, regulations and policies will be interpreted or implemented. If in the future the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently, the value of our ADSs or ordinary shares may decline or become worthless.

**The approval of, filing, or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.**

The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to operate in mainland China could be undermined if our Chinese subsidiaries are not able to obtain or maintain approvals to operate in mainland China. The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations.

## RISK FACTORS

We are not currently required to obtain prior approval or prior permission from the CSRC or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. On February 17, 2023, the CSRC promulgated the Trial Measures and five supporting guidelines, which became effective on March 31, 2023. Pursuant to the Trial Measures, we may be 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. For more details, see “Material Developments of Government Regulation — Other Significant Chinese Regulation Affecting Our Business Activities in China — Regulations on Securities Offering and Listing Outside of China.” As there are uncertainties with respect to the Chinese legal system and changes in laws, regulations, and policies, including how those laws, regulations and policies will be interpreted or implemented, there can be no assurance that we will not be subject to additional requirements, approvals, or permissions in the future. We are required to obtain certain approvals from Chinese authorities in order to operate our Chinese subsidiaries.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (the “M&A Rules”) appear to require that offshore special purpose vehicles, controlled by Chinese companies or individuals formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of Chinese domestic companies or assets in exchange for the shares of the offshore special purpose vehicles, obtain CSRC approval prior to publicly listing their securities on an overseas stock exchange.

Furthermore, in July 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly promulgated the Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law, pursuant to which Chinese regulators are required to accelerate rulemaking related to the overseas issuance and listing of securities, and update the existing laws and regulations related to data security, cross-border data flow, and management of confidential information. Numerous regulations, guidelines and other measures have been or are expected to be adopted under the umbrella of or in addition to the Cyber Security Law and Data Security Law.

Additionally, the Trial Measures and supporting guidelines will implement a new regulatory framework requiring China-based companies to submit filings to the CSRC following the completion of future issuances of equity securities to foreign investors. The Circular on Administrative Arrangements for Filing of Overseas Issuance and Listing of Domestic Companies released by the CSRC provides that companies already listed on overseas exchanges will be grandfathered, such that prior offerings will not need to be filed with the CSRC. However, we may be required to submit filings to the CSRC in connection with future offerings, including follow-on offerings, secondary offerings, or other shelf offerings, within three working days following the completion of any such offering(s).

As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities, and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

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



To operate our general business activities currently conducted in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the State Administration for Market Regulation, or SAMR. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied.

We have not yet received any inquiry, notice, warning, or sanction regarding obtaining approval, completing filing, or other procedures in connection with our previous issuances of securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. Based on our understanding of the Trial Measures and supporting guidelines, we will not be required to submit an application to the CSRC for our previous issuances of securities to foreign investors, but we may be required to submit filings with the CSRC after the completion of future securities offering in the same overseas markets. There remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. If, for any reason, we were to fail to obtain any approvals or to complete any filings or other procedures subsequently 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 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, as well as the trading price of our ADSs and ordinary shares. Any uncertainties and/or negative publicity regarding the aforementioned approvals, filings, or other procedures or any further laws, regulations, or interpretations that may be released or enacted in the future could have a material adverse effect on the trading price of our ADSs and the ordinary shares, including potentially making those ADSs and ordinary shares worthless.

**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 our reputation.**

We are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly mainland China. As our business continues to expand, the applicability of the FCPA and other anti-bribery laws to our operations will continue to increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions, and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

Our Chinese subsidiaries' ability to obtain foreign exchange 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

## RISK FACTORS

the state administration of foreign exchange, or SAFE. In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, 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 SAMR or its local branch, reporting of foreign investment information with the Chinese Ministry of Commerce or registration with other governmental authorities in mainland China.

In the light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we cannot assure you that we will 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 approval, 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 and 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 and adverse effect on our ability to conduct our business.**

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 Latest Practicable Date, 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 we nor any of our subsidiaries have ever directly or indirectly paid dividends or made distributions to U.S. investors. Zai Lab (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$416.5 million in capital contributions via twenty-three separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2022, 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, as the case may be.

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

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 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, 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 these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.**

In 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37. SAFE Circular 37 requires residents of mainland China to register with local branches of SAFE or competent banks designated by SAFE in connection with

## RISK FACTORS

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, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by residents of mainland China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle. If the shareholders of the offshore holding company who are residents of mainland China do not complete their registration with the local SAFE branches, 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 and amendment requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions.

We will request residents of mainland China who we know hold direct or indirect interests in the Company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not be informed of the identities of all the residents of mainland China holding direct or indirect interest in the Company, and we cannot provide any assurance that these residents will comply with our request to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, restrict our cross-border investment activities, limit the ability of our wholly foreign-owned subsidiaries in mainland China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

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

Chinese regulations and rules concerning mergers and acquisitions including the M&A Rules and other regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified 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 economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or Chinese time-honored brand. Moreover, according to the Anti-Monopoly Law of China promulgated in August 2007 and amended in June 2022 with effect from August 2022 and the Provisions on Thresholds for Reporting of Concentrations of Undertakings issued by the State Council in August 2008 and amended in September 2018, 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 must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the applicable threshold is

crossed and such concentration shall not be implemented without the clearance of prior reporting. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In addition, Measures for the Securities Review of Foreign Investment, which became effective in January 2021, require acquisitions by foreign investors of Chinese companies engaged in military-related or certain other industries that are crucial to national security be subject to security review before communication on any such acquisitions. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in mainland China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

**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.**

To obtain FDA, NMPA, and EMA approval for our product candidates in the United States, mainland China, and Europe, we will need to undergo strict pre-approval inspections of our manufacturing facilities, which are located in China, or the manufacturing facilities of our CMOs located in mainland China and elsewhere. Historically, some manufacturing facilities in mainland China have had difficulty meeting the FDA’s, NMPA’s or EMA’s standards. When inspecting ours or our contractors’ Chinese manufacturing facilities, the FDA, NMPA or EMA might cite GMP deficiencies, both minor and significant, which we may not be required to disclose. Remediating deficiencies can be laborious and costly and might consume significant periods of time. Moreover, if the FDA, NMPA or EMA notes deficiencies as a result of its inspection, it will generally reinspect the facility to determine if the deficiency was remediated to its satisfaction. The FDA, NMPA or EMA may note further deficiencies as a result of its re-inspection, either related to the previously identified deficiency or otherwise. If we cannot satisfy the FDA, NMPA, and EMA as to our compliance with GMP in a timely basis, marketing approval for our product candidates could be seriously delayed, which in turn would delay 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 results of operations.**

Local governments within mainland China have granted certain financial incentives from time to time 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 before

## RISK FACTORS

we actually receive any financial incentive. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations. Government grant and subsidies recognized in the income statement in 2022 and 2021 were \$11.5 million and \$4.1 million, respectively.

### **It may be difficult for overseas regulators to conduct investigations or collect evidence within mainland China.**

Shareholder claims or regulatory investigation that is common in the United States generally are difficult to pursue as a matter of law or practicality in mainland China. For example, in mainland China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside mainland China. Although the authorities in mainland China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanisms. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of mainland China. While detailed interpretations of or implementation rules under Article 177 of the PRC Securities Law have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within mainland China may further increase difficulties you may face in protecting your 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.**

The Enterprise Income Tax Law of the People's Republic of China (the "EIT Law"), which was promulgated in March 2007, became effective in January 2008 and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008 and amended in April 2019, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, employees, accounts and assets of enterprises." 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. The Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as Chinese Tax Resident Enterprises on the Basis of De Facto Management Bodies, or SAT Circular 82, issued by the State Taxation Administration of the People's Republic of China (the "SAT") in April 2009, and as amended in November 2013 and December 2017, further specifies certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in mainland China and therefore be considered a Chinese resident enterprise. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in mainland China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in mainland China; (iii) the enterprise's primary assets, accounting books and records, company seals, and



board and shareholders' meeting minutes are located or maintained in mainland China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in mainland China. Although SAT Circular 82 only applies to foreign enterprises that are majority-owned and controlled by Chinese enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the Chinese tax authorities as the test for determining whether the enterprises are Chinese tax residents, regardless of whether they are majority-owned and controlled by Chinese enterprises.

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 the Chinese tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body." If the 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. Dividends paid to a Chinese resident enterprise from its wholly owned subsidiaries in mainland China may be regarded as tax-exempt income if such dividends are deemed to be "dividends between qualified Chinese resident enterprises" under the EIT Law and its implementation rules. However, we cannot assure you that such dividends will not be subject to Chinese withholding tax, as the Chinese tax authorities, which enforce the withholding tax, have not yet issued relevant guidance.

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 shares and ADSs 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-China 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 face uncertainties 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 SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises, or SAT Circular 7, sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding Chinese assets directly or indirectly in the course of a group's overseas restructuring, and the factors to consider in determining whether an Indirect Transfer has a commercial purpose.

## RISK FACTORS

An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the Chinese taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in mainland China, or 90% or more of its income is derived directly or indirectly from mainland China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the Chinese taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-Chinese tax payable on the gain derived from the indirect transfer of the Chinese taxable assets is lower than the potential Chinese income tax on the direct transfer of such assets. Nevertheless, a non-resident enterprise's buying and selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 and will not be subject to Chinese tax pursuant to SAT Circular 7. Under SAT Circular 7, the entities or individuals obligated to pay the transfer price to the transferor shall be the withholding agent and shall withhold the Chinese tax from the transfer price. If the withholding agent fails to do so, the transferor shall report to and pay the Chinese tax to the Chinese tax authorities. In case neither the withholding agent nor the transferor complies with the obligations under SAT Circular 7, the tax authority may hold the withholding agent liable and impose a penalty of 50% to 300% of the unpaid tax on the withholding agent. The penalty imposed on the withholding agent may be reduced or waived if the withholding agent has submitted the relevant materials in connection with the indirect transfer to the Chinese tax authorities in accordance with SAT Circular 7.

However, there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on 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. Zai Lab Limited and other non-resident enterprises in the Company may be subject to filing obligations or being taxed if Zai Lab Limited and other non-resident enterprises in the Company are transferors in such transactions and may be subject to withholding obligations if Zai Lab Limited and other non-resident enterprises in the Company are transferees in such transactions. For the transfer of shares in Zai Lab Limited by investors that are non-Chinese resident enterprises, our Chinese subsidiaries may be requested to assist in the filing under the rules and notices. As a result, we may be required to expend valuable resources to comply with these rules and notices or to request the relevant transferors from whom we purchase taxable assets to comply, or to establish that Zai Lab Limited and other non-resident enterprises in the Company should not be taxed under these rules and notices, which may have a material adverse effect on our financial condition and results of operations. There is no assurance that the tax authorities will not apply the rules and notices to our offshore restructuring transactions where non-Chinese residents were involved if any of such transactions were determined by the tax authorities to lack reasonable commercial purpose. As a result, we and our non-Chinese resident investors may be at risk of being taxed under these rules and notices and may be required to comply with or to establish that we should not be taxed under such rules and notices, which may have a material adverse effect on our financial condition and results of operations or such non-Chinese resident investors' investments in us. We may conduct acquisition transactions in the future. We cannot assure you that the Chinese tax authorities will not, at their discretion, adjust any capital gains and impose tax return filing obligations on us or require us to provide assistance for the investigation of Chinese tax authorities with respect thereto. Heightened scrutiny over acquisition transactions by the Chinese tax authorities may have a negative impact on potential acquisitions we may pursue in the future.



**Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition, and results of operations.**

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the “Stock Option Rules”). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in mainland China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in mainland China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our Chinese individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under Chinese law.

**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.**

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.

On September 15, 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 mainland China, may adversely impact our business and operating results.**

The U.S. government has recently made statements and taken certain actions that led to changes to United States and international trade policies and relations, including imposing several rounds of tariffs affecting certain products manufactured in mainland China, as well as imposing certain sanctions and restrictions in relation to mainland China. It is unknown whether and to what extent new

## RISK FACTORS

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, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation, executive orders and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. or Chinese governments takes retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition, and results of operations.

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

In July 2006, Hong Kong and mainland China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (the “Arrangement”), pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in mainland China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. In January 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (the “New Arrangement”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and mainland China. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court, completion of the relevant legislative procedures in the Hong Kong and announcement by both sides of a date on which the New Arrangement shall commence. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. Additionally, there are uncertainties about the outcomes and effectiveness of enforcement or recognition of judgments under the New Arrangement.

Furthermore, 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. 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 AND NEED FOR ADDITIONAL CAPITAL**

**We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. To date, we have not generated sufficient revenue from product sales to cover corresponding expenses, and we may never achieve or sustain profitability.**

We currently have four approved, commercialized products — ZEJULA, Optune, QINLOCK, and NUZYRA. Although we have launched ZEJULA in Hong Kong, Macau, and mainland China, Optune in Hong Kong, and mainland China, QINLOCK in mainland China, Hong Kong, and Taiwan, and NUZYRA in mainland China, it will take some time to attain profitability, and we may never do so. We have also obtained the rights to commercialize many clinical-stage product candidates. 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 private placements, our initial public offering in September 2017 and multiple follow-on offerings on Nasdaq, and our secondary listing and initial public offering on the Hong Kong Stock Exchange in September 2020. For 2022 and 2021, we generated net revenue, mainly from product sales, of \$215.0 million and \$144.3 million, respectively. We continue to incur significant development, commercialization and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2013. For 2022 and 2021, we reported a net loss of \$443.3 million and \$704.5 million, respectively.

We expect to continue to incur losses in the foreseeable future, and we expect these losses to increase as we:

- continue to commercialize, and maintain and expand sales, marketing and commercialization infrastructure for our approved products and any other products for which we may obtain regulatory approval;
- maintain and expand regulatory approvals for our products and product candidates that successfully complete clinical trials;
- continue our development and commence clinical trials of our product candidates;

## RISK FACTORS

- acquire or in-license other intellectual property, product candidates and technologies;
- maintain and expand our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- seek to identify additional product candidates;
- obtain, maintain, expand and protect our intellectual property portfolio; and
- enforce and defend intellectual property-related claims.

To become and remain profitable, we must continue the commercialization efforts of our approved products and develop and eventually commercialize other product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including manufacturing, marketing, and selling our approved products as well as completing pre-clinical testing and clinical trials of and obtaining marketing approval for our clinical and pre-clinical stage product candidates. We will also need to be successful in satisfying any post-marketing requirements with respect to all of our products. We may not succeed in any or all of these activities and, even if we do, we may never generate product revenues that are significant or large enough to achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts and commercialization efforts, expand our business, or continue our operations. A decline in the value of the Company also could cause you to lose all or part of your investment.

**We will continue to require substantial additional funding for our product development programs and for our commercialization efforts for our approved products and other products for which we may obtain regulatory approval, 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 incur losses or be forced to delay, reduce or terminate such efforts.**

In 2022 and 2021, we generated net revenue, mainly from product sales, of \$215.0 million and \$144.3 million, respectively. Our operations have consumed substantial amounts of cash since inception, and we continue to incur significant development and other expenses related to our ongoing operations. To date, we have financed our activities primarily through private placements, our initial public offering in September 2017 and multiple follow-on offerings on Nasdaq, and our secondary listing and initial public offering on the Hong Kong Stock Exchange in September 2020. As of February 28, 2023, we have raised approximately \$164.6 million in private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses in our initial public offerings and follow-on offerings. For 2022 and 2021, the net cash used in our operating activities was \$367.6 million and \$549.2 million, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue to commercialize our approved products, continue our research and development efforts related

## RISK FACTORS

to our clinical and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek and/or expand regulatory approval for, ZEJULA, Optune, QINLOCK, NUZYRA, and our other products and product candidates. In addition, if we obtain regulatory approval for any additional product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. In particular, if more of our product candidates are approved, additional costs may be substantial as we may have to, among other things, modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers and increase our commercial workforce. We have incurred, and may continue to incur, expenses as we create additional infrastructure to support our operations. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure that we will have sufficient cash from other sources to fund our operations. We will likely need to obtain substantial additional funding in connection with our continuing 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 and be forced to delay, reduce, or terminate our research and development programs or commercialization efforts.

Although we believe our cash and cash equivalents and short-term investments as of December 31, 2022 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:

- the cost and timing of future commercialization activities for ZEJULA, Optune, QINLOCK, NUZYRA, and any other product candidates for which we receive regulatory approval;
- the pricing of and product revenues received, if any, from future commercial sales of our approved products and any other products for which we receive regulatory approval;
- the scope, progress, timing, results, and costs of clinical development of our products in additional indications, if any;
- the scope, progress, timing, results, and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the cost, timing, and outcome of seeking, obtaining, maintaining, and expanding regulatory approval of our products and product candidates;
- 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;
- 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;
- the extent to which we acquire or in-license other product candidates and technologies and the economic and other terms, timing, and success of such collaboration and licensing arrangements;

## RISK FACTORS

- cash requirements of any future acquisitions;
- the number, characteristics, and development requirements of the product candidates we pursue;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to confirm that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- our headcount growth and associated costs; and
- the costs of operating as a public company in both the United States and Hong Kong.

**Raising additional capital or entering into certain other arrangements may cause dilution to our shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.**

Identifying and acquiring rights to develop potential product candidates, conducting pre-clinical testing and clinical trials, and commercializing products for which we receive regulatory approval is a time-consuming, expensive, and uncertain process that may take years to complete. To date, we have generated revenue mainly from the sales of our approved products, after we received respective regulatory approval in the relevant jurisdictions. Our near-term commercial revenue will continue to be derived from sales of our approved products. Additional commercial revenue, if any, will be derived from sales of product candidates that we do not expect to be commercially available until we receive regulatory approval, if at all. We may never generate the necessary data or results required to obtain regulatory approval and achieve product sales of some of our product candidates, and even if we obtain regulatory approval, our products may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may seek additional funding through a combination of 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, 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 could also result in certain 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 ordinary shares and/or ADSs to decline. Additionally, to finance any acquisitions, licensing arrangement or strategic alliance, we may choose to issue our ordinary shares as consideration, which could dilute the ownership of our stockholders. 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 on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

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

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

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

## **RISKS RELATED TO OUR BUSINESS AND INDUSTRY**

### **We are invested in the commercial success of our four approved products and our ability to generate product revenues in the near future is highly dependent on the commercial success of each of those products.**

A substantial portion of our time, resources and effort are focused on, and our ability to generate product revenues will depend heavily on the success of the commercialization of our four approved products. Our ability to successfully commercialize those products will depend on, among other things, our ability to:

- maintain commercial manufacturing or supply arrangements with third-party manufacturers for ZEJULA, Optune, QINLOCK, and NUZYRA;
- produce, through a validated process or procure, both internally or from third-party manufacturers sufficient quantities and inventory of each of our approved products to meet demand;



## RISK FACTORS

- build and maintain internal sales, distribution and marketing capabilities sufficient to generate commercial sales of each of our approved products;
- secure widespread acceptance of ZEJULA, Optune, QINLOCK, and NUZYRA from physicians, healthcare payors, patients, and the medical community;
- properly price and obtain coverage and adequate reimbursement of each of our approved products by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing regulatory labeling, packaging, storage, advertising, promotion, recordkeeping, safety, and other post-market requirements;
- manage our growth and spending as costs and expenses increase due to commercialization; and
- manage business interruptions resulting from the occurrence of any pandemic, epidemic, including from the outbreak of COVID-19, or any other public health crises, natural catastrophe, or other disasters.

There are no guarantees that we will be successful in completing these tasks. In addition, we have invested, and will continue to invest, substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales, and other personnel in support of our sales of each of our approved products.

**Sales of our commercial products may be slow or limited for a variety of reasons including competing therapies or safety issues. If any of our four approved products is not successful in gaining broad commercial acceptance, our business would be harmed.**

Sales of each of our four approved products will be dependent on several factors, including our and our partners' ability to educate and increase physician awareness of the benefits, safety and cost-effectiveness of such products relative to competing therapies. The degree of market acceptance of ZEJULA, Optune, QINLOCK, and NUZYRA among physicians, patients, healthcare payors, and the medical community will 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 third-party 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 continuing effectiveness of manufacturing and supply chain;
- warnings and limitations contained in the approved labeling for such product;
- safety concerns with similar products marketed by others;
- the prevalence and severity of any side effects as a result of treatment with such product;
- our ability to comply with regulatory post-marketing requirements associated with the approval of such product;
- the actual market-size for such product, which may be larger or smaller than expected;
- competitor's entry timing and price; and
- our ability to manage complications or barriers that inhibit our commercialization team from reaching the appropriate audience to promote our product(s) because of the outbreak of COVID-19 or any other public health crises, natural catastrophe or other disasters.

**We may never obtain approval of our commercialized products for other indications outside of the regulatory approvals we have already obtained, which would limit our ability to realize their full market potential.**

In order to market products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. The approval of our four commercial products, ZEJULA, Optune, QINLOCK, and NUZYRA for certain indications in certain jurisdictions does not mean that the regulatory authorities will approve those products for other indications. Approval procedures vary among jurisdictions and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other jurisdiction.

**We have limited experience in commercializing our products. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate substantial product sales revenue.**

We continue to build our salesforce in China to commercialize our approved products, and any additional products or product candidates that we may develop or in-license, which will require significant capital expenditures, management resources and time.

## RISK FACTORS

We have limited experience in commercializing our products. For example, we have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our products. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize our products may involve more inherent risk, take longer and cost more than it would if we were a company with substantial experience launching products.

We compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our products, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our products ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our products.

There can be no assurance that we will be able to further develop and successfully maintain internal sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators, all of which may be necessary to successfully commercialize any product. As a result, we may not be able to generate substantial product sales revenue.

**We have limited experience manufacturing our products and product candidates on a large clinical or commercial scale. We are or will be dependent on third party manufacturers for the manufacture of certain of our products and product candidates as well as 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 results of operations.**

If our two manufacturing facilities are unable to meet our intended production capacity in a timely fashion, we may have to engage a CMO for the production of clinical supplies of our products or product candidates.

Additionally, in order to successfully commercialize our products and product candidates, we will need to identify qualified CMOs for the scaled production of a commercial supply of certain of our products and product candidates. The CMOs should be drug manufacturers holding manufacturing permits with a scope that can cover our drug registration candidates. We have not yet identified suppliers to support scaled production. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our products or product candidates, or market or distribute them.

We may build a large-scale manufacturing plant in Suzhou to potentially support our ability to manufacture our products in the scale necessary. However, if there are delays in bringing the Suzhou manufacturing plant on-line, we may not have sufficient large scale manufacturing capacity to meet our long-term manufacturing requirements. In addition, we are making significant investments in connection with the building of this manufacturing facility with no assurance that this investment will be recouped. Charges resulting from either excess capacity or insufficient capacity would have a negative effect on our financial condition and results of operations.

### **We rely on third-party manufacturers and suppliers to manufacture at least some of our products and product candidates.**

We rely on third-party manufacturers to manufacture at least some of our products and product candidates. For example, we rely on BMS (formerly Turning Point) to manufacture and supply repotrectinib (TPX-0005), argenx to manufacture and supply efgartigimod, MacroGenics to manufacture and supply margetuximab and a pre-clinical multi-specific TRIDENT molecule, Entasis to manufacture and supply SUL-DUR, NovoCure to manufacture and supply Optune, Deciphera to manufacture and supply QINLOCK, Regeneron to manufacture and supply odronextamab, Mirati to manufacture and supply adagrasib, Blueprint to manufacture and supply BLU-945, and CMOs to manufacture and supply NUZYRA and ZL-1102.

Such reliance on third-party manufacturers entails risks to which we would not be subject to if we manufactured product candidates or products 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 product candidates or any products we may eventually commercialize 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 any 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 hikes, manufacturing or supply related issues, could harm our business. We anticipate that, in the near term, all 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 drugs. 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 for an ongoing clinical study 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 these key materials after regulatory approval has been obtained for our product candidates, the commercialization of our products 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 our products and product candidates.

## RISK FACTORS

Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products and drugs. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have limited experience manufacturing pharmaceutical products or drugs on a commercial scale and some of our current suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

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

We are a commercial-stage biopharmaceutical company. Our operations to date have been limited to organizing and staffing the Company, identifying potential partnerships and product candidates, acquiring product and technology rights, conducting research and development activities for our product candidates and, more recently, commercializing products for which we have obtained regulatory approval. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. Additionally, we have limited experience in the sale, marketing, or distribution of pharmaceutical and medical device products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our commercialized products, we may not be able to generate substantial product sales revenue.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate, may make it difficult to evaluate our current business and prospects for future performance. Our short history makes any assessment of our future performance or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by companies in rapidly evolving fields as we continue to expand our commercial activities. In addition, as a recently commercial-stage business, we may be more likely to encounter unforeseen expenses, difficulties, complications and delays due to limited experience. If we do not address these risks and difficulties successfully, our business will suffer.

**If we are unable to obtain regulatory approval for and ultimately commercialize our many product candidates or experience significant delays in doing so, our business, financial condition, results of operations, and prospects may be materially adversely affected.**

Many of our product candidates are in clinical development and various others are in 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 never occur. Each of our product candidates will require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. The success of our product candidates will depend on several factors, including the following:

- successful enrollment of patients in, and completion of, clinical trials as well as completion of pre-clinical studies, which may be adversely impacted by the effects of the COVID-19 pandemic;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;

## RISK FACTORS

- 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;
- making and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining 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;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and alternative drugs;
- 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.

The success of our business is substantially dependent on our ability to complete the development of our product candidates and to maintain, expand or obtain regulatory approval for, and successfully commercialize our products and, if approved, product candidates in a timely manner.

We are not permitted to market any of our products or product candidates in Greater China, the United States, and other jurisdictions unless and until we receive regulatory approval from the NMPA, FDA, and EMA, and other comparable authorities, respectively. The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of mainland China and approval may not be granted. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product's or product candidate's safety and efficacy. Securing regulatory approval may also require the submission of information about the product or drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our products and product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining of the regulatory approval or prevent

## RISK FACTORS

or limit commercial use. The NMPA, FDA, and EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. Our products and product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA, FDA, and EMA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA, FDA, and EMA or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- failure of CROs, clinical study sites or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the NMPA, FDA, and EMA or comparable regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the NMPA, FDA, and EMA or comparable regulatory authorities for approval;
- failure to demonstrate that a product's or product candidate's clinical and other benefits outweigh its safety risks;
- the NMPA, FDA, and EMA or comparable regulatory authorities disagreeing with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in Greater China, the United States, or elsewhere;
- the NMPA, FDA, and EMA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA, FDA, or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA, FDA, or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions that materially and adversely impact the clinical trials.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. For example, even if a product is approved by the FDA or comparable foreign regulatory authorities, we would still need to seek approval from the NMPA to

commercialize the product in mainland China and we may need to conduct clinical trials of each of our product candidates in patients in mainland China prior to seeking regulatory approval from the NMPA. Even if our product candidates have successfully completed clinical trials outside of mainland China, there is no assurance that clinical trials conducted with patients in mainland China will be successful. Any safety issues, product recalls or other incidents related to products approved and marketed in other jurisdictions may impact approval of those products by the NMPA. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, or are imposed on certain product candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the commercialization of our products and the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future.

**We may allocate our limited resources to pursue a particular product, product candidate or indication and fail to capitalize on products, product candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.**

Because we have limited financial and managerial resources, we must limit our licensing, research, development, and commercialization programs to specific products and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may 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.

**Our products and product candidates are subject to extensive regulation, and we cannot give any assurance that any of our products or product candidates will receive any additional regulatory approval or be successfully commercialized.**

Our products and product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, and export are subject to comprehensive regulation by the NMPA, FDA, and EMA, and other regulatory agencies in Greater China, the United States, and the EU, and by comparable authorities in other countries.

The process of obtaining regulatory approvals in Greater China, the United States, and other countries is expensive, may take many years of additional clinical trials and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product or product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, pre-market approval or equivalent application type, may cause delays in the approval or rejection of an application.

In addition, even if we were to obtain approval, regulatory authorities may revoke approval, may approve any of our products or product candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our products or drugs, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product or



## RISK FACTORS

product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product or product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our products or product candidates.

**The market opportunities for our products and product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.**

In markets with approved therapies, we have and expect to initially seek approval of our product candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first-line therapy, but there is no guarantee that our product and product candidates, even if approved, would be approved for second-line or first-line therapy.

Our projections of both 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 later stage therapy and who have the potential to benefit from treatment with our products, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our products and product candidates may be limited or may not be amenable to treatment with our products and product candidates. Even if we obtain significant market share for our products, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first- or second-line therapy.

**The incidence and prevalence for target patient populations of, and our sales and revenue forecasts for, our products and product candidates are based on estimates and third-party sources, and they may prove to be wrong. If the market opportunities for our products and product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.**

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases and regarding sales and revenue forecasts for our products and product candidates based on various third-party sources and internally generated analysis, and they may prove to be wrong. We may also use such estimates in making decisions regarding our product development strategy, including acquiring or in-licensing products or product candidates and determining indications on which to focus in pre-clinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, their acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations, and prospects.



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

In Greater China, the United States, the EU, and some other jurisdictions, manufacturing, sales, promotion, and other activities related to drug candidates and approved drug therapies are subject to extensive regulation by numerous regulatory authorities.

As discussed under Business — Material Developments of Government Regulation, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare that could prevent or delay regulatory approval of our products and product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain regulatory approval. The commercial success of our approved products depends in part on coverage and adequate 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 drug which could adversely affect pricing for such a drug. 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 prevent us from being able to generate revenue, attain profitability, or commercialize our products and product candidates. Various laws that address “fraud and abuse” may restrict our activities, including interactions with healthcare providers, third-party payors and patients, or impose additional obligations (such as government reporting obligations).

Specifically, the pharmaceutical industry in mainland China is subject to comprehensive government regulation and supervision, encompassing the approval, manufacturing, distribution and marketing of new drugs. In recent years, the pharmaceutical laws and regulations in mainland China have undergone significant changes, including but not limited to the adoption of some exploratory programs in pilot regions, and we expect that the transformation will continue. Any changes or amendments with respect to government regulation and supervision of the pharmaceutical industry in Greater China may result in uncertainties with respect to the interpretation and implementation of the relevant laws and regulations or adversely impact the development or commercialization of our drugs and product candidates in Greater China.

For instance, in 2013, the State Council decided to set up the BMTPZ as a pilot zone for the promotion of international medical tourism. With support by the central government, the BMTPZ enjoys multiple policy incentives, including accelerated special approval process for medical devices and drugs, tariff concession for imported devices and drugs, and less restrictions for foreign investors to invest in medical institutions. To enhance patient access to drugs that meet unmet clinical needs, the State Council launched a pilot program in April 2019 where local hospitals are allowed to import and use certain urgently needed drugs that have not been approved for marketing by the NMPA, subject to the approval of Hainan Medical Products Administration and Hainan Health Commission. In March 2020, Hainan Medical Products Administration promulgated the Interim Measures for the Administration of Taking Away the Imported Urgently Needed Drug from the BMTPZ. In June 2022, Hainan Medical Products Administration and Hainan Health Commission jointly promulgated the Measures for the Administration of Taking Away the Imported Urgently Needed Drug from the BMPTZ in replace of the interim measures. These Measures permit a patient to take away, following his or her therapeutic schedules, a reasonable amount of the legally imported drugs from hospitals in the BMTPZ. This program is also known as the special Named

## RISK FACTORS

Patient Program. However, as the special Named Patient Program is newly adopted and evolving, any change in future policies or implementing measures, which we may not be able to predict or control, could create uncertainties affecting our development and commercialization of our drugs candidates.

Efforts to comply with these extensive regulatory requirements may involve substantial costs. If our operations were found to be in violation of applicable 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.

**If safety, efficacy, manufacturing, or supply issues arise with any therapeutic that we use in combination with our products and product candidates, 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.**

In May 2020, Optune was approved by the NMPA in combination with TMZ for the treatment of patients with newly diagnosed GBM. We may also develop certain other products and product candidates for use as a combination therapy, in which case we would seek to develop and obtain regulatory approval for, and, if approved, manufacture and sell, such product in combination with other therapeutics.

If the NMPA, FDA, or another regulatory agency revokes its approval of any therapeutic we use in combination with our products and product candidates, we will 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 applicable 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 current timeline or at all.

Even after obtaining regulatory approval for use in combination with any therapeutic, we continue to be subject to the risk that the NMPA, FDA, or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing, or supply issues could arise with any of our combination therapeutics. This could result in our products being removed from the market or being less successful commercially.

**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 medical device products and drugs 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 worldwide. For example, there are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the field of poly ADP ribose polymerase, or PARP, inhibition to treat cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or 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. Specifically, there are a large number of companies developing or marketing treatments for oncology, autoimmune disorders, infectious diseases, and neuroscience, including many major pharmaceutical and biotechnology companies.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being 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 qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products or drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than products or drugs that we may develop. Our competitors also may obtain NMPA, FDA, or other regulatory approval for their products or drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our products or potential product candidates uneconomical or obsolete, and we may not be successful in marketing our products or product candidates against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

### **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 from regulatory authorities for the sale of any product candidate, our product candidates must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, especially in light of the COVID-19 pandemic.

## RISK FACTORS

The outcomes of pre-clinical development 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.

Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the NMPA, FDA and/or other regulatory authorities, as applicable. The NMPA, FDA, and other regulatory authorities could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or equivalent filing) to the NMPA, FDA, and/or other regulatory authorities for each product or product candidate and, consequently, the ultimate approval and commercial marketing 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, if at all. Our future clinical trial results may not 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 products and product candidates. You may lose all or part of your investment if we are unable to successfully complete clinical development, obtain regulatory approval and successfully commercialize our products and 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, future 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 or them, 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;

## RISK FACTORS

- 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;
- the ability to conduct a companion diagnostic test to identify patients who are likely to benefit from our products and product candidates;
- 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 of our products and product candidates may be greater than we anticipate;
- the supply or quality of our products and product candidates or other materials necessary to conduct clinical trials of our product candidates 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 cancer 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 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 governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that 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 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. You may lose all or part of your investment if we are unable to successfully complete clinical development, obtain regulatory approval and successfully commercialize our products and product candidates.

## RISK FACTORS

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, including in light of the COVID-19 pandemic, 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 similar regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future 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 altogether. 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.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product or product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability of competing therapies also undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the occurrence of any pandemic, epidemic, including from the outbreak of COVID-19, or any other public health crises, natural catastrophe or other disasters may cause a delay in enrollment of patients in clinical trials.

**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 regulatory approval, if any.**

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 of product liability and create issues of 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.



## RISK FACTORS

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 regulatory authorities. In particular, as is the case with all oncology products, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology products or product candidates. For example, the common side effects for ZEJULA include thrombocytopenia, anemia, and neutropenia, and for Optune, the most common side effects when used together with TMZ were low blood platelet count, nausea, constipation, vomiting, tiredness, scalp irritation from the device, headache, seizure, and depression. The common side effects for QINLOCK include tiredness, muscle ache/pain, constipation or diarrhea, itchy/dry skin, headache, loss of appetite, stomach/abdominal pain, nausea, and vomiting. For NUZYRA, the most common side effects include nausea, vomiting, and infusion site reaction. The results of our products' or product candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, trials of our products or product candidates could be suspended or terminated and the NMPA, FDA or comparable regulatory authorities could order us to cease further development of 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 potentially significant negative consequences could result, including:

- our revenue may be negatively impacted;
- the NMPA, FDA or other comparable regulatory authorities may withdraw or limit their approval of such products or product candidates;
- the NMPA, FDA or other comparable 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;

- the NMPA, FDA or other comparable 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 and could substantially increase the costs of commercializing our products and product candidates, if approved, and 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 Category 1 drug designation, it may not lead to a faster development, review, or approval process.**

The NMPA designates innovative drug 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 has 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 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 introduced since 2015 which significantly accelerated time to market for innovative drugs, the regulatory process in mainland China 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 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 one or more jurisdictions, 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 product candidates or any other product candidate that we may in-license, acquire, or develop in the future.

## RISK FACTORS

**We continue to be subject to ongoing obligations and continued regulatory review with respect to our products and any product candidates for which we receive regulatory approval, 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 products or product candidates, we may be subject to penalties.**

Even after obtaining regulatory approval, our products and product candidates will be subject to, among other things, ongoing regulatory requirements governing the labeling, packaging, promotion, recordkeeping, data management and submission of safety, efficacy, and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. For example, ZEJULA, Optune, QINLOCK, and NUZYRA will continue to be subject to post-approval development and regulatory requirements, which may limit how they 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. Additionally, to the extent we want to make certain changes to the approved products, product labeling or manufacturing processes, we will need to submit new applications or supplements to the Hong Kong Department of Health and the NMPA and obtain the agencies' approval.

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

In addition, once a product is approved by the NMPA, FDA, or a comparable 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 NMPA, FDA or comparable 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 the members of our research and development team, as well as the other principal members of our management, including Samantha (Ying) Du, our founder, Chief Executive Officer, and Chairperson of the Board of Directors. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time with one month's prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing, and sales and marketing personnel will also be critical to our success. 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 these 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. In addition, our management will be required to devote significant time to new compliance initiatives from our status as both a U.S. public company and a Hong Kong public company, which may require us to recruit more management personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

**We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.**

We expect to experience significant 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 our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, 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.

## RISK FACTORS

**We may explore the licensing of development and/or commercialization rights or other forms of collaboration worldwide, which will expose us to additional risks of conducting business in additional international markets.**

We are currently focused on developing and commercializing products that target serious, life-threatening medical conditions affecting patients in Greater China. We have and may in the future explore licensing or development and/or commercialization rights or other forms of collaboration in territories outside of Greater China and any such licensing, development, commercialization, or collaboration may subject us to additional risks that may adversely affect our ability to attain or sustain profitable operations or our other business plans. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain our operating goals, including:

- efforts to enter into collaboration or licensing arrangements with third parties may increase our expenses or divert our management's attention from the acquisition or development of product candidates;
- difficulty of effective enforcement of contractual provisions in local 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 the anti-bribery laws in mainland China, Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act and other anti-bribery and corruption laws; and
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, disease or public health epidemics, such as the coronavirus impacting mainland China and elsewhere, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

**We may engage in future partnership, in-licensing, joint ventures, or future business acquisitions that could disrupt our business, cause dilution to holders of our ordinary shares and/or ADSs and harm our financial condition and operating results.**

We have, from time to time, evaluated partnership or strategic collaboration opportunities or investments and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for the Company. In connection with these partnership or collaboration opportunities, acquisitions, or investments, we may:

- issue ordinary shares that would dilute the percentage of ownership of the holders of our ordinary shares and/or ADSs;
- 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 BV 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 and any future products and product candidates that we may develop. 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, we cannot assure you that it will ultimately strengthen our competitive position or that it will not 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;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;

## RISK FACTORS

- diversion of management’s attention from their day-to-day responsibilities;
- 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, particularly those of the acquired entity.

We may not be able to realize the benefit of current or future collaborations, strategic partnerships or the license of our third-party 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. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies 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 our products and product candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition, and results of operations.

**We may need to significantly reduce our prices for our approved products or our other product candidates and devices for which we may receive regulatory approval in mainland China and face uncertainty of reimbursement, which could diminish our sales or 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 newly created National Healthcare Security Administration (“NHSA”), an agency responsible for administering mainland China’s social security system, organized a price negotiation with drug companies for 119 new drugs that had not been included in the NRDL at the time of the negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. In December 2020, 119 drugs were added to the 2020 NRDL, and the average price reduction was about 50.64%. In December 2021, 74 drugs were added to the 2021 NRDL, and the average price reduction was about 61.71%. In January 2023, 111 drugs were added to the 2022 NRDL, and the average price reduction of the 108 drugs participating in price negotiations is 60.1%. 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. We lowered the selling price of ZEJULA due to its inclusion in the NRDL in December 2021 and December 2020 for certain therapies, and we lowered the selling price of QINLOCK and NUZYRA in June 2022 in preparation for their inclusion in the NRDL in January 2023. As a result, the potential revenue from the sales of these products could be negatively affected.

We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in mainland China, but we will likely need to significantly reduce our prices and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. If we were to successfully launch commercial sales of our oncology-based product and product candidates,



our revenue from such sales is largely expected to be self-paid by patients, which may make our product candidates and devices less desirable. On the other hand, if the NHSA or any of its local counterparts includes our drugs and devices in the NRDL, which may increase the demand for our product candidates and devices, if and when approved, our potential revenue from the sales of our product candidates and devices may still decrease as a result of lower prices.

Eligibility for reimbursement in mainland China does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale, and distribution.

Moreover, the centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products, and we cannot assure you that our drug price will not be adversely affected.

**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 product candidates.**

The life sciences industry in mainland China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including approval, registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and certification requirements and procedures, periodic renewal and re-evaluation processes, registration of new products and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. 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.

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.

## RISK FACTORS

The regulatory framework governing the pharmaceutical industry in mainland China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services without incurring significant fiscal burden. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the level we expect, if at all. Moreover, the reform could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

For further information regarding government regulation in mainland China and other jurisdictions, see “Material Developments of Government Regulation”.

**If we breach our license or other intellectual property-related agreements for our products or product candidates or otherwise experience disruptions to our business relationships with our licensors and collaboration partners, we could lose the ability to continue the development and commercialization of our products and product candidates.**

Our business relies, in large part, on our ability to develop and commercialize products and product candidates from third parties as described above in the Overview of Our Licensing and Strategic Collaboration Agreements. If we have not obtained a license to all intellectual property rights that are relevant to our products and product candidates and that are owned or controlled by our licensors and collaboration partners or owned or controlled by affiliates of such licensors and collaboration partners, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors and collaboration partners breach such agreements, we may not be able to enforce such agreements against our licensors’ parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable product candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such product candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and other intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such product candidates and/or maintaining the confidentiality of information we receive from our licensors. We are also obligated to use commercially reasonable efforts to develop and commercialize our in-licensed assets in certain of their respective territories under their respective agreements.

If we fail to meet any of our obligations under our license and other intellectual property-related agreements, our licensors have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable products and product candidates and other third parties may be able to market products or product candidates similar or identical to ours. In such case, we may be required to provide a grant back license or expand an existing license to the licensors under our own intellectual property with respect to the terminated products.

For example, if our agreement with GSK for ZEJULA terminates for any reason, we are required to grant GSK an exclusive license to certain of our intellectual property rights that relate to ZEJULA to develop, manufacture, and commercialize ZEJULA outside of the licensed territory. Furthermore, if our agreement with MacroGenics for margetuximab and a pre-clinical multi-specific TRIDENT molecule is terminated by MacroGenics or by us for certain reasons, we are required to grant MacroGenics an option to convert the non-exclusive license granted to MacroGenics to use certain of our intellectual property rights that relate to margetuximab and a pre-clinical multi-specific TRIDENT molecule in Greater China to an exclusive license. Similarly, if our agreement with Entasis for durlobactam is terminated, we are required to grant Entasis an exclusive, fully paid, royalty free, perpetual, irrevocable and sublicensable (through multiple tiers) license under certain of our intellectual property rights to make (or have made), use, import, offer for sale and sell durlobactam in the licensed territory. If our agreement with Deciphera for ripretinib is terminated, we are required to grant Deciphera a worldwide, perpetual and irrevocable license under certain of our intellectual property rights, if any, that relate to QINLOCK to develop, manufacture, and commercialize ripretinib. Likewise, if our agreements with BMS (formerly Turning Point) for Repotrectinib or with Taiho (formerly Cullinan Pearl) for Zipalertinib (formerly CLN-081) are terminated for certain reasons, we are required to extend the scope of their respective licenses under certain intellectual property of our own to include Greater China. If our agreement with argenx is terminated, we are required to grant argenx and its affiliates an exclusive, worldwide license under certain intellectual property of our own to exploit the licensed products in Greater China. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Furthermore, some of the milestone payments under our licensing agreements are payable upon our product candidates reaching development milestones before we have commercialized or received any revenue from the sales of such product candidates. We cannot guarantee, therefore, that we will have sufficient resources to make such milestone payments. Any uncured, material breach under our licensing agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable product candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, disputes may further arise regarding intellectual property subject to a license and/or collaboration agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

## RISK FACTORS

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. For example, our licenses from GSK, Paratek, and argenx comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses and our ability to produce and sell our products and product candidates may be materially harmed. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, the agreements under which we currently license or have rights to use intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed, sublicensed or obtained rights to use prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable 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.

### **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 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 the 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 ordinary shares and/or our ADSs.

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 director and officer insurance to cover other commercial liability claims, these insurances 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.

**The research and development projects under our internal discovery programs are at an early-stage of development. As a result, we are unable to predict if or when we will successfully develop or commercialize any product candidates under such programs.**

Our internal discovery programs are at an early-stage of development and will require significant investment and regulatory approvals prior to commercialization. Each of our product candidates will require additional clinical and pre-clinical development, management of clinical, pre-clinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before they generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the NMPA, the FDA, or comparable regulatory authorities, and we may never receive such regulatory approval for any such product candidates.

We cannot be certain that clinical development of any product candidates from our internal discovery programs will be successful or that we will obtain regulatory approval or be able to successfully commercialize any of our product candidates and generate revenue. Success in pre-clinical testing does not ensure that clinical trials will be successful, and the clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. Any such failure could cause us to abandon further development of any one or more of our product candidates and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs with the NMPA, the FDA or comparable regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenue.

## RISK FACTORS

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

In 2017, we built a small molecule facility capable of supporting clinical and commercial production, and in 2018, we built a large molecule facility in Suzhou, China using Cytiva FlexFactory platform technology capable of supporting clinical production of our product candidates. These facilities were approved for clinical and commercial production of our product candidates and, accordingly, we intend to rely on these facilities for the manufacture of clinical and commercial supply of some of our products or product candidates. If either facility were damaged or destroyed, or otherwise subject to disruption, for example due to the COVID-19 pandemic, 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 contract manufacturers for an indefinite period. Any new facility needed to replace an existing production facility would need to comply with the 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 are ultimately approved. Any disruptions or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialize our products or product candidates, which would adversely affect our business and results of operations.

**We may become involved in lawsuits to protect or enforce our intellectual property.**

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. If we are unable to protect our intellectual property, our competitors could use our intellectual property to market offerings similar to ours and we may not be able to compete effectively. Moreover, others may independently develop technologies that are competitive to ours or infringe on our intellectual property. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. We may not be able to prevent third parties from infringing upon or misappropriating our intellectual property, particularly in countries where the laws may not protect intellectual property rights as fully as in the United States. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Furthermore, some of our intellectual property rights are licensed from our partners who may have the first right and/or who we may need to cooperate with to assert claims of infringement against third parties or defend against claims or counterclaims brought by third parties against us alleging that we infringe their intellectual property rights, and our partners may be unwilling to assert or allow us to assert such intellectual property rights against perceived infringers or in defense of such claims or counter claims to avoid provoking these third parties to assert invalidity claims or other challenges to the validity or enforceability of such intellectual property rights. This may limit our ability to effectively prevent third parties from infringing upon or misappropriating such intellectual property rights or adequately defend against claims or counterclaims that we infringe their intellectual property rights.

**Our internal computer systems, or those used by our CROs, CMOs, or other contractors or consultants, may fail or suffer cybersecurity breaches.**

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to cyberattacks, malware, and other system failures that may result in unauthorized access, damage, and other harms to our business or reputation. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

The data privacy regimes in mainland China and in the United States are evolving and there may be more stringent compliance requirements for the collection, processing, use, and transfer of personal information and important data. In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at the Company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, cause damage to our reputation or a loss of revenues and invite regulator's scrutiny, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of the Company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. Because we have outsourced elements of our information technology infrastructure to vendors, such vendors may or could have access to our confidential information. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes, including the recruitment and retention of experienced information technology professionals, who are in high demand, is costly and



## RISK FACTORS

requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

**We 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 are subject to data privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. 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.

Within the United States, there are numerous federal and state laws and regulations related to the privacy and security of personal information. For example, at the federal level, our operations may be affected by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (collectively, “HIPAA”), which impose obligations on certain “covered entities” and their “business associates” contractors with respect to the privacy, security, and transmission of certain individually identifiable health information. Although we believe that we are not currently directly subject to HIPAA, HIPAA affects the ability of healthcare providers and other entities with which we may interact to disclose patient health information to us. As another example, at the state level, we are subject to the California Consumer Privacy Act, as amended by the California Privacy Rights Act, which gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose details about the personal information they collect, as well as other rights such as the right to ask companies to delete a consumer’s personal information and opt out of the sale of personal information. Colorado, Connecticut, Utah, and Virginia have also passed comprehensive privacy laws that may impact our operations, and there are similar legislative proposals being advanced in other U.S. states, as well as in Congress.

Numerous other jurisdictions regulate the privacy and security of personally identifiable data. For example, the General Data Protection Regulation (“GDPR”) imposes obligations on companies that operate in our industry with respect to the processing of personal data collected in relation to an establishment located in the European Economic Area (“EEA”) or in connection with the offering of goods and services to, monitoring the behavior of, individuals located in the EEA. The GDPR also forms part of the law of England and Wales, Scotland, and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy, and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419), known as “UK GDPR.” The GDPR and UK GDPR impose onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If we or our service providers fail to comply with any applicable GDPR or UK GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million/GBP 17.5 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational

harm and a potential loss of business and goodwill. The GDPR and UK GDPR additionally place restrictions on the cross-border transfer of personal data from the EEA to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the People's Republic of China and the United States. In July 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA or UK to the United States. This CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation.

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.

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

The definition of scientific data is quite broad, but the Chinese government has not issued further guidance to clarify if clinical study data would fall within the definition of scientific data. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data 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 all 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.

# RISK FACTORS

## RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

**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.**

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 parties for execution of our pre-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol 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 (“GLP”), 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 comparable foreign 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 or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. 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 or not they devote sufficient time and resources to our on-going clinical, nonclinical, and pre-clinical programs. If 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.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We rely on third-party vendors and CROs for some of our pre-clinical studies and clinical trials related to our product or drug 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 it can be reasonably demonstrated 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. Identifying, qualifying, and managing performance of third-party service providers can be difficult, time-consuming, and cause delays in our development programs. 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. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

**We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.**

We have licensed and sublicensed patent rights from third parties for some of our development programs as described above in the Overview of Significant License and Strategic Collaboration Agreements. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that the patents and patent applications for our products and product candidates have been or will be prepared, filed, prosecuted, or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our product candidates. If our licensors or such third parties fail to prepare, prosecute, or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control prosecution, maintenance or enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed and sub-licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected. By way of illustration, under our agreements with BMS (formerly Turning Point) for repotrectinib, Taiho (formerly Cullinan Pearl) for Ziplertinib (formerly CLN-081), NovoCure for TTFields, argenx for Efgartigimod,

## RISK FACTORS

Karuna for KarXT, and Blueprint for BLU-945, each of our licensors has the first right to prosecute and maintain the respective licensed patents and joint patents in Greater China. With respect to the patent portfolio for ZEJULA, which we sub-license from GSK, we have the first right to enforce such patent portfolio within mainland China, Hong Kong, and Macau. However, GSK maintains the right to enforce such patent portfolio in all other territories or, if we fail to bring an action within 90 days, within Greater China. In the case where GSK controls such enforcement actions, although GSK has the obligation to consult with us on such actions within Greater China, rights granted by GSK under ZEJULA to another licensee, such as Janssen Biotech, Inc. to whom GSK has granted an exclusive right to develop ZEJULA for the treatment of prostate cancer, could potentially influence GSK's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

### **We have relied on a limited number of customers for a substantial portion of our revenue.**

A substantial amount of our revenue is derived from sales to a limited number of customers, which are distributors as consistent with industry norm. Because of this concentration among a small number of customers, if an event were to adversely affect one of these customers, it would have a material impact on our business. For 2022 and 2021, the aggregate amount of product revenue generated from our five largest customers accounted for approximately 37.7% and 39.9% of our product revenue, respectively. Product revenue generated from our largest customer for the same periods accounted for approximately 22.4% and 21.5% of our product revenue, respectively. While we are continuing to expand our customer base for our four approved products in mainland China, we may continue to rely on such major customers in ramping up the sales of our commercialized products. There is no assurance that our five largest customers will continue to purchase from us at the current levels or at all in the future. If any of our five largest 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, there is no assurance that our major customers will not negotiate for 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 conditions may be materially and adversely affected. Therefore, any risks which could have a negative impact on our major customers could in turn have a negative impact on our business.

### **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 distribute our commercialized products. We also expect to rely on third-party distributors to distribute our other products and internally discovered products, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributors, who may fail to distribute our products in the manner we contemplate. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our products to hospitals, medical institutions, and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our products is interrupted, our sales volumes and business prospects could be 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, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and an impairment in the carrying value of our short-term investments could negatively affect our consolidated results of operations.**

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 we continue to expand our business, the amount and duration of our credit exposure will be expected to increase over the next few years, 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.

Also, 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, 2022 and 2021, we had cash and cash equivalents of \$1,008.5 million and \$964.1 million, restricted cash of \$0.8 million and \$0.8 million, and short-term investments of nil million and \$445.0 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, 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. As of December 31, 2022 and 2021, our short-term investments consisted of time deposits with original maturities between three months and one year.

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.

# RISK FACTORS

## RISKS RELATED TO INTELLECTUAL PROPERTY

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

Our success depends, in part, on our ability to protect our products and product candidates from competition by obtaining, maintaining, and enforcing our intellectual property rights, including patent rights. We seek to protect the products and product candidates and technology that we consider commercially important by filing Chinese and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and product candidates. We do not own or exclusively license any issued patents with respect to certain of our products and product candidates in all territories in which we plan to commercialize our products and product candidates. For example, we do not own or exclusively license any issued patents covering ZEJULA in Macau. We do not own or exclusively license any issued patents covering margetuximab and a pre-clinical multi-specific TRIDENT molecule in Macau, but we do exclusively license issued patents or pending patent applications in mainland China, Hong Kong or Taiwan covering them. We do not own or exclusively license any issued patents or pending patent applications covering Tumor Treating Fields in Macau or Taiwan, but we do exclusively license issued patents and pending patent applications covering Tumor Treating Fields in mainland China and Hong Kong. We in-license one issued patent in Taiwan, two pending patent applications in mainland China, one pending patent application in each of Taiwan and Hong Kong, which are all related to retifanlimab (INCMGA0012 (PD-1)). We in-license two issued patents in each of mainland China, Hong Kong, and Taiwan relating to durlobactam, but we do not own or exclusively license any issued patents or pending application in Macau. We cannot predict whether such patent applications or any of our other owned or in-licensed pending patent applications will result in the issuance of any patents that effectively protect our products and product candidates. If we or our licensors are unable to obtain or maintain patent protection with respect to our products or product candidates and technology we develop, 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, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, our license and intellectual property-related agreements may not provide us with exclusive rights to use our in-licensed intellectual property rights relating to the applicable products and product candidates in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. For example, under our agreements with GSK for ZEJULA, our licenses are limited to mainland China, Hong Kong, and Macau. In the case of our agreements with argenx for efgartigimod, Paratek for omadacycline (ZL-2401), and Deciphera for QINLOCK, our licenses or, as applicable, our rights are limited to Greater China. Also, in the case of our agreement with Entasis for durlobactam, our license is limited to mainland China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand, and Japan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.



## RISK FACTORS

Patents may be invalidated and patent applications relating to bemarituzumab (FPA144), Tumor Treating Fields, margetuximab, durlobactam, a pre-clinical multi-specific TRIDENT molecule or retifanlimab (INCMGA0012 (PD-1)) as well as Regeneron's patents relating to odronextamab (REGN1979), may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, mainland China and the United States have adopted the "first-to-file" or the "first-inventor-to file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file or the first-inventor-to file system third parties may be granted a patent relating to a technology, which we invented.

In addition, under Chinese Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in mainland China is required to report to the CNIPA for confidentiality examination. Otherwise, if an application is later filed in mainland China, the patent right will not be granted. Moreover, even if patents do grant from any of the applications, the grant of a patent is not conclusive as to its scope, validity, or enforceability.

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 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. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

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 in mainland China, United States, and abroad. We and our licensors and collaboration partners may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or may become involved in opposition, derivation, revocation, re-examination, post-grant, and *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products or product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or one of our licensors or collaboration partners, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as

## RISK FACTORS

oppositions in a foreign patent office, that challenge the priority of our or our licensor's or collaboration partner's invention or other features of patentability of our owned or in-licensed patents and patent applications. 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 our ability to stop others from using or commercializing similar or identical technology and products, limit the duration of the patent protection of our technology, or limit the price at which we can sell our products and product candidates. 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 terms of patents are finite. The patents we own or in-license and the patents that may issue from our currently pending owned and in-licensed patent applications generally have a 20-year protection period starting from such patents' filing date (or the priority date, if priority is claimed). 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. While the patent laws in jurisdictions we operate in, including in the United States and mainland China, enable the term of the patent term to be extended to account for the time required for the development, testing and regulatory review of products and new product candidates, we may not be able to successfully obtain any extension of terms of our owned or in-licensed patents, and, in mainland China, the legal regime for obtaining patent term extensions is being developed and not yet mature. As a result, our owned or in-licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents 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 USPTO or comparable foreign authority.**

We or our licensors or collaboration partners may become involved in patent litigation against third parties to enforce owned or in-licensed patent rights, to invalidate patents held by such third parties or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that patents owned or in-licensed by us, our licensors or our collaboration partners do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate, or otherwise violate their intellectual property 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 commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed

intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our products and product candidates.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. 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. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

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 would lose at least part, and perhaps all, of the patent protection covering such products or product candidates. Competing products or drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products or drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations, and prospects.

### **We may not be able to protect our intellectual property in mainland China or other jurisdictions.**

The validity, enforceability, and scope of protection available under the relevant intellectual property laws in mainland China are uncertain and still evolving. Implementation and enforcement of Chinese intellectual property-related laws have historically been deficient and ineffective. Accordingly, intellectual property and confidentiality legal regimes in mainland China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or our licensors to determine the enforceability, scope, and validity of our proprietary rights or those of others. As noted above, we may need to rely on our licensors to enforce and defend our technologies. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our operations, which could harm our business, financial condition, and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects, and reputation.

## RISK FACTORS

Filing, prosecuting, maintaining, and defending patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or mainland China or from selling or importing products made using our inventions in and into the United States, mainland China or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including mainland China. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims 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 around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 in patent law could have a negative impact on our business.**

Changes in either the patent laws or interpretation of the patent laws in the United States, mainland China, and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, including changing the standards of patentability, and any such changes could have a negative impact on our business. For example, in the United States, the Leahy-Smith America Invents Act (the “America Invents Act”), which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a “first-to-invent” system to a “first-to-file” to a “first-inventor-to file” system as of March 2013, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These include allowing third party submission and explanation of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post grant proceedings, including post grant review, *inter partes* review, and derivation proceedings. As a result of these changes, patent law in the United States may favor larger and more established companies that have

greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-inventor-to-file provisions became effective in March 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In mainland China, it has become challenging to obtain patents that claim aspects of a product other than the direct compound structure of the active pharmaceutical ingredient of a pharmaceutical or biopharmaceutical product, such as selection patents, polymorphs, enantiomers, salts, ethers and esters, compositions, doses, combinations, prodrugs, metabolites, and new medical uses. Additionally, because a Markush claim lists alternative elements and thus claims numerous lots of chemicals, a Markush claim is much easier than a direct compound structure of the active pharmaceutical ingredient claim to be invalidated. Even if these so-called “secondary patents” are granted in mainland China, they remain challenging to enforce against potential infringers and are invalidated or declared unenforceable at a high rate when challenged. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the Chinese government, the People’s Courts and the China National Intellectual Property Administration, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

In addition to the protection afforded by registered patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. If any of the partners, collaborators, scientific advisors, employees, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim

## RISK FACTORS

that a third party illegally disclosed or misappropriated our trade secrets, including through intellectual property litigations or other proceedings, is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts in mainland China and other jurisdictions inside and outside the United States are less prepared, less willing or unwilling to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. For example, competitors could purchase our products and product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate, or otherwise violate our intellectual property rights, design around our intellectual property protecting such technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be disclosed or independently developed by a competitor, we would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition, and results of operations.

**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 commercial success depends significantly on our ability to develop, manufacture, market, and sell our products and product candidates 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. In mainland China and the United States, invention patent applications are generally maintained in confidence until their publication 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third-party may have filed a patent application without our knowledge while we are still developing or producing that product. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or product candidates we may develop, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or product candidates we may develop and any other products, product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. There is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

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

- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, if 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, and could require us to make substantial licensing and royalty payments;
- defend litigation or administrative proceedings;
- reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming;
- cease developing, manufacturing, and commercializing the infringing technology, products, or product candidates; and
- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Even if we are successful in such litigations or administrative proceedings, such litigations and proceedings may be costly and could result in a substantial diversion of management resources. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition, and results of operations.

**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 legal proceedings relating to our, our licensor's or other third parties' intellectual property claims 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 ordinary shares. 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.



## RISK FACTORS

**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 our employees', consultants' or advisors' current or former employers. 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 ensure that our employees, consultants and advisors do not improperly use the intellectual property, proprietary information, know-how or trade secrets of their current or former employers in their work for us, we may be subject to claims that we or these individuals have breached the terms of any confidentiality, non-disclosure, non-use, non-competition or non-solicitation agreements we or these individuals have with such current or former employers, or that we or these individuals have, inadvertently or otherwise, improperly used or disclosed the alleged trade secrets or other proprietary information of such current or former employers.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could 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 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 the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our 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 thereof may adversely affect our ability to hire employees or contract with independent sales representatives or research 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, results of operations, and financial condition.

In addition, while it is our policy to 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 an agreement with each employee or contractor who, in fact, conceives or develops intellectual property that we regard as our own. 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 or contractors or other third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our 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 necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.**

Although we also intend to develop product candidates through our own internal research, our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license product candidates to grow our product candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any

such product candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as oncology and inflammatory and infectious diseases. In that 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 intellectual property relating to, or necessary for, 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 third-party intellectual property rights for product candidates is a competitive area, and a number of more established 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 established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, 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 for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment.

**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 FDA marketing approval of our products or any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

The China Patent Law, which was most recently amended by the SCNPC on October 17, 2020, and became effective on June 1, 2021, for the first time, provides for patent term extension and adjustments for patents and a patent linkage system. Under the China Patent Law, patent term extensions can be obtained for regulatory delays in the review and approval of new drugs but are limited to no more than five years and the total post-marketing patent term of the new drug cannot exceed 14 years. The China Patent Law also provides for patent term adjustments where there is an unreasonable delay caused during patent examination. A patentee may apply for a patent term adjustment where the patent is granted at least four years after the filing date, and at least three years after substantive

## RISK FACTORS

examination was requested. In addition, the China Patent Law, for the first time, introduces in mainland China a patent linkage system for the early resolution of patent disputes concerning generic drug applications similar to the Hatch Waxman Act in the United States, and around the same time of the China Patent Law, the National Medical Products Administration and the China National Intellectual Property Administration jointly issued on September 11, 2020 a draft of the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) for public comment which sets forth, for the first time, details of how such patent linkage system would be implemented. However, to be implemented, the patent term extensions and adjustments require further promulgation of regulations and detailed implementation measures. Additionally, in mainland China, there is currently no effective law or regulation providing for data exclusivity, although Chinese regulators have proposed a framework for integrating data exclusivity into the Chinese regulatory regime. Until the new provisions of the China Patent Law providing for patent term extensions and adjustments and the proposed framework for data exclusivity can be implemented through the promulgation of additional laws, regulations and detailed implementation measures, a lower-cost generic or biosimilar drug can emerge onto the market more quickly. Consequently, the absence of currently implemented laws and regulations on patent term extension and adjustment and 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. For instance, if we are unable to obtain patent term extension or adjustment or the term of any such extension or 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. The Beijing IP Court accepted a first patent linkage litigation in November 2021. In October 2021, CNIPA announced that it had received 23 requests for administrative adjudication and accepted 12 of them. The first patent linkage case (generic filed with a Type IV Certificate on August 16, 2021) received a first court decision on April 15, 2022 by the Beijing IP Court, and a second court decision on August 5, 2022 by the Supreme People's Court, which upheld the first decision in rejecting the originators' case and finding the generic did not fall into the scope of the revised claims after the patent invalidation process. Since similar cases would usually take several months to conclude and require additional months thereafter for the decision to be made publicly available, the Company will monitor future administrative rulings/court decisions on patent linkage and their impact on the protection patent linkage in mainland China provides to originators in practice.

If the originator of chemical drug gets a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires. If the originator for biological drug cannot secure a favorable decision before the NMPA's issuance of the marketing authorization, the NMPA will grant marketing authorization to the biosimilar applicant accordingly. If originator receives court judgment after the issuance of marketing authorization, the court will normally support an infringement claim in a future infringement lawsuit based on the effective decision of patent coverage based on Article 76 of Patent Law, if the relevant patent and relevant drug are the same. If the originator fails the patent linkage litigation, the generic drug marketing authorization applicant can sue at Beijing IP court for damages to be paid by the patentee or interested party, if the patentee or interested party knew or should have known that (a) the relevant patent is invalid or (b) the generic drug applied for registration does not fall within the scope of the relevant patent.

**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.**

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. 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. 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. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could 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 any product or product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

## RISK FACTORS

- 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 harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may discover certain technologies containing such trade secrets or know how through independent research and development and/or subsequently file a patent covering such intellectual property.

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 financial reporting controls, 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 ordinary shares and/or ADSs 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 the Nasdaq Global Market.

**We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our ordinary shares and/or ADSs.**

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on their ordinary shares and/or ADSs at least in the near term, and the success of an investment in our ordinary shares and/or ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of our ordinary shares and/or ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that our ordinary shares and/or ADSs will appreciate in value or even maintain the price at which our investors purchased the ordinary shares and/or ADSs.

**The market price of our ADSs and/or our ordinary shares may be volatile, which could result in substantial loss to you.**

The market price of our ADSs and/or ordinary shares has been volatile. From September 20, 2017 to February 24, 2023, the closing price of our ADSs on the Nasdaq Global Market ranged from a high of \$191.71 to a low of \$14.95 per ADS. From September 28, 2020 to February 24, 2023, the closing price of our ordinary shares on the Hong Kong Stock Exchange ranged from a high of HK\$150.40 to a low of HK\$17.16 per ordinary share.

The market price of our ADSs and ordinary shares are likely to continue to be highly volatile and subject to wide fluctuations in response to factors, including the following:

- announcements of competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;
- 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 ADSs or ordinary shares; and
- sales or perceived sales of additional ADSs or ordinary shares.

## RISK FACTORS

In addition, the securities markets have from time to time experienced 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 ADSs or ordinary shares, regardless of our actual operating performance. For example, in March 2020, the exchanges in the United States and mainland China experienced a sharp decline as the COVID-19 pandemic negatively affected stock market and investors sentiment and resulted in significant volatility, including temporary trading halts. In 2022, there were multiple severe daily drops in the global stock market. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs and/or ordinary shares, which would also negatively affect the trading prices for our ADSs and ordinary shares.

### **Fluctuations in the value of the RMB or HK dollars may have a material adverse effect on our results of operations and the value of your investment.**

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. On July 21, 2005, the Chinese government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar, and the RMB appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the People's Bank of China ("PBOC"), announced that the Chinese government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the RMB by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively. On October 1, 2016, the RMB joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right, or SDR, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, the RMB depreciated significantly while the U.S. dollar surged and mainland China experienced persistent capital outflows. With the development of the foreign exchange market and progress towards interest rate liberalization and RMB internationalization, the Chinese government may in the future announce further 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 in the future. 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 ADSs will, therefore, be affected by the foreign exchange rates between U.S. dollars, HK dollars and the RMB. For example, to the extent that we need to convert U.S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or the HK dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars or HK dollars for the purpose of making payments for dividends on our ADSs or ordinary shares or for other business purposes, appreciation of the U.S. dollar or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us.

Since 1983, the Hong Kong Monetary Authority ("HKMA") has pegged the HK dollar to the U.S. dollar at the rate of approximately HK\$7.80 to US\$1.00. However, there is no assurance that the HK dollar will continue to be pegged to the U.S. dollar or that the HK dollar conversion rate will remain at HK\$7.80 to US\$1.00. If the HK dollar conversion rate against the U.S. dollar changes and the



value of the HK dollar depreciates against the U.S. dollar, 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 your investment. 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 dividends on our ADSs or ordinary shares or for other 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 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 sixth 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 all 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 ensure that you can 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.

## RISK FACTORS

Under the deposit agreement, for the ADSs, the depository 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 depository, unless (i) we have failed to timely provide the depository with our notice of meeting and related voting materials, (ii) we have instructed the depository that we do not wish a discretionary proxy to be given, (iii) we have informed the depository 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 depository, 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.

**You may not receive distributions on our ADSs 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 distribution available to you.**

Although we do not have any present plan to pay any dividends, the depository of our ADSs has agreed to pay to you 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. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depository 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 of 1933, as amended (the "Securities Act") but are not so properly registered or distributed under an applicable exemption from registration. The depository may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depository 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.

**Your right to participate in any future rights offerings may be limited, which may cause dilution to your 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 you 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 depository will not make rights available to you 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 depository does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

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

We are incorporated 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 succeed in growing 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 the PFIC for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our ADSs or ordinary shares 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 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.

## RISK FACTORS

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 (including cash raised in this offering) 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 in the next paragraph, 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 ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to such investor for all succeeding years during which the investor own ADSs or shares (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 our ADSs or ordinary shares, which would result in U.S. federal income tax consequences to holders of our ADSs or ordinary shares that are different from those described above.

If a U.S. investor owns our ADSs or ordinary shares 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. Holder 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. Holder (as defined below under "Material United States Federal Income Tax Considerations") 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. Holder may be treated as a "United States 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 United States 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 United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries, if any, are treated as a CFC or whether such investor is treated as a United States shareholder with respect to any of such CFCs. Further, we cannot provide any assurances that we will furnish to any United States shareholders 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 you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs or ordinary shares.

### **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.

For example, on August 16, 2022, the Inflation Reduction Act (the “IRA”) was signed into law in the United States and significantly revised the Internal Revenue Code of 1986, as amended (the “Internal Revenue Code”). Among other provisions, the IRA includes a 15% corporate minimum tax rate which applies to certain corporations and a 1% excise tax on certain corporate stock repurchases made after December 31, 2022. We urge holders of our ADSs or ordinary shares to consult with their legal and tax advisors with respect to such legislation and about the potential tax consequences of investing in or holding our ADSs or ordinary shares.

### **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 the ordinary shares and/or ADSs and deprive you of an opportunity to receive a premium for your ordinary shares and/or ADSs.**

These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, or other business combination transactions. This concentration of ownership may also discourage, delay, or prevent a change in control of the Company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of the Company and reducing the price of our ordinary shares and/or ADSs. These actions may be taken even if they are opposed by our other shareholders. In addition, these shareholders could divert business opportunities away from us to themselves or others.

### **You may have difficulty enforcing judgments obtained against us.**

Zai Lab Limited is a company incorporated under the laws of the Cayman Islands, and a substantial portion of our assets are located outside the United States. A substantial portion of our current operations is conducted 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. A substantial

## RISK FACTORS

portion of the assets of these persons is located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States or Hong Kong upon these persons, or to bring an action against us or against these individuals in the United States or Hong Kong in the event that they believe that their rights have been infringed under the U.S. federal securities laws, Hong Kong laws or otherwise. Even if shareholders are successful in bringing an action of this kind, 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 the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under PRC Civil Procedures Law. Chinese courts may recognize and enforce foreign judgments in accordance with the requirements of PRC Civil Procedures Law based either on treaties between mainland China and the country where the judgment is made or on principles of reciprocity between jurisdictions. Mainland China does not have any treaties or other forms of reciprocity with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. 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. As a result, it is uncertain whether and on what basis a Chinese court would enforce a judgment rendered by a court in the United States.

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

ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer, or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 in the public market could cause the price of our ordinary shares and/or ADSs to decline.**

Sales of our ordinary shares, ADSs, or other equity or equity-linked securities in the public market, or the perception that these sales could occur, could cause the market price of our ordinary shares and/or ADSs 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 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 Securities Act, under trading plans adopted pursuant to Rule 10b5-1 or otherwise.

Divestiture in the future of our ordinary shares and/or ADSs by shareholders, the announcement of any plan to divest our ordinary shares and/or ADSs 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 ordinary shares and/or ADSs to decline.

Furthermore, although all of our directors and executive officers have agreed to a lock-up of their ordinary shares, any major disposal of our ordinary shares and/or ADSs by any of them upon expiration of the relevant lock-up periods (or the perception that these disposals may occur upon the expiration of the lock-up period) may cause the prevailing market price of our ordinary shares and/or ADSs to fall, which could negatively impact our ability to raise equity 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 ordinary shares and/or ADSs.**

We are subject to Hong Kong and Nasdaq listing and regulatory requirements. The Hong Kong Stock Exchange and Nasdaq have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing 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 allowing for currency differences. Fluctuations in the price of our ordinary shares due to circumstances peculiar to the Hong Kong capital markets could materially and adversely affect the price of our ordinary shares and/or ADSs, or vice versa. Certain events having significant negative impact specifically on the Hong Kong capital markets may result in a decline in the trading price of our ADSs notwithstanding that such event may not impact the trading prices of securities listed in Hong Kong generally or to the same extent, or vice versa.

**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 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. 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 each other.**

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. In the event that 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.



## RISK FACTORS

**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 our 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 effecting 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 depository 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 the Shareholders may anticipate.

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

In connection with our initial public offering of our ordinary shares in Hong Kong, we established a branch register of members in Hong Kong (the “Hong Kong Share Register”). Our ordinary shares that are traded on the Hong Kong Stock Exchange are registered on the Hong Kong Share Register, and the trading of these ordinary shares on the Hong Kong Stock Exchange will be subject to the Hong Kong stamp duty. 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 your investment in our ADSs and/or ordinary shares may be affected.

## GENERAL RISK FACTORS

### **We are subject to the risks of doing business globally.**

Because we operate in Greater China and other countries outside of the United States, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results could be adversely affected due to a variety of factors, including: changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; enforcement of anti-corruption and anti-bribery laws, such as the FCPA; economic sanctions and export control laws, such as the Export Administration Regulations promulgated by the U.S. Department of Commerce; laws and regulations on foreign investment, including the CFIUS regulations in the United States; the effects of applicable local tax regimes and potentially adverse tax consequences; the impact of public health epidemics on employees, our operations and the global economy, such as the COVID-19 outbreak impacting China and elsewhere; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates.

**We face risks related to the COVID-19 pandemic, including government actions and quarantine measures taken in response as well as increased infection rates after restrictions were lifted or eased, particularly in mainland China where our operations are primarily located. For example, the COVID-19 pandemic has adversely affected our sales, marketing, development activities of our proprietary products and our licensor's products, and our clinical trial operations, and it may continue to adversely affect our business and results of operations, perhaps significantly, depending on the nature, severity, and duration of the continuing effects of the pandemic. We also face risks related to other public health crises or disasters, which could have a material adverse effect on our business and results of operations.**

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

In 2022, there were a number of COVID-19 cases in Greater China, including in large cities like Shanghai, where one of our principal executive offices is located, that experienced a wave of intermittent full or partial government shutdowns in connection with COVID-19 control measures. In the last several months, the Chinese government has eased COVID-related restrictions and lifted lockdown measures, shifting away from its "zero-COVID" policy, which changes were followed by spikes in the number of COVID cases across mainland China. The effects of the COVID-19 pandemic, including as a result of restrictive quarantine measures imposed by the Chinese government and increased infection rates when such restrictions were lifted or eased, have adversely affected our business, and may continue to adversely affect our business, perhaps significantly, in 2023 and beyond. The extent of the impact will depend on the nature, severity, and duration of the ongoing effects of the COVID-19 pandemic, particularly in mainland China where our operations are primarily located.

## RISK FACTORS

Specifically, the COVID-19 pandemic has adversely impacted our operations, business, and financial results, including our manufacturing and supply chain; sales, marketing, and clinical trial operations of our third-party partners; and our ability to advance our research and development activities and pursue the development of our pipeline products. For example, some patients have experienced difficulties in accessing hospital care during periods of lockdown measures or heightened COVID infection rates and, as a result, they have had limited or no access to ZEJULA, Optune, QINLOCK, or NUZYRA, our four commercial products. The ability to conduct in-person interactions between medical representatives and physicians has also been adversely affected. Decreased access to our products has an adverse effect on our revenues. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to outbreaks of COVID-19 and lockdown measures where we are conducting such trials. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to outbreaks of COVID-19 and lockdown measures in their respective territories. Although so far none of our NDA submissions and acceptances, key clinical development milestones, or CTA approvals have been materially delayed, there is no guarantee this will continue to be the case.

Additionally, the COVID-19 pandemic may cause us or our commercial partners, licensors, and CMOs to experience delays or interruptions in the ability to manufacture and supply the products we are selling commercially in Greater China. For example, increased infection rates or COVID-related restrictions may negatively impact the distribution and sale of our products or limit our distributor's ability to successfully sell our commercial product in Greater China, even if we implement contingency plans. In addition, increased infection rates or lockdown measures may restrict our executives and employees, or those of our third-party partners, from traveling or performing their responsibilities, which could negatively affect our business, such as through operational disruptions. Any or all of these adverse effects arising from the COVID-19 pandemic may adversely affect our business and results of operations or cause the value of the Company to decline, potentially limiting our ability to obtain additional financing on terms acceptable to the Company or at all.

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

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

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

Although our business and financial results have not yet been adversely affected by the war in Ukraine, and we do not conduct business in Russia or Ukraine, our business and financial results, including our development programs, our ability to raise capital or raise capital on favorable terms, and the market price of our ordinary shares and/or our ADSs, may be adversely affected by Russia's

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

**If we or our CROs or CMOs fail to comply with environmental, health and safety laws and regulations of mainland China, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of 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 laws and regulations as well as U.S. laws and regulations concerning the discharge of wastewater, gaseous waste, and solid waste during our processes of research and development drugs. We generally contract with third parties for the disposal of these materials and wastes. We may not at all times comply fully with environmental regulations and we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources or insurance coverage. We also could incur significant costs associated with civil, administrative, or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government or the U.S. government may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade, or supplement our facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business 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.

## RISK FACTORS

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

### **We may be at an increased risk of securities class action litigation.**

We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought, whether warranted or not, against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years, including during 2022 when we, like other biotechnology and biopharmaceutical companies, suffered significant share price declines. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

### **If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price for our ordinary shares and/or ADSs and trading volume could decline.**

The trading market for our ADSs and/or ordinary shares relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades our ordinary shares and/or ADSs or publishes inaccurate or unfavorable research about our business, the market price for our ADSs and/or ordinary shares 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 the ADSs and/or ordinary shares 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 overly restrictive regulatory actions, or incur other harm to our business, including damage to the reputation of our products or Company.

# CHAIRPERSON'S STATEMENT

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**Samantha Du, PhD**  
*Founder, Chairperson  
and Chief Executive Officer*

April 21, 2023

Dear Zai Lab Shareholders,

In 2022, Zai Lab made great strides as a leading global biotech with relevant scale, a world-class pipeline, a growing commercial portfolio in China and a strong balance sheet.

We have executed on our corporate strategy to become a fully integrated global biopharmaceutical company with substantial research and development, business development, and commercialization capabilities. To date, we have expanded our pipeline to increase our product candidates under development from four in 2015 to 22 today, including 13 programs in late-stage clinical development.

Our portfolio of products has strong potential in China, within our four key therapeutic areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. We are focused on differentiated assets that can help address significant unmet needs for patients in China and beyond. For example, we have a world-class portfolio in GI cancer and lung cancer, the two largest tumor types in China.

We are proud of the tremendous growth we have achieved in just nine short years since I founded the company. But what we are most proud of is not the quantity of our products, but the quality. They all have the potential to be first-in-class and/or best-in-class.

In 2022, our four marketed products each experienced substantial sales growth, and we made exciting progress across our pipeline globally.

- We had numerous, positive late-stage data readouts, including adagrasib in non-small cell lung cancer, KarXT in schizophrenia, and efgartigimod in primary immune thrombocytopenia and generalized myasthenia gravis.
- We contributed to several successful global registrational studies, including the Tumor Treating Fields LUNAR study and the repotrectinib TRIDENT-1 study.
- We added QINLOCK and NUZYRA to China's National Reimbursement Drug List (NRDL) in 2023.

## CHAIRPERSON'S STATEMENT

- We further deepened our women's cancer franchise through our strategic collaboration with Seagen for TIVDAK.
- We continued to significantly enhance our talented global team.

In 2022, we also established our ESG Trust for Life strategy, which includes three commitments: to 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 seek to continue to develop and integrate our Trust for Life strategy into our business and operations.

In 2023, we will focus on the following strategic priorities to drive innovation in China and beyond.

### REGULATORY AND COMMERCIAL

- BLA approval by China's National Medical Products Administration (NMPA) and commercial launch for efgartigimod alfa injection for the treatment of adult patients with generalized myasthenia gravis (gMG)
- NDA submission to the NMPA for repotrectinib for ROS1+ advanced non-small cell lung cancer (NSCLC)
- BLA submission to the NMPA for SC efgartigimod for gMG in mid-2023
- ZEJULA to become the leader in PARP inhibitor sales for ovarian cancer in China
- A significant increase in sales of QINLOCK and NUZYRA following their inclusion on the NRDL

### RESEARCH AND CLINICAL DEVELOPMENT

- Topline data readouts of the SC efgartigimod study for chronic inflammatory demyelinating polyneuropathy (CIDP) in the second quarter of 2023, and for pemphigus and immune thrombocytopenia (ITP) in the second half of 2023
- Full data readout of the Tumor Treating Fields LUNAR study in NSCLC in the first half of 2023
- Clinical data update for adagrasib in combination with pembrolizumab in first-line KRASG12C-mutated NSCLC in the second half of 2023
- Complete enrollment in the global Phase 3 innovaTV 301 study of TIVDAK in second- and third-line cervical cancer in the first half of 2023
- Join the global Phase 3 FORTITUDE-101 study of becharituzumab in first-line gastric cancer in China in mid-2023
- Initiate a bridging study of KarXT for schizophrenia in China in mid-2023
- Initiate a global Phase 2 study for ZL-1102 (IL-17 Humabody®) in chronic plaque psoriasis (CPP)
- Initiate a global Phase 1 study for ZL-1218 (CCR8) in the first half of 2023



## CHAIRPERSON'S STATEMENT

We are preparing to launch eight additional products and achieve overall corporate profitability by the end of 2025. As we generate operating leverage, we will continue to invest in our future through research and development, including internal discovery activities, as we seek to advance our product pipeline and accelerate medicines to patients in need. We also aim to strengthen our portfolio and strategic positioning with potentially transformative assets and regional and global partnerships and collaborations.

We have built a solid foundation for continued growth, with patients always at the center of everything we do. Our mission is to be a leading global biopharmaceutical company focused on discovering, developing, and commercializing innovative therapies that improve the lives of patients in China and worldwide. We look forward to continuing to execute on that mission in 2023 through our corporate strategic priorities and with your continued support.

Sincerely,

**Samantha Du, PhD**

*Founder, Chairperson, and CEO*

**Zai Lab Limited**

# FINANCIAL SUMMARY

	For the year ended December 31,				
	2018 US\$'000	2019 US\$'000	2020 US\$'000	2021 US\$'000	2022 US\$'000
<b>Operating results</b>					
Product revenue, net	129	12,985	48,958	144,105	<b>212,672</b>
Collaboration revenue	—	—	—	207	<b>2,368</b>
Total revenues	129	12,985	48,958	144,312	<b>215,040</b>
Gross profit	86	9,236	32,222	92,073	<b>141,022</b>
Loss before income tax expense	(139,075)	(195,071)	(268,905)	(704,471)	<b>(443,286)</b>
Net Loss	(139,075)	(195,071)	(268,905)	(704,471)	<b>(443,286)</b>
Net loss attributable to the Company	(139,075)	(195,071)	(268,905)	(704,471)	<b>(443,286)</b>
<b>Profitability</b>					
Gross margin (%)	67%	71%	66%	64%	<b>66%</b>
Net profit margin (%)	(107,810)%	(1,502)%	(549)%	(488)%	<b>(206)%</b>

	For the year ended December 31,				
	2018 US\$'000	2019 US\$'000	2020 US\$'000	2021 US\$'000	2022 US\$'000
<b>Financial position</b>					
Cash, cash equivalents, and restricted cash	62,952	76,442	442,859	964,903	<b>1,009,273</b>
Short-term investments	200,350	200,000	744,676	445,000	—
Working capital	220,303	245,811	1,117,993	1,307,980	<b>984,494</b>
Total assets	301,987	355,153	1,297,638	1,609,956	<b>1,220,140</b>
Total liabilities	50,906	60,493	128,293	230,000	<b>174,545</b>
Non-controlling interest	—	—	—	—	—
Total equity	251,081	294,660	1,169,345	1,379,956	<b>1,045,595</b>

Note:

Financial results and financial position for the relevant periods are prepared based on annual report, which were filed with SEC.

# MANAGEMENT DISCUSSION AND ANALYSIS

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## 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, autoimmune disorders, infectious diseases, and neuroscience. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. We currently have four commercial products that have received marketing approval in one or more territories in Greater China and thirteen programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high-quality product candidates requires 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 four commercial products — ZEJULA, Optune, QINLOCK, and NUZYRA — and to successfully expand the indications for these products and develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates based on annual net sales of the licensed products in the licensed territories. We recorded \$53.4 million of research and development expense related to upfront license fees and development milestones in 2022. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

As we pursue our strategy of growth and development, 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 products in our pipeline, including new indications for our current commercial products, 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 product or whether or when such product may become profitable.

# MANAGEMENT DISCUSSION AND ANALYSIS

To date, we have also:

- partnered with established biopharmaceutical and leading healthcare companies in the United States, the European Union, and Japan such as GSK, NovoCure, Deciphera, Paratek, argenx, Entasis, MacroGenics, Seagen, Mirati, Amgen, BMS, Karuna, Regeneron, Taiho, and Blueprint through in-licensing product candidates to position ourselves as a partner of choice for the development and commercialization of novel therapeutics in Greater China;
- achieved reimbursement for ZEJULA, QINLOCK, and NUZYRA in mainland China through their inclusion in the NRDL;
- built a strong leadership team of seasoned industry veterans with extensive pharmaceutical research and development and commercialization experience in both global and Chinese biopharmaceutical companies as well as strong research and development and commercialization teams to execute our corporate strategic priorities;
- advanced our in-house discovery pipeline and capabilities targeting global markets; and
- continued to develop the necessary facilities and infrastructure in the United States and China to support our global leadership and corporate functions as well as our regulatory, clinical, manufacturing, and commercial activities.

In 2022, despite challenges from the COVID-19 pandemic in China, sales for our four commercial products continued to increase. We expect our sales for these products to further increase in 2023, in part because of ZEJULA's continued gain of share of hospital sales for ovarian cancer in China, the new listings for QINLOCK and NUZYRA on the NRDL, and the increased number of supplemental insurance plan listings for Optune. We also continued to make progress across our product pipeline. For example, we had several positive data readouts during the year, including for adagrasib in non-small cell lung cancer, efgartigimod in primary immune thrombocytopenia and generalized myasthenia gravis, and KarXT in schizophrenia. We contributed to successful registrational studies, including the LUNAR study for Tumor Treating Fields and the TRIDENT-1 study for repotrectinib. And, we increased our pipeline assets through our business development activities with our strategic collaboration with Seagen for the license of TIVDAK, which further deepened our women's cancer franchise.

We also continued to strengthen our business in 2022 through corporate developments, including key additions to our global leadership team, enhancements to our corporate governance practices, and our voluntary conversion to primary listing status on the Hong Kong Stock Exchange and the subsequent inclusion of our ordinary shares in the Shanghai and Shenzhen Stock Connect Programs. For example, with respect to our global leadership team, we appointed Rafael G. Amado, M.D. as President, Head of Global Oncology Research and Development in December 2022. Dr. Amado joined us from Allogene Therapeutics and brings deep expertise in the field of oncology and significant global biopharmaceutical R&D leadership. And, as we have previously disclosed, we made other key additions to our global leadership team in 2022, including in August when Josh Smiley became Chief Operating Officer and in

# MANAGEMENT DISCUSSION AND ANALYSIS

November when Dr. Peter Huang became Chief Scientific Officer. With respect to corporate governance, in April, we appointed KPMG LLP, a U.S.-based auditor, to be our independent registered public accounting firm and auditor, and in July, the Board established a lead independent director role, appointing Dr. John Diekman to serve in this important position. Finally, our transition to primary listing status on the Hong Kong Stock Exchange and participation in the Stock Connect programs should help us increase access to our business by investors in Greater China.

We further discuss below key factors affecting our results of operations, key components and primary drivers of changes in our results of operations in 2022, and our liquidity and capital resources.

## RECENT DEVELOPMENTS

On March 20, 2023, our partner Karuna reported positive topline results from its Phase 3 EMERGENT-3 trial evaluating the efficacy, safety, and tolerability of its lead investigational therapy, KarXT (xanomeline-trospium) in adults with schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 8.4-point reduction in Positive and Negative Syndrome Scale (“PANSS”) total score compared to placebo (-20.6 KarXT vs. -12.2 placebo;  $p < 0.0001$ ) at Week 5 (Cohen’s  $d$  effect size of 0.60). Consistent with prior trials, KarXT demonstrated an early and sustained statistically significant reduction of symptoms from Week 2 ( $p < 0.05$ ) through the end of the trial as assessed by PANSS total score.

In April 2023, we presented new data including a translational and biomarker data analysis from our internal oncology discovery program ZL-1211 at the 2023 AACR Annual Meeting.

## FACTORS AFFECTING OUR RESULTS OF OPERATIONS

### Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in research and development. As a result of this commitment, our pipeline of product candidates has been advancing and expanding, with thirteen late-stage clinical product candidates being investigated as of December 31, 2022.

# MANAGEMENT DISCUSSION AND ANALYSIS

We have financed our activities primarily through private placements, our initial public offering in September 2017 and multiple follow-on offerings on Nasdaq and our secondary listing and initial public offering on the Hong Kong Stock Exchange in September 2020. Through December 31, 2022, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offerings and follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$367.6 million and \$549.2 million in 2022 and 2021, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our thirteen late-stage clinical product candidates, research and develop our clinical and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. We review such expenditures for prioritization and efficiency purposes. These expenditures include:

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

For more information on our research and development expenses, see Key Components of Results of Operations — Research and Development 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, professional service fees for legal, intellectual property, consulting, auditing, and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies used in selling, general, and administrative activities. We anticipate that our selling, general, and administrative expenses will increase in future periods to support increases in our commercial and research and development activities and as we continue to discover, develop, commercialize, and manufacture our products and assets. These increases will likely include expanded infrastructure as well as increased headcount and share-based compensation, product distribution, promotion, and insurance costs. We also anticipate incurring additional legal, compliance, accounting, and investor and public relations expenses associated with being a public company.

# MANAGEMENT DISCUSSION AND ANALYSIS

## **Our Ability to Commercialize Our Product Candidates**

As of December 31, 2022, thirteen of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may not occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, manufacturing supply, substantial investment, and significant marketing efforts before we generate any revenue from product sales.

## **Our License Arrangements**

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration, and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and sales-based milestones for the relevant 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. We recorded research and development expense related to upfront license fees and development milestones of \$53.4 million and \$384.1 million in 2022 and 2021, respectively.

## **The COVID-19 Pandemic**

Our results of operations have been, and we expect them to continue to be, adversely affected by the COVID-19 pandemic, including government actions and quarantine measures taken in response or increased infection rates after restrictions were lifted or eased, particularly in mainland China where our operations and product markets are primarily located. For example, the pandemic has adversely affected patient access to our products, such as through reduced hospital access during periods of lockdown or high infection rates, fewer newly diagnosed oncology patients, and delayed or interrupted treatments. The pandemic has also adversely affected our manufacturing and supply chain and our research and development, sales, marketing, and clinical trial activities. The operations of our suppliers, CROs, CMOs, and other contractors and third parties on which we rely also have been, and may continue to be, adversely affected. Although our net product revenues increased in 2022, as compared to the prior year, these revenue increases were negatively affected by the effects of the pandemic, and we expect additional adverse revenue impacts in the coming year and possibly in future years depending on the nature, severity, and duration of future effects from the pandemic.



# MANAGEMENT DISCUSSION AND ANALYSIS

## FINANCIAL REVIEW

### Key Components of Results of Operations

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

	Year Ended December 31		Change	
	2022	2021	\$	%
Revenues				
Product revenue, net	<b>212,672</b>	144,105	68,567	48 %
Collaboration revenue	<b>2,368</b>	207	2,161	1,044 %
Total revenues	<b>215,040</b>	144,312	70,728	49 %
Expenses				
Cost of sales	<b>(74,018)</b>	(52,239)	(21,779)	42 %
Research and development	<b>(286,408)</b>	(573,306)	286,898	(50)%
Selling, general and administrative	<b>(258,971)</b>	(218,831)	(40,140)	18 %
Loss from operations	<b>(404,357)</b>	(700,064)	295,707	(42)%
Interest income	<b>14,582</b>	2,190	12,392	566 %
Foreign currency (loss) gain	<b>(56,403)</b>	4,661	(61,064)	(1,310)%
Other income (expenses), net	<b>3,113</b>	(10,201)	13,314	(131)%
Loss before income tax and share of loss from equity method investment	<b>(443,065)</b>	(703,414)	260,349	(37)%
Income tax expense	—	—	—	— %
Share of loss from equity method investment	<b>(221)</b>	(1,057)	836	(79)%
Net loss	<b>(443,286)</b>	(704,471)	261,185	(37)%
Net loss attributable to ordinary shareholders	<b>(443,286)</b>	(704,471)	261,185	(37)%

# MANAGEMENT DISCUSSION AND ANALYSIS

## Revenues

### Product Revenue, Net

The following table presents the components of the Company's product revenue, net (\$ in thousands):

	Year Ended December 31		Change	
	2022	2021	\$	%
Product revenue — gross	<b>234,009</b>	190,180	43,829	23 %
Less: Rebates and sales returns	<b>(21,337)</b>	(46,075)	24,738	(54)%
Product revenue — net	<b>212,672</b>	144,105	68,567	48 %

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong, net of sales returns and rebates to distributors in mainland China with respect to the sales of these products. Our net product revenue increased by \$68.6 million in 2022, primarily driven by increased sales volumes and decreased rebates. Although our sales volumes increased, these volumes were negatively affected by the effects of the COVID-19 pandemic, including government restrictions or lockdown measures in mainland China, which negatively affected patient access to our products. The decrease in rebates was primarily due to fewer products being sold at prices prior to reduction that required such rebates. We had price reductions for QINLOCK and NUZYRA in June 2022, compared to price reductions for ZEJULA in December 2020 and December 2021.

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

	Year Ended December 31		Change	
	2022	2021	\$	%
ZEJULA	<b>145,194</b>	93,579	51,615	55%
Optune	<b>47,321</b>	38,903	8,418	22%
QINLOCK	<b>14,957</b>	11,620	3,337	29%
NUZYRA	<b>5,200</b>	3	5,197	173,233%
Total	<b>212,672</b>	144,105	68,567	48%

### Collaboration Revenue

Collaboration revenue was \$2.4 million in 2022 compared to \$0.2 million in 2021 due to increased revenue from our exclusive promotion agreement with Huizheng.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Cost of Sales

Cost of sales increased by \$21.8 million to \$74.0 million in 2022 primarily due to increasing sales volumes, higher product costs, and higher royalties.

## Research and Development Expenses

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

	Year Ended December 31		Change	
	2022	2021	\$	%
Personnel compensation and related costs	105,561	77,227	28,334	37 %
Licensing fees	53,441	384,104	(330,663)	(86)%
CROs/CMOs/Investigators expenses	100,544	82,571	17,973	22 %
Other costs	26,862	29,404	(2,542)	(9)%
Total	286,408	573,306	(286,898)	(50)%

Research and development expenses decreased by \$286.9 million in 2022 primarily due to:

- a decrease of \$330.7 million in licensing fees in connection with decreased upfront and milestone payments for our license and collaboration agreements; partially offset by
- an increase of \$28.3 million in personnel compensation and related costs primarily due to headcount growth and grants of share options and restricted shares and the continued vesting of option and restricted share awards; and
- an increase of \$18.0 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials.

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

	Year Ended December 31		Change	
	2022	2021	\$	%
Clinical programs	155,792	433,021	(277,229)	(64)%
Pre-clinical programs	6,644	47,768	(41,124)	(86)%
Unallocated research and development expenses	123,972	92,517	31,455	34 %
Total	286,408	573,306	(286,898)	(50)%

Research and development expenses attributable to clinical programs decreased by \$277.2 million and research and development expenses attributable to pre-clinical programs decreased by \$41.1 million in 2022, both decreases driven by decreased license fees.

# MANAGEMENT DISCUSSION AND ANALYSIS

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

## Selling, General and Administrative Expenses

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

	Year Ended December 31		Change	
	2022	2021	\$	%
Personnel compensation and related costs	<b>162,045</b>	124,675	37,370	30 %
Professional service fees	<b>35,414</b>	22,901	12,513	55 %
Other costs	<b>61,512</b>	71,255	(9,743)	(14)%
Total	<b>258,971</b>	218,831	40,140	18 %

Selling, general and administrative expenses increased by \$40.1 million in 2022, primarily due to:

- an increase of \$37.4 million in personnel compensation and related costs which was primarily driven by headcount growth, particularly in commercial and administrative personnel, and grants of share options and restricted shares and the continued vesting of option and restricted share awards; and
- an increase of \$12.5 million in professional service fee mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; partially offset by
- a decrease of \$9.7 million in other costs mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan.

## Interest Income

Interest income increased by \$12.4 million to \$14.6 million in 2022, due to increased interest rates.

## Foreign Currency (Loss) Gain

Foreign currency loss was \$56.4 million in 2022 primarily driven by remeasurement loss due to USD appreciating against RMB in 2022, compared to foreign currency gain of \$4.7 million in 2021 driven by remeasurement gain due to USD depreciating against RMB in 2021.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Other Income (Expenses), Net

Other income, net was \$3.1 million in 2022, compared to other expense, net of \$10.2 million in 2021. The shift from other expense, net to other income, net is primarily due to an increase of \$7.4 million in government grant income and a decrease of \$5.7 million in loss on equity investments with readily determinable fair value.

## Share of Loss from Equity Method Investment

Share of loss from equity method investment decreased by \$0.8 million to \$0.2 million in 2022, due to increased losses from our investment in JING Medicine Technology (Shanghai) Ltd., an entity that provides services for drug discovery and development, consultation, and transfer of pharmaceutical technology.

## Income Tax Expense

There was no change in our income tax expense, which was zero in both 2022 and 2021. For more information on taxes to which we are subject in the Cayman Islands, PRC, and Hong Kong, see Note 13 to the consolidated financial statements.

## DISCUSSION OF CERTAIN KEY BALANCE SHEET ITEMS

### Cash, Cash Equivalents, and Restricted Cash

As of December 31, 2022, the Company's cash, cash equivalents, and restricted cash amounted to \$1,009.3 million and primarily comprised of (1) \$958.6 million denominated in US dollars; (2) \$45.5 million denominated in RMB; and (3) \$5.2 million in aggregate denominated in Hong Kong dollar, Australian dollar, and Taiwan dollar.

### Accounts Receivable

Accounts receivable decreased by \$7.5 million to \$40.0 million as of December 31, 2022, primarily due to the collection of receivable from Huizheng of \$11.0 million for the upfront payment and partially offset by the increased receivables from our customers arising from product sales in 2022.

### Inventories, Net

The inventories increased by \$12.7 million to \$31.6 million as of December 31, 2022, mainly because we built up the inventory balance in anticipation of increasing sales in mainland China.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Property and Equipment, Net

The property and equipment increased by \$14.8 million to \$57.9 million as of December 31, 2022, primarily attribute to our on-going buildout of the Suzhou manufacturing facility, expansion of business development and research and development activities.

## Accounts Payable

Accounts payable includes amounts due to third parties and decreased by \$60.2 million to \$66.0 million as of December 31, 2022, primarily due to payments for licensing fees.

The following table presents an aging analysis of accounts payable, which is based on invoice date (\$ in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Within 3 months	<b>65,249</b>	125,709
3 months to 6 months	<b>132</b>	416
6 months to 1 year	<b>577</b>	22
Over 1 year	<b>16</b>	16
Total	<b>65,974</b>	126,163

## Other Current Liabilities

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

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Payroll	<b>31,689</b>	25,685
Accrued professional service fee	<b>4,080</b>	4,319
Payables for purchase of property and equipment	<b>5,269</b>	2,568
Accrued rebate to distributors	<b>8,443</b>	15,001
Tax payables	<b>13,283</b>	8,817
Others	<b>4,054</b>	4,421
Total	<b>66,818</b>	60,811

Other current liabilities increased by \$6.0 million to \$66.8 million as of December 31, 2022 primarily due to increased accrued bonus and the withholding tax, partially offset by the settlement of rebate to distributors.

# MANAGEMENT DISCUSSION AND ANALYSIS

## CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

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

### Revenue Recognition

#### Description

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

#### Judgments and Uncertainties

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. We estimate rebates based on contracted rates, sales volumes, and level of distributor inventories.

#### Sensitivity of Estimate to Change

Actual amounts of rebates paid or billed may differ from our estimates. We regularly review the factors and judgments underlying these estimates and adjust the amounts of rebates accordingly. If actual results vary from our estimates, we also adjust these estimates accordingly, which would affect net product revenue and earnings in the period such variances become expected or known.



# MANAGEMENT DISCUSSION AND ANALYSIS

## Research and Development Expenses

### Description

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

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

### Judgments and Uncertainties

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

### Sensitivity of Estimate to Change

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

## Share-Based Compensation

### Description

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

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

# MANAGEMENT DISCUSSION AND ANALYSIS

## Judgments and Uncertainties

We determine the fair value of stock options granted to employees using the Black-Scholes option valuation model. Using this model, fair value is calculated based on assumptions with respect to (i) the expected volatility of our ADS price, (ii) the periods of time over which grantees are expected to hold their options prior to exercise (expected lives), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the expected lives of the options. Expected volatility has been estimated based on actual movements in some comparable companies' stock price over the most recent historical periods equivalent to the options' expected lives. The expected term of the share options represents the average period the share options are expected to remain outstanding. As the Company does not have sufficient historical information since its IPO to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term of options granted 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.

## Sensitivity of Estimate to Change

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

## Income Taxes

### Description

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

### Judgments and Uncertainties

We consider positive and negative evidence when determining whether some portion or all of our deferred tax assets will not be realized. This assessment considers, among other matters, the nature, frequency, and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax

# MANAGEMENT DISCUSSION AND ANALYSIS

planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the level of our historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe it is more likely than not that we will not realize the deferred tax assets resulted from the tax loss carried forward in the future periods.

## Sensitivity of Estimate to Change

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts and circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of December 31, 2022 and 2021, we did not have any significant unrecognized uncertain tax positions.

## Liquidity and Capital Resources

The following table represents our cash and cash equivalents, short-term investments, and restricted cash (\$ in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash and cash equivalents	<b>1,008,470</b>	964,100
Short-term investments	—	445,000
Restricted cash, non-current	<b>803</b>	803
Total	<b>1,009,273</b>	1,409,903

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. Through December 31, 2022, we have raised approximately \$164.6 million in private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering and subsequent follow-on offerings on Nasdaq and our initial public offering on the Hong Kong Stock Exchange. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$367.6 million and \$549.2 million in 2022 and 2021, respectively. We have commitments for capital expenditures of \$9.0 million as of December 31, 2022, mainly for the purpose of plant construction and installation. We currently do not have any known events that are reasonably likely to cause a material change in the relationship between our costs and revenues.

As of December 31, 2022, we had cash and cash equivalents, restricted cash, and short-term investments of \$1,009.3 million. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash, and short-term investments as of March 31, 2023, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, in order to bring to fruition our research and development objectives, we may ultimately need additional funding sources, and there can be no assurances that such funding will be made available to us on acceptable terms or at all.

# MANAGEMENT DISCUSSION AND ANALYSIS

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

	Year Ended December 31,		Change
	2022	2021	\$
Net cash used in operating activities	<b>(367,642)</b>	(549,231)	181,589
Net cash provided by investing activities	<b>420,016</b>	249,957	170,059
Net cash (used in) provided by financing activities	<b>(1,730)</b>	820,202	(821,932)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	<b>(6,274)</b>	1,116	(7,390)
Net increase in cash, cash equivalents and restricted cash	<b>44,370</b>	522,044	(477,674)

## Net Cash Used in Operating Activities

Net cash used in operating activities decreased by \$181.6 million in 2022, primarily due to a decrease of \$261.2 million in net loss and an increase of \$20.4 million in adjustments to reconcile net loss to net cash used in operating activities, partially offset by a decrease of \$100.0 million in net changes in operating assets and liabilities.

## Net Cash Provided by Investing Activities

Net cash provided by investing activities increased by \$170.1 million in 2022, primarily due to a decrease of \$184.7 million in purchases of short-term investments and a decrease of \$30.0 million in payments for investment in equity investee, partially offset by a decrease of \$38.6 million in proceeds from maturity of short-term investments and an increase of \$6.3 million in purchases of property and equipment.

## Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was \$1.7 million in 2022, compared to net cash provided by financing activities of \$820.2 million in 2021. The shift from cash provided by to cash used in financing activities was primarily because we had proceeds of \$818.9 million from our issuance of ordinary shares upon public offerings in 2021 while there were no such transactions in 2022.

## Effect of Exchange Rates on Cash

We have substantial operations in mainland China, which generate a significant amount of RMB-denominated cash from product sales and require a significant amount of RMB-denominated cash to pay our obligations. Since the reporting currency of the Company is the U.S. dollar, periods of volatility in exchange rates may have a significant impact on our consolidated cash balances.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Operating Capital Requirements

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue to commercialize our approved products, continue our research and development efforts related to our clinical and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek and/or expand regulatory approval for, ZEJULA, Optune, QINLOCK, NUZYRA, and our other products and product candidates. In addition, if we obtain regulatory approval for any additional product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. In particular, if more of our product candidates are approved, additional costs may be substantial as we may have to, among other things, modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers and increase our commercial workforce. We have incurred, and may continue to incur, expenses as we create additional infrastructure to support our operations. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure that we will have sufficient cash from other sources to fund our operations. We will likely need to obtain substantial additional funding in connection with our continuing 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 and be forced to delay, reduce, or terminate our research and development programs or commercialization efforts.

Although we believe our cash and cash equivalents and short-term investments as of December 31, 2022 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:

- the cost and timing of future commercialization activities for ZEJULA, Optune, QINLOCK, NUZYRA, and any other product candidates for which we receive regulatory approval;
- the pricing of and product revenues received, if any, from future commercial sales of our approved products and any other products for which we receive regulatory approval;
- the scope, progress, timing, results, and costs of clinical development of our products in additional indications, if any;
- the scope, progress, timing, results, and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the cost, timing, and outcome of seeking, obtaining, maintaining, and expanding regulatory approval of our products and product candidates;
- 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;

# MANAGEMENT DISCUSSION AND ANALYSIS

- 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;
- the extent to which we acquire or in-license other product candidates and technologies and the economic and other terms, timing, and success of such collaboration and licensing arrangements;
- cash requirements of any future acquisitions;
- the number, characteristics, and development requirements of the product candidates we pursue;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to confirm that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- our headcount growth and associated costs; and
- the costs of operating as a public company in both the United States and Hong Kong.

## Contractual Obligations and Commitments

As of December 31, 2022, purchase commitments amounted to \$9.0 million, which is related to purchase of property and equipment contracted and expected to be incurred within one year. We do not have any other purchase commitments beyond one year.

For our obligations under our pension scheme, please refer to Note 21 to the consolidated financial statements.

## 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 RMB316.8 million and RMB151.7 million, which were denominated in RMB, as of December 31, 2022 and 2021, respectively, representing 5% and 2% of the cash and cash equivalents as of December 31, 2022 and 2021, respectively.

## MANAGEMENT DISCUSSION AND ANALYSIS

Our business mainly operates in mainland China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have significant direct foreign exchange risk and have not used derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs 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. On July 21, 2005, the Chinese government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that the Chinese government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, in August 2015, the PBOC significantly devalued the RMB.

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



# MANAGEMENT DISCUSSION AND ANALYSIS

## Credit Risk

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2022 and 2021, we had cash and cash equivalents of \$1,008.5 million and \$964.1 million and short-term investments of nil and \$445.0 million, respectively. As of December 31, 2022 and 2021, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and for which we monitor continued credit worthiness.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangements. We manage credit risk related to our accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and credit worthiness. Historically, we have collected receivables from customers within the credit terms with no significant credit losses incurred. As of December 31, 2022, our two largest customers accounted for approximately 28% of our total accounts receivable collectively.

During the year ended December 31, 2022, certain accounts receivable balances were settled in the form of notes receivable. As of December 31, 2022, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

## Inflation

In recent years, mainland China has not experienced significant inflation. Although the global economy, including the U.S. economy, has experienced rising inflation in recent quarters, which can increase the costs of our products and product candidates purchased from third parties and, as a result, adversely affect our results of operations, inflation has not had a material impact on our results of operations. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in mainland China or in other countries in which our third-party partners operate.

## Off-Balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under the rules of the U.S. Securities and Exchange Commission, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Gearing Ratio

The gearing ratio of the Company, which was calculated by dividing total interest-bearing loans by total shareholders' equity as of the end of the year, were both nil as of December 31, 2022 and 2021, because we do not have any interest-bearing loans.

## Significant Investment Held

Except as disclosed in Note 8 to the consolidated financial statements, we did not hold any other significant investments as of December 31, 2022 and 2021.

## Future Plans for Material Investments and Capital Assets

We do not have any future plans for material investments or capital assets as of December 31, 2022.

## Material Acquisitions and Disposals of Subsidiaries, Associates, and Joint Ventures

During the Reporting Period, we did not have any acquisitions and disposals of subsidiaries and affiliated companies.

## Employee and Remuneration Policy

### Human Capital Resources

We know that 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, 2023, we had 2,036 full-time employees, of which 1,956 were located in Greater China. The number of full-time employees by function as of such date was as follows:

<b>By Function</b>	<b>Number of Employees</b>
Research and Development	832
Commercial	965
Manufacturing	84
General and Administrative*	155
<b>Total</b>	<b>2,036</b>

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

# MANAGEMENT DISCUSSION AND ANALYSIS

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, in addition to our health and welfare benefits and parental leave, we provide retirement benefits in the form of certain matching contributions to tax-qualified 401(k) plans.

We 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; 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 seek to engage our employees through our Culture Committee with the launch of our Diversity, Equity, and Inclusion Council and 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 to support our growth 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 belief. Our commitment to diversity is reflected in the composition of our workforce. For example, with respect to gender diversity, the majority of our full-time employees are women, and the majority of STEM-related positions are held by women.

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. Further, we have been able to recruit strong employees to support our business and operations.

# MANAGEMENT DISCUSSION AND ANALYSIS

## Employee Remuneration Policy

The remuneration policy and package of our employees are periodically reviewed by the Compensation Committee of the Board. The packages were set by benchmarking with companies in similar industries and companies with similar complexity and size. In addition to cash compensation and benefits, we may issue share options, share appreciation rights, restricted shares, unrestricted shares, share units including restricted share units, performance awards, and other types of awards to our employees in accordance with our equity incentive plans.

For more details about share-based compensation, please refer to the section headed “Equity Incentive Plans” and Note 17 to the consolidated financial statements contained in this annual report. The total remuneration cost incurred by the Company was \$263.9 million and \$193.4 million for the years ended December 31, 2022 and 2021, respectively.

## Charges on Group Assets

As of December 31, 2022 and 2021, we did not have any charges on the Company’s assets.

## Contingent Liabilities

As of December 31, 2022 and 2021, we did not have any material contingent liabilities. See Note 18 to the consolidated financial statements for contractual obligations under licenses and collaborative agreements.

## Final Dividend

The Board did not recommend any final dividend for 2022 or 2021.

## Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included in this annual report for information regarding recent accounting pronouncements.

## Segmental Information

See Note 2 to our consolidated financial statements included in this annual report for information regarding segmental information.

# DIRECTORS AND SENIOR MANAGEMENT

## DIRECTORS

Our Board consists of ten Directors, comprising one executive Director, and nine independent non-executive Directors. The following table sets forth the name, age, and position of each of our directors as of April 1, 2023:

Name	Age	Position(s)	Director Since
Samantha (Ying) Du	58	Founder, Chairperson, and Chief Executive Officer	2014
John D. Diekman	80	Lead Independent Director	2017
Kai-Xian Chen	77	Director	2018
Richard Gaynor	73	Director	2021
Nisa Leung	52	Director	2014
William Lis	58	Director	2018
Leon O. Moulder Jr.	65	Director	2020
Scott Morrison	65	Director	2021
Michel Vounatsos	61	Director	2023
Peter Wirth	72	Director	2017

Set forth below is biographical information as of April 1, 2023 for our directors, which has been confirmed by each of them for inclusion in this annual report. We have provided their current Board and Committee roles as well as a summary of the experiences, qualifications, attributes, and skills that led the Board to conclude that each director should serve as a director in light of our business and structure.

### Samantha (Ying) Du, Ph.D. (“Dr. Samantha Du”)

#### Executive Director

Age	Director Since	Board Committees	Other Public Company Boards
58	2014	Research and Development	None

Dr. Samantha Du is an experienced executive and entrepreneur with significant global leadership experience who brings to the Board a deep knowledge of the capital markets and the biotechnology, healthcare, and pharmaceutical industries as well as a considerable scientific background. In addition, as the Company’s Founder and Chief Executive Officer, Dr. Samantha Du provides valuable knowledge of the Company and its business.

# DIRECTORS AND SENIOR MANAGEMENT

## Key Experience and Qualifications

- Founder, Chief Executive Officer, and Chairperson of the Board of Directors of Zai Lab (2014–Present)
- Healthcare Partner (2012–2014) and Venture Partner (2014–2017) at Sequoia Capital China, leading several major healthcare investments
- Co-Founder and Chief Executive Officer of Hutchison MediPharma and Co-Founder and Chief Scientific Officer of Hutchison China MediTech (2001–2011)
- Began her research career at Pfizer Inc. in the United States, where she led the global metabolic licensing program and was involved in the development of multiple early and late-stage products (1994–2001)
- Ph.D. in Biochemistry from the University of Cincinnati and a B.S. in Molecular Biology from Jilin University, China

## John David Diekman, Ph.D. (“Dr. John Diekman”)

### Lead Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
80	2017	Audit Compensation Nominating and Corporate Governance	None

Dr. John Diekman is an experienced executive who brings to the Board extensive business, management, policy, and capital markets experience as well as deep expertise in the life sciences and venture capital industries, including in the area of oncology.

## Key Experience and Qualifications

- Founder and Managing Partner of 5AM Ventures (2002–Present)
- Chairman of the Board of Directors of IDEAYA Biosciences, Inc. (NASDAQ) (2015–June 2020)
- Chairman of The Scripps Research Institute and on the Advisory Board of the Schaeffer Center for Health Policy and Economics at the University of Southern California (2014–March 2021), Charter Trustee of Princeton University (2008–June 2019), and Trustee of The California Institute of Technology (2004–2008)
- Ph.D. in Chemistry from Stanford University and an A.B. in Organic Chemistry from Princeton University

# DIRECTORS AND SENIOR MANAGEMENT

## Kai-Xian Chen, Ph.D. (“Dr. Kai-Xian Chen”)

Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
77	2018	Research and Development	Innovent Biologics, Inc. (HKSE) InnoCare Pharma Limited (HKSE) Jiangsu Kanion Pharmaceutical Co., Ltd. (SSE)

Dr. Kai-Xian Chen brings to the Board an extensive and distinguished scientific and academic background and considerable service as a member of several prestigious Chinese institutional and research organizations and as a member of the board of directors for various biopharmaceutical companies.

### Key Experience and Qualifications

- Member of the Chief Specialists Board and Deputy Chief Technical Officer of the major science and technology projects “innovative drugs and modernization of traditional Chinese medicine” and “Innovative Drug Research & Development,” where he participated in the organization and promotion of new drug research and development for China’s 10th–13th Five Year Plans (2001–Present)
- Member of the Board of Directors of InnoCare Pharma Limited (March 2020–Present)
- Member of the Board of Directors of Jiangsu Kanion Pharmaceutical Co., Ltd. (December 2019–Present)
- Member of the Board of Directors of Innovent Biologics, Inc. (October 2018–Present)
- Professor at the Shanghai Institute of Materia Medica (“SIMM”) Chinese Academy of Sciences (1990–Present) and Shanghai University of Traditional Chinese Medicine (2004–Present)
- Elected member of the Chinese Academy of Sciences since 1999
- Member of the National Committee of the Chinese People’s Political Consultative Conference (2007–2017)
- President of the Shanghai Association for Science and Technology (2011–2018)
- President of Shanghai University of Traditional Chinese Medicine (2005–2014)



## DIRECTORS AND SENIOR MANAGEMENT

- Various roles at SIMM Chinese Academy of Sciences, in addition to serving as Professor, including Director (1996–2004) and Deputy Director (1993–1996)
- Principal Scientist for two National Basic Research Programs by the MOST (1998–2009)
- Postdoctoral research at Institut de Biologie Physico-Chimique in Paris, Ph.D. and Master of Science from the SIMM, Chinese Academy of Sciences, and B.S. in Radiochemistry from Fudan University

### **Richard Brian Gaynor, M.D. (“Richard Gaynor, M.D.”)**

#### Independent Director

<b>Age</b>	<b>Director Since</b>	<b>Board Committees</b>	<b>Other Public Company Boards</b>
73	2021	Research and Development, Chair	Infinity Pharmaceuticals, Inc. (NASDAQ) Alkermes plc (NASDAQ)

Richard Gaynor, M.D. brings to the Board significant experience as a senior business executive in the biopharmaceutical industry, deep experience as an oncologist, and expertise in research and development.

#### Key Experience and Qualifications

- President and Chief of Research and Development at BioNTech US Inc. (formerly Neon Therapeutics, Inc.) (May 2020–Present), after serving in this role at Neon Therapeutics from November 2016 to May 2020
- Member of the Board of Directors of Infinity Pharmaceuticals, Inc. (March 2020–Present)
- Member of the Board of Directors of Alkermes plc (September 2019–Present)
- Various senior clinical development and medical affairs roles at Eli Lilly and Company (2002–2016), including Senior Vice President of Clinical Development and Medical Affairs
- Professor at the UCLA School of Medicine (1982–1991) and service on the faculty at the University of Texas Southwestern Medical School (1991–2002), including as the Chief of Hematology-Oncology and Director of the Simmons Cancer Center
- Author of nearly 150 publications and participant on numerous advisory boards and committees, including currently serving as a Director for the Damon Runyon Cancer Research Foundation and on several committees for the American Association of Cancer Research and other cancer organizations
- M.D. from the University of Texas Southwestern Medical School, where he served a residency in internal medicine; fellowship training in hematology-oncology at the UCLA School of Medicine

# DIRECTORS AND SENIOR MANAGEMENT

## Nisa Bernice Wing-Yu Leung (“Ms. Nisa Leung”)

Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
52	2014	None	CanSino Biologics Inc. (HKSE, SSE) Hong Kong Exchanges and Clearing Limited (HKSE)

Ms. Nisa Leung brings to the Board significant venture capital experience in the healthcare industry, particularly in China, as well as extensive corporate governance experience through her service on the boards of companies listed on the Shanghai Stock Exchange and Hong Kong Stock Exchange.

### Key Experience and Qualifications

- Managing Partner at Qiming Venture Partners, where she leads healthcare investments (2006–Present)
- Member of the Board of Directors and Nomination Committee of CanSino Biologics Inc. (2015–Present)
- Member of the Board of Directors of Caidya (formerly dMed Biopharmaceuticals Company Ltd.), a Clinical Contract Research Organization (“CRO”) designed to facilitate the development and globalization of innovative drugs (2016–Present)
- Member of the Board of Directors of Hong Kong Exchanges and Clearing Limited (June 2021–Present)
- Member of the Board of Directors of New Horizon Health Limited (HKSE) (2017–October 2022)
- Member of the Board of Directors of Venus Medtech (Hangzhou) Inc. (HKSE) (2013–January 2023)
- Member of the Board of Directors of Gan & Lee (SSE) (2009–March 2021)
- MBA from Stanford Graduate School of Business, B.S. in Hotel Administration from Cornell University

# DIRECTORS AND SENIOR MANAGEMENT

## William David Lis (“Mr. William Lis”)

Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
58	2018	Commercial Nominating and Corporate Governance Research and Development	Jasper Therapeutics, Inc. (NASDAQ)

Mr. William Lis brings to the Board over 30 years of experience in the biopharmaceutical industry at the executive and board level, including considerable leadership and business, financial, and product development expertise.

### Key Experience and Qualifications

- Various board and executive positions at Jasper Therapeutics, Inc., including Chairperson of the Board of Directors (March 2022–Present) and Chief Executive Officer and Executive Chairman of the Board (November 2019–March 2022)
- Member of the Board of Directors of Eidos Therapeutics, Inc. (NASDAQ) (December 2018–its acquisition by Bridge Bio Pharma, Inc. in January 2021)
- Various executive and board positions at Portola Pharmaceuticals, Inc. (later acquired by Alexion Pharmaceuticals, Inc. in 2020), including Chief Executive Officer and Member of the Board of Directors (December 2009–August 2018), Chief Operating Officer (2009), and Chief Business Officer (2008–2009)
- Various executive positions at Scios, Inc. (a Johnson & Johnson company) (2003–2008), including Senior Vice President of New Product Development and Business Development
- Various roles of increasing responsibility at Millennium Pharmaceuticals, Inc. (previously COR Therapeutics, Inc.) in sales, marketing, medical affairs, and business development (1998–2003)
- Member of the Biotechnology Innovation Organization (“BIO”) Emerging Companies Section (“ECS”) (2015–2016)
- B.S. from the University of Maryland

# DIRECTORS AND SENIOR MANAGEMENT

## Scott William Morrison (“Mr. Scott W. Morrison”)

Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
65	2021	Audit, Chair and Audit Committee Financial Expert	Corvus Pharmaceuticals, Inc. (NASDAQ) IDEAYA Biosciences Inc. (NASDAQ) Tarsus Pharmaceuticals, Inc. (NASDAQ) Vera Therapeutics, Inc. (NASDAQ)

Mr. Scott W. Morrison brings to the Board financial expertise obtained from his extensive business, accounting, and financial background obtained from his over 35 years of experience serving public and private companies in the life sciences industry until his retirement in 2015 as well as his significant board and audit committee experience.

### Key Experience and Qualifications

- Partner with Ernst & Young LLP (1996–2015), serving as U.S. Life Sciences Leader from 2002 to 2015
- Member of the Board of Directors, Chairperson of the Audit Committee, and Member of the Compensation Committee of Corvus Pharmaceuticals, Inc. (2015–Present)
- Member of the Board of Directors, Chair of the Audit Committee, Chair of the Transaction and Financing Committee, and Member of the Compensation Committee and Commercial Committee of Global Blood Therapeutics, Inc. (2016–its acquisition by Pfizer Inc. in October 2022)
- Member of the Board of Directors, Chair of the Audit Committee, and Member of the Nominating and Corporate Governance Committee of IDEAYA Biosciences Inc. (July 2018–Present)
- Member of the Board of Directors and Chair of the Audit Committee of Vera Therapeutics, Inc. (April 2020–Present)
- Member of the Board of Directors, Chair of the Audit Committee, and Member of the Commercial Committee of Tarsus Pharmaceuticals, Inc. (October 2022–Present)
- Member of the Board of Directors and Chairman of the Audit Committee of Audentes Therapeutics, Inc. (NASDAQ) (2016–its sale to Astellas in January 2020)

## DIRECTORS AND SENIOR MANAGEMENT

- Has served as a director on several life sciences industry boards, including BIO ECS (2002–2006), the Bay Area Biosciences Board (now California Life Sciences) (1989–2012), the Biotechnology Institute (1998–2012), and the Life Sciences Foundation (2014–its merger with the Chemical Heritage Foundation in 2015)
- Awarded the CLS Pantheon 2016 Life Sciences Leadership Award
- B.S. in Business Administration from the Haas School at University of California, Berkeley and Certified Public Accountant (inactive)

### Leon Oliver Moulder, Jr. (“Mr. Leon O. Moulder, Jr.”)

#### Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
65	2020	Nominating and Corporate Governance, Chair Commercial Compensation	Trevena, Inc. (NASDAQ)

Mr. Leon O. Moulder, Jr. brings to the Board significant operational and senior management experience in the biopharmaceutical industry as well as extensive experience as a director on public and private boards in the industry.

#### Key Experience and Qualifications

- Founder and Managing Member of Tellus BioVentures, LLC, a life sciences investment fund (March 2019–Present)
- Member of the Board of Directors of Trevena, Inc. (2011–Present), serving as Chairman since 2013
- Member of the Board of Directors of the Helsinn Group (January 2020–Present)
- Co-Founder, Chief Executive Officer, and Member of the Board Directors of Tesaro, Inc. (NASDAQ) (May 2010–its acquisition by GSK plc in January 2019)
- President, Chief Executive Officer, and Vice Chairman of the Board of Directors of Abraxis BioScience, Inc. (NASDAQ) (2009–2010)
- Vice Chairman of the Board of Directors of Eisai Corporation of North America, a research-based pharmaceutical company and wholly owned subsidiary of Eisai Co., Ltd. (2008–2009)

## DIRECTORS AND SENIOR MANAGEMENT

- President, Chief Executive Officer, and Member of the Board of Directors of MGI PHARMA, Inc. (2003–its acquisition by Eisai Corporation of North America in 2008), after serving as President and Chief Operating Officer (2002–2003) and Executive Vice President (1999–2002)
- Temple University Trustee (January 2013–Present), Council Member for the University of Chicago Booth School of Business and the Polsky Center for Entrepreneurship and Innovation (June 2016–Present), and Board Member of the Fox Chase Cancer Center (March 2013–Present)
- MBA from The University of Chicago Booth School of Business and B.S. in Pharmacy from Temple University

### Michel Pericles Vounatsos (“Mr. Michel Vounatsos”)

#### Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
61	2023	Commercial, Chair Research and Development	PerkinElmer, Inc. (NYSE)

The Board, upon the recommendation of the Nominating and Corporate Governance Committee, appointed Mr. Michel Vounatsos to the Board, effective January 7, 2023. Mr. Michel Vounatsos was recommended to the Nominating and Corporate Governance Committee by our Chairperson and Chief Executive Officer and our Chief Legal Officer in light of his experience, our corporate priorities, and the needs of the Board. He brings to the Board extensive global leadership and management experience in the biopharmaceutical industry, including more than 25 years of service at leading companies. His expertise includes significant commercial experience in China and worldwide in the areas of primary care and neuroscience.

#### Key Experience and Qualifications

- Chief Executive Officer and Member of the Board of Directors of Biogen Inc. (NASDAQ) (January 2017–November 2022), after serving as Executive Vice President and Chief Commercial Officer (2016)
- Member of the Board of Directors and Audit Committee of PerkinElmer, Inc. (March 2020–Present) and Chair of the Nominating and Corporate Governance Committee (October 2022–Present)
- Various roles of increasing responsibility at Merck & Co. (1996–2016), including President, Primary Care & Merck Customer Centricity (2014–2016), President, Merck Customer Centricity (2012–2014), President of MSD China (2008–2012), and other leadership positions across Europe (1996–2008)

## DIRECTORS AND SENIOR MANAGEMENT

- Member of the Advisory Board of Tsinghua University School of Pharmaceutical Sciences in Beijing, China (December 2020–Present) and Chairman of the Supervisory Board of Liryc, the Electrophysiology and Heart Modeling Institute at the University of Bordeaux (May 2019–Present)
- MBA from HEC School of Management in Paris, France and Certificate of Clinical and Therapeutic Synthesis in Medicine from Université Victor Segalen, Bourdeaux II, France

### Peter Karl Wirth (“Mr. Peter Wirth”)

Independent Director

Age	Director Since	Board Committees	Other Public Company Boards
72	2017	Compensation, Chair Audit	Syros Pharmaceuticals, Inc. (NASDAQ)

Mr. Peter Wirth brings to the Board expertise in corporate governance and significant experience in corporate strategy, product development, business development, and the legal issues relating to the operation of a global biopharmaceutical company.

### Key Experience and Qualifications

- Venture Partner at Quan Capital Management, LLC, a global venture capital firm (August 2018–Present)
- Chairman of the Board of Directors at Syros Pharmaceuticals, Inc. (2017–Present)
- Chairman of the Board of Directors of FORMA Therapeutics Holdings, Inc. (NASDAQ) (2012–its acquisition by Novo Nordisk A/S in October 2022)
- Co-Founder, President, and Member of the Board of Directors of Lysosomal Therapeutics, Inc. (2011–2014)
- Various senior executive roles at Genzyme Corporation (1996–its acquisition by Sanofi-Aventis SA in 2011), most recently as Executive Vice President, Legal and Corporate Development, Chief Risk Officer, and Corporate Secretary
- Partner at Palmer & Dodge LLP, where he was head of the firm’s biotechnology practice group and served as outside general counsel for Genzyme and a number of other biotechnology companies (1975–1996)
- J.D. from Harvard Law School and B.A. in Political Science from the University of Wisconsin at Madison



# DIRECTORS AND SENIOR MANAGEMENT

## SENIOR MANAGEMENT

The following table sets forth the name, age, and position of each of our senior management as of April 1, 2023, other than Dr. Samantha Du, who is included above as an executive Director:

Name	Age	Position(s)
Samantha (Ying) Du	58	Founder, Chairperson, and Chief Executive Officer
Billy Cho	45	Chief Financial Officer
Rafael G. Amado	59	President, Head of Global Oncology Research and Development
F. Ty Edmondson	57	Chief Legal Officer
Harald Reinhart	71	President, Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases
Joshua Smiley	53	President, Chief Operating Officer

Biographical information for our senior management as of April 1, 2023 is set forth below:

**Billy Cho, M.B.A., M.A. (“Mr. Cho”)** joined our Company as Chief Financial Officer in March 2018. Prior to joining our Company, Mr. Cho served as Managing Director and Head of Asia Healthcare Investment Banking at Citigroup. Based in Hong Kong since 2011, Mr. Cho was responsible for healthcare client coverage at Citigroup across the Asia Pacific region and led many biopharma transactions in China, including Zai Lab’s U.S. initial public offering. Prior to this, he was based in New York in healthcare M&A investment banking and also spent time in corporate development for a pharmaceutical services company. Mr. Cho started his career at Ernst & Young LLP performing financial audits of U.S.-based healthcare companies. Mr. Cho earned an MBA. from the Wharton School of the University of Pennsylvania, an M.S. in Accounting from the University of Virginia, and a B.S. in Business Administration from the University of Southern California’s Marshall School of Business.

**Rafael G. Amado (“Dr. Amado”)** joined our Company as President, Global Oncology Research and Development in December 2022. Dr. Amado joined Zai Lab from Allogene Therapeutics, Inc., where he had served as Executive Vice President, Head of Research and Development and Chief Medical Officer since September 2019. Prior to Allogene, he served as President of Research and Development and Chief Medical Officer of Adaptimmune, LLC from August 2018 to July 2019 and as Chief Medical Officer from March 2015 to July 2018. In these roles, he was responsible for directing discovery and clinical development strategy as well as execution activities for several gene-engineered cell therapies, chairing the R&D leadership team and providing medical guidance for pipeline prioritization. Prior to Adaptimmune, Dr. Amado held various roles of increasing responsibility at GlaxoSmithKline from 2008 to 2015, most recently as Senior Vice President and Global Head of Oncology Research and Development, and at Amgen Inc. from 2003 to 2008, where he was last Executive Director of Clinical Research and Global Development in Therapeutic Oncology. In these roles, he has been instrumental in the development of multiple medicines across therapeutic modalities. Prior to joining Amgen, he held academic roles at the University of California, Los Angeles (UCLA) in the Department of Medicine, Division of Hematology/Oncology. Dr. Amado received an M.D. from the University of Seville School of Medicine in Seville, Spain and completed his internship and residency in Internal Medicine at the Michael Reese Hospital and Medical Center and a fellowship in Hematology/Oncology at UCLA.

## DIRECTORS AND SENIOR MANAGEMENT

**F. Ty Edmondson (“Mr. Edmondson”)** joined our Company as Chief Legal Officer in August 2020. Mr. Edmondson joined our company from Biogen Inc. where he served in various legal and compliance roles during his tenure beginning in 2014, including Senior Vice President, Chief Corporation Counsel, and Assistant Secretary from November 2019 to August 2020 and in several roles of increasing responsibility, including Chief Compliance Officer, Chief Commercial Counsel, Chief International Counsel, and Chief US Counsel from August 2014 to November 2019. Prior to Biogen, Mr. Edmondson served as Vice President, Associate General Counsel, and Corporate Secretary for Sepracor Inc. from 2005 until its acquisition by Sumitomo Dainippon Pharma Co., Ltd. in 2010. He then served with Sumitomo in various senior legal and compliance roles in Japan, China, and the United States until August 2014. Before Sumitomo, Mr. Edmondson served in various legal roles with life sciences companies with a focus on international and U.S. FDA work, including Eisai, Inc. from 2004 to 2005, Boston Scientific from 1999 to 2004, and Bristol-Myers Squibb from 1997 to 1999. Before his work in the life sciences industry, he was an associate with the admiralty law firm, Royston Rayzor in Houston, Texas from 1993 to 1997. Mr. Edmondson received a B.A. in History from Washington & Lee University and a J.D. from the Widener University School of Law.

**Harald Reinhart, M.D. (“Dr. Reinhart”)** joined our Company in 2017 and currently serves as President, Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases. He is Adjunct Clinical Professor of infectious diseases at Yale School of Medicine. Prior to joining the Company, Dr. Reinhart worked at Shionogi US from 2011 to 2013 as the US Head of Clinical Development and Medical Affairs, directing a broad portfolio of drug candidates in anti-infectives, diabetes, allergy, GI, and pain medications. He guided several compounds through regulatory meetings and obtained approval for ospemifene. Between 2003 and 2010, he held increasingly senior roles at Novartis where he oversaw successful filings of SNDAs and NDAs for Coartem, Famvir, Sebivo, and Cubicin and managed global clinical development groups for infectious disease, immunity, transplantation, and renal disease. At NIBR (Novartis Institutes for Biomedical Research), he supervised the transitioning of research projects into clinical development. From 1991 until 2003, he worked as the International Clinical Project Manager in charge of ciprofloxacin and acarbose at Bayer Corp. with several successful SNDAs and approvals. Dr. Reinhart holds a medical degree from the University of Würzburg in Germany where he trained in anesthesiology. He completed his medical specialty training in the United States with board-certifications in internal medicine and infectious diseases. He has been a Yale faculty member since 1992.

**Joshua Smiley (“Mr. Smiley”)** was appointed in March 2022 as our Chief Operating Officer, effective in August 2022 following the completion of his leave with his prior employer, and was promoted to President, Chief Operating Officer in April 2023. Mr. Smiley is responsible for our corporate strategy and for overseeing our commercial, manufacturing, business development, finance, human resources, information technology, and corporate affairs functions. Mr. Smiley brings to the Company over 26 years of experience working in the biopharmaceutical industry, including experience leading finance, corporate strategy, business development, venture capital, and global business services operations. Prior to joining the Company, Mr. Smiley worked for Eli Lilly and Company (“Lilly”) from 1995 to March 2022. While at Lilly, he held various global leadership roles with responsibility over finance, corporate strategy, business development, and capital markets activities, including Senior Vice President and Chief Financial Officer from January 2018 to February 2021. Prior to joining Lilly, he worked in investment banking and consulting. Mr. Smiley earned a B.A. in History from Harvard University.

## DIRECTORS AND SENIOR MANAGEMENT

### DISCLOSURE OF CHANGES IN DIRECTORS' INFORMATION PURSUANT TO RULE 13.51B(1) OF THE HK LISTING RULES

Upon specific inquiry by the Company and following confirmations from Directors, except as disclosed hereunder, there is no change in information of the Directors required to be disclosed pursuant to Rule 13.51B(1) of the HK Listing Rules during the Reporting Period. The changes in Directors' information are set out below:

<b>Directors</b>	<b>Changes in Positions held with the Company</b>
Dr. John Diekman	Appointed as Lead Independent Director and stepped down as Chairperson of the Audit Committee and continued to serve as a member of the Audit Committee, effective July 22, 2022; Elected as member of the Compensation Committee (in replacement of Ms. Nisa Leung), effective October 19, 2022;
Mr. Scott W. Morrison	Appointed as Chairperson the Audit Committee, effective July 22, 2022;
Ms. Nisa Leung	Ceased to be a member of Compensation Committee, effective October 19, 2022.

The Board is pleased to present the annual report and the audited financial statements of the Company for the Reporting Period.

## GENERAL INFORMATION

The Company was incorporated in the Cayman Islands on March 28, 2013 as an exempted limited liability company under the laws of the Cayman Islands. The Company's Shares have been listed on the Main Board of the HKEX since September 28, 2020 under the stock code 9688. The Company's ADSs have been listed on the NASDAQ Global Market since September 20, 2017 under the symbol "ZLAB". The Company completed its voluntary conversion from secondary listing status to primary listing status on the Hong Kong Stock Exchange, effective June 27, 2022.

## PRINCIPAL ACTIVITIES

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, autoimmune disorders, infectious diseases, and neuroscience. We intend to leverage our competencies and resources to positively impact human health in Greater China and worldwide. We currently have four commercial products that have received marketing approval in one or more territories in Greater China and thirteen programs in late-stage product development.

## BUSINESS REVIEW

The business review of the Company for the Reporting Period is set out in the sections of Business, Risk Factors, Chairperson's Statement, Financial Summary, Management Discussion and Analysis, and the Company's 2022 ESG Report which will be published on the same date, and the paragraphs below.

## SHARE CAPITAL

Details of movements in the share capital of the Company for the Reporting Period are set out in the consolidated statements of shareholders' equity.

## SUBSIDIARIES

Particulars of the Company's subsidiaries are set out in Note 1 to the consolidated financial statements.

## FINANCIAL SUMMARY

A summary of the consolidated results and financial position of the Company is set out on page 152 of this annual report.

# DIRECTORS' REPORT

## RESULTS

The results of the Company for the Reporting Period are set out in the consolidated statements of operations on page 246 of this annual report.

## MAJOR CUSTOMERS AND SUPPLIERS

During the Reporting Period, the Company's sales to its five largest customers accounted for approximately 37.7% of the Company's product revenue and the Company's single largest customer accounted for approximately 22.4% of the Company's product revenue. For the year ended December 31, 2021, the Company's sales to its five largest customers accounted for approximately 39.9% of the Company's product revenue and the Company's single largest customer accounted for approximately 21.5% of the Company's product revenue.

For the Reporting Period and the year ended December 31, 2021, the five largest suppliers of the Company accounted for approximately 29.1% and 50.9% of the Company's total purchases, respectively, while the largest supplier of the Company accounted for approximately 8.1% and 25.0% of the Company's total purchases, respectively.

During the Reporting Period, none of our Directors, their close associates or any of our shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital had any interest in any of the above customers or suppliers.

## ENVIRONMENTAL POLICIES AND PERFORMANCE

The Company is committed to doing its part to protect the environment, including by minimizing the environmental footprint from its operations. Details of this commitment, and the steps we are taking in response, will be set out in the Company's 2022 ESG Report to be published. Please refer to the Company's 2022 ESG Report by accessing the website of the Hong Kong Stock Exchange and the Company's website at <https://ir.zailaboratory.com> under section "Financials & Filings — HKEX Announcements & Notices" (or via the link <https://ir.zailaboratory.com/financials-filings/hkex-announcements-notice>).

## COMPLIANCE WITH THE RELEVANT LAWS AND REGULATIONS

During the Reporting Period, as far as the Board is aware, the Company has complied with the relevant laws and regulations that have a significant impact on the Company in all material respects.

## IMPORTANT EVENTS AFTER THE REPORTING PERIOD

There is no important event subsequent to December 31, 2022 and up to the Latest Practicable Date.

## PRINCIPAL RISKS AND UNCERTAINTIES

The summary below 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 Risk Factors.

- Uncertainties in the Chinese legal system could materially and adversely affect us;
- Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital, and the market price of our ordinary shares and/or our ADSs;
- The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs and ordinary shares, including potentially making those ADSs or ordinary shares worthless;
- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act;
- Compliance with China's Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, and any other future laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, which could materially and adversely impact our operating results;
- The economic, political, and social conditions in mainland China, as well as governmental policies, could affect the business environment and financial markets in mainland China, our ability to operate our business, our liquidity, and our access to capital;
- If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our ADSs or ordinary shares may decline in value or become worthless;
- The approval of, filing, or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures;

## DIRECTORS' REPORT

- 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 our reputation;
- 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 us could have a material and adverse effect on our ability to conduct our business;
- Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us;
- Chinese regulations establish complex procedures for some acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China;
- Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which may result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third-party contract manufacturers;
- Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations;
- It may be difficult for overseas regulators to conduct investigations or collect evidence within mainland China;
- If we are classified as a Chinese resident enterprise for Chinese income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders;
- We and our shareholders face uncertainties in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises;
- Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition, and results of operations;
- Certain of our investments may be subject to CFIUS review, which may delay or block a transaction from closing;



- Changes in United States and international trade policies and relations, particularly with regard to mainland China, may adversely impact our business and operating results;
- It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts;
- Any inability to renew our current leases on desirable terms or otherwise locate desirable alternatives for our leased properties could materially and adversely affect our business;
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. To date, we have not generated sufficient revenue from product sales to cover corresponding expenses, and we may never achieve or sustain profitability;
- We are invested in the commercial success of our approved products, and our ability to generate product revenues in the near future is highly dependent on the commercial success of these products;
- We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates, and our business could be substantially harmed;
- If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us;
- If we fail to maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired; and
- The effects of the COVID-19 pandemic, including increased infection rates and any government actions and lockdown measures taken in response, particularly in mainland China, could materially and adversely affect us.

## USE OF NET PROCEEDS

### Use of Net Proceeds from April 2021 Offering

In April 2021, the Company issued 224,000 ordinary shares (2,240,000 ordinary shares after the Share Subdivision) of the Company at a price of HK\$1,164.20 per share (HK\$116.42 per share after the Share Subdivision) and 5,492,400 ADSs at a price of US\$150.00 per ADS for aggregate cash consideration (before deducting underwriting discounts and commissions and other offering expenses) of approximately \$857.5 million. See Note 2(a) to the consolidated financial statements for additional information on the Share Subdivision.

## DIRECTORS' REPORT

As of the Latest Practicable Date, there has been no change in the intended use of net proceeds raised from this offering, which amounted to approximately \$818.0 million, as disclosed in the announcement of the Company dated April 21, 2021:

- approximately 30% of the net proceeds to fund new business and corporate development and licensing opportunities;
- approximately 30% of the net proceeds to complete clinical trials and advance new drug candidates;
- approximately 20% of the net proceeds to expand the Company's commercialization efforts;
- approximately 15% of the net proceeds to enhance the Company's global pipeline; and
- approximately 5% of the net proceeds for working capital and other general corporate purposes.

The following table sets forth a summary of the utilization of the net proceeds from this offering as of December 31, 2022 (\$ in millions):

<b>Purpose</b>	<b>Percentage to total amount</b>	<b>Net proceeds from the offering</b>	<b>Actual use of proceeds up to December 31, 2022</b>	<b>Unutilized amount as of December 31, 2022</b>
fund new business and corporate development and licensing opportunities	30%	245.4	—	245.4
complete clinical trials and advance new drug candidates	30%	245.4	135.8	109.6
expand the Company's commercialization efforts	20%	163.6	93.4	70.2
enhance the Company's global pipeline	15%	122.7	—	122.7
working capital and other general corporate purposes	5%	40.9	—	40.9
<b>Total</b>	<b>100%</b>	<b>818.0</b>	<b>229.2</b>	<b>588.8</b>

The Company plans to gradually utilize the remaining net proceeds in accordance with such intended purpose depending on actual business, which is expected to be fully utilized by the end of 2025.

## Use of Net Proceeds from the Global Offering

Dealings in ordinary shares on the Hong Kong Stock Exchange commenced on September 28, 2020. The net proceeds raised from the global offering ("Global Offering") as described in the prospectus of the Company dated September 17, 2020 (the "Prospectus"), after deduction of the underwriting fees and commissions and other estimated expenses payable by the Company in connection with the Global Offering, were approximately HK\$6,636.2 (\$850.8 million). As of the Latest Practicable Date, being latest practicable date prior to the issue of this annual report, there has been no change in the intended use of net proceeds and the expected timeline as previously disclosed in the section "Use of Proceeds" in the Prospectus. The net proceeds received by the Company from the Global Offering will be used for the following purposes:

- approximately 16.0% will be allocated for ZEJULA to seek indication expansion and hire high-caliber R&D staff dedicated to its development, and to develop and improve the Company's manufacturing facilities to bring ZEJULA to commercialization;
- approximately 6.2% will be used to fund ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications;
- approximately 16.0% will be used for ZEJULA to enhance the Company's commercialization capabilities through increasing its sales and marketing headcounts, among other efforts;
- approximately 8.0% will be used to strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch;
- approximately 11.8% will be used to fund the Company's ongoing and planned clinical trials and preparation for registration filings of other drug candidates in the pipeline, especially late-stage drug candidates;
- approximately 25.0% will be used to explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/first-in-class assets with clinical validation, synergistic with the Company's current pipeline, and aligned to its expertise;
- approximately 7.0% will be used to continue investing in and expanding the Company's internal discovery pipeline and recruit and train talent globally; and
- approximately 10.0% will be used to fund working capital and other general corporate purposes.

## DIRECTORS' REPORT

The following table presents a summary of the utilization of the net proceeds from the Global Offering as of December 31, 2022 (\$ in millions):

<b>Purpose</b>	<b>Percentage to total amount</b>	<b>Net proceeds from the offering</b>	<b>Actual use of proceeds up to December 31, 2022</b>	<b>Unutilized amount as of December 31, 2022</b>
for ZEJULA to seek indication expansion and hire high-caliber R&D staff dedicated to its development, and to develop and improve the Company's manufacturing facilities to bring ZEJULA to commercialization	16.0%	136.1	56.9	79.2
fund ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications	6.2%	52.7	18.8	33.9
for ZEJULA to enhance the Company's commercialization capabilities through increasing its sales and marketing headcounts, among other efforts	16.0%	136.1	96.3	39.8
strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch	8.0%	68.1	42.8	25.3
fund the Company's ongoing and planned clinical trials and preparation for registration filings of other drug candidates in the pipeline, especially late-stage drug candidates	11.8%	100.4	100.4	—
explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/first-in-class assets with clinical validation, synergistic with the Company's current pipeline and aligned to its expertise	25.0%	212.7	168.3	44.4
continue investing in and expanding the Company's internal discovery pipeline and recruit and train talent globally	7.0%	59.6	23.0	36.6
fund working capital and other general corporate purposes	10.0%	85.1	54.4	30.7
<b>Total</b>	<b>100%</b>	<b>850.8</b>	<b>560.9</b>	<b>289.9</b>

The Company plans to gradually utilize the remaining net proceeds in accordance with such intended purpose depending on actual business, which is expected to be fully utilized by the end of 2025.

### **DIVIDEND POLICY AND RESERVES**

We have 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. The declaration and payment of any dividends in the future will be determined by our Board in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

The Board did not recommend any final dividend for the Reporting Period.

The Company did not have any reserves available for distribution to shareholders as of December 31, 2022. Details of movements in the reserves of the Company and Zai Lab Limited during the Reporting Period are set out in the consolidated statements of shareholders' equity on pages 248 and 297 of this annual report, respectively.

### **PROPERTY AND EQUIPMENT**

Details of movements in the property, plant and equipment of the Company during the Reporting Period are set out in Note 9 to the consolidated financial statements.

### **BORROWINGS**

The Company did not have any borrowings from banks or any other financial institutions during the Reporting Period.

### **DONATION**

During the Reporting Period, the Company made charitable donations of approximately \$22.0 million (2021: approximately \$9.0 million).

### **DEBENTURE ISSUED**

The Company did not issue any debentures during the Reporting Period.

# DIRECTORS' REPORT

## EQUITY-LINKED AGREEMENTS

Except as disclosed in the section headed "Equity Incentive Plans", Note 17 to the consolidated financial statements and the section headed "Collaboration and License Agreement with argenx BV ("argenx") (Efgartigimod)" in Note 18 to the consolidated financial statements, no equity-linked agreements were entered into by the Company or existed during the Reporting Period.

## DIRECTORS

The Directors who held office during the Reporting Period and up to the Latest Practicable Date are:

### Executive Director

Dr. Samantha Du (*Chairperson and Chief Executive Officer*)

### Independent Directors

Dr. Kai-Xian Chen

Dr. John Diekman (*appointed as Lead Independent Director on July 22, 2022*)

Ms. Nisa Leung

Mr. William Lis

Mr. Leon O. Moulder, Jr.

Mr. Peter Wirth

Mr. Scott W. Morrison

Richard Gaynor, M.D.

Mr. Michel Vounatsos (*appointed on January 7, 2023*)

For the Reporting Period, the Company has received from each of the independent non-executive Directors an annual confirmation of independence pursuant to Rule 3.13 of the HK Listing Rules and considers each of the independent non-executive Directors are independent.

## BOARD OF DIRECTORS AND SENIOR MANAGEMENT

Biographical details of the Directors and senior management of the Company are set out in "Directors and Senior Management" above in this annual report.

## EMOLUMENT POLICY AND DIRECTORS' REMUNERATION

### Director Remuneration

The remunerations of the directors are determined pursuant to our non-employee director compensation policy.

For 2022, each member of the Board who is not an employee of the Company or one of our affiliates was entitled to the following compensation under our non-employee director compensation policy:

- Annual cash retainer of \$50,000 for each non-employee director;
- Additional annual cash retainer of \$35,000 for the Lead Independent Director;
- Additional annual cash retainer of \$20,000 for the Audit Committee chair;
- Additional annual cash retainer of \$10,000 for each Audit Committee member;
- Additional annual cash retainer of \$15,000 for the Compensation Committee chair;
- Additional annual cash retainer of \$7,500 for each Compensation Committee member;
- Additional annual cash retainer of \$10,000 for the Nominating and Corporate Governance Committee chair;
- Additional annual cash retainer of \$5,000 for each Nominating and Corporate Governance Committee member;
- Additional annual cash retainer of \$10,000 for the Research and Development Committee chair through October 19, 2022, upon which date this retainer was increased to \$15,000 in recognition of the time commitment of the committee and in consideration of market practices;
- Additional annual cash retainer of \$5,000 for each Research and Development Committee member through October 19, 2022, upon which date this retainer was increased to \$7,500 in recognition of the time commitment of the committee and in consideration of market practices; and
- An annual grant of restricted shares under our 2022 Plan.

Our non-employee directors are also reimbursed by the Company for reasonable and customary expenses incurred in connection with attendance at board of director and committee meetings, in accordance with the Company's policies. Dr. Samantha Du and Ms. Nisa Leung do not receive separate compensation for their service as directors.

Details of Directors' remuneration for the Reporting Period are set out in Note 23 to the consolidated financial statements, respectively.



# DIRECTORS' REPORT

## Executive Remuneration

The Compensation Committee of the Board actively reviews and assesses our executive compensation program in light of the highly competitive employment environment; the challenge of recruiting, motivating, and retaining executives in an industry that generally has longer business cycles than other commercial industries; significant risks associated with success in our industry; and evolving compensation governance and best practices. In evaluating these considerations, the Compensation Committee strives to act in the long-term best interests of the Company and our shareholders and believes that our executive compensation program is strongly aligned with the long-term interests of our shareholders.

Details of the remuneration of the senior management of the Company by band, whose biographies are set out on pages 186 to 187 of this annual report for the Reporting Period are set out below:

Remuneration band	Number of Individuals
<\$10,000 <sup>(1)</sup>	1
\$1,000,001-\$2,000,000 <sup>(2)</sup>	1
\$3,000,001-\$12,000,000	4

Notes:

(1) The remuneration of applicable member of senior management is calculated on pro-rata basis since he joined the Company from December 30, 2022;

(2) The remuneration of applicable member of senior management is calculated on pro-rata basis since he joined the Company from August 1, 2022.

For more details about share-based compensation, please refer to the section headed "Equity Incentive Plans" and Note 17 to the consolidated financial statements contained in this annual report.

Details of five highest paid individuals for the Reporting Period are set out in Note 24 to the consolidated financial statements.

## Employee Remuneration Policy

The remuneration policy and package of our employees are periodically reviewed by the Compensation Committee of the Board. The packages were set by benchmarking with companies in similar industries and companies with similar complexity and size. For more details about employee remuneration policy, please refer to the section headed "Employee and Remuneration Policy" contained in this annual report.

## DIRECTORS' SERVICE CONTRACTS

The service contract entered into with Dr. Samantha Du, an executive Director, Chairperson, and Chief Executive Officer of the Company, is determinable within one year, subject to payment of compensation in the sum of 18-month remuneration.

Save as disclosed above, none of the Directors proposed for election or re-election at the 2023 annual general meeting of shareholders has a service contract with members of the Company that is not determinable by the Company within one year without payment of compensation, other than statutory compensation.

### **DIRECTORS' INTERESTS IN TRANSACTIONS, ARRANGEMENTS OR CONTRACTS OF SIGNIFICANCE**

Except as disclosed in the sections headed "Directors' Service Contracts", "Connected Transactions and Continuing Connected Transactions", "Related Party Transaction" and Note 16 to the consolidated financial statements contained in this annual report, none of the Directors nor any entity connected with the Directors had a material interest, either directly or indirectly, in any transactions, arrangements or contracts of significance to which the Company or any of its subsidiaries was a party subsisting during or at the end of the Reporting Period.

### **PERMITTED INDEMNITY**

Pursuant to our Sixth Restated Articles and subject to the applicable laws and regulations, every Director shall be indemnified and held harmless out of the assets and profits of the Company against all actions, proceedings, costs, charges, expense losses, damages or liabilities which they or any of them may incur or sustain in or about the execution of their duty in their offices, other than by reason of such person's dishonesty, willful default or fraud.

Such permitted indemnity provision has been in force for the Reporting Period. The Company has taken out liability insurance to provide appropriate coverage for the Directors.

### **MANAGEMENT CONTRACTS**

Except as disclosed in the section headed "Directors' Service Contracts" in this annual report, no contract concerning the management and administration of the whole or any substantial part of the business of the Company was entered into or existed during the Reporting Period.

### **DIRECTORS' RIGHTS TO ACQUIRE SHARES OR DEBENTURES**

Except as disclosed in this annual report, at no time during the Reporting Period was the Company or any of its subsidiaries a party to any arrangements to enable the Directors to acquire benefits by means of the acquisition of shares in, or debentures of the Company or any other body corporate; and none of the Directors, or any of their spouse or children under the age of 18, had any right to subscribe for equity or debt securities of the Company or any other body corporate, or had exercised any such right.

### **DIRECTORS' INTERESTS IN COMPETING BUSINESS**

During the Reporting Period, none of our Directors had any interest in a business, apart from the business of our Company, which competes or is likely to compete, directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the HK Listing Rules.

## DIRECTORS' REPORT

### DIRECTORS' AND CHIEF EXECUTIVE'S INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES AND DEBENTURES OF THE COMPANY OR ANY OF ITS ASSOCIATED CORPORATIONS

As of December 31, 2022, so far as was known to the Directors and chief executive of the Company, the interests and short positions of the Directors and chief executive of the Company in the Shares, underlying Shares, and debentures of the Company or its associated corporations within the meaning of Part XV of the SFO, which were required to be (a) notified to the Company and the Hong Kong Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they had taken or were deemed to have under such provisions of the SFO); (b) recorded in the register required to be kept by the Company pursuant to Section 352 of the SFO; or (c) otherwise notified to the Company and the Hong Kong Stock Exchange pursuant to the Model Code were as follows:

Name of Director	Nature of interest	Number of Shares	Approximate percentage of holding <sup>(1)</sup>
Kaixian Chen	Beneficial owner	310,160	0.03%
John David Diekman	Beneficial owner	487,820	0.04%
Ying Du	Beneficial owner	40,957,406 <sup>(2)</sup>	4.18%
	Beneficiary of a trust (other than a discretionary interest)	7,897,924	0.81%
	Other	3,061,410 <sup>(3)</sup>	0.31%
	Founder of a discretionary trust who can influence how the trustee exercises his discretion	215,700 <sup>(4)</sup>	0.02%
Richard Brian Gaynor	Beneficial owner	89,120	0.01%
William David Lis	Beneficial owner	287,640	0.02%
Scott William Morrison	Beneficial owner	73,450	0.01%
Leon Oliver Moulder Jr.	Beneficial owner	216,150	0.02%
Peter Karl Wirth	Beneficial owner	3,427,630	0.35%

Notes:

- (1) These calculations are based on the total number of 979,087,430 Shares in issue as of December 31, 2022.
- (2) Includes Dr. Samantha Du's entitlements to receive up to (1) 36,847,250 Shares pursuant to share options granted to her and not yet exercised or expired, subject to any applicable conditions thereof; and (2) 3,659,750 Shares pursuant to other share awards granted to her and not yet vested, subject to any applicable conditions thereof.
- (3) 3,061,410 Shares are held by certain other shareholders, including members of the Company's management and their affiliates, who have granted to Dr. Samantha Du the right to vote their shares and for which Dr. Samantha Du may be deemed to have an "interest" based on her right to vote such Shares, however Dr. Samantha Du has no pecuniary interest therein.
- (4) These Shares are held by Ying Du Revocable Trust for the benefit of Dr. Samantha Du, of which Dr. Samantha Du is the trustee and is the founder having power to influence the exercise of the trustee's discretion.

All interests stated above are long positions.

## SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES

As of December 31, 2022, so far as was known to the Directors and chief executive of the Company and based on the information filed with the Disclosure of Interest Online (DION) System, the following persons (other than the Directors and chief executive of the Company) had interests and/or short positions in the Shares or underlying Shares which would be required to be disclosed to the Company pursuant to Divisions 2 and 3 of Part XV of the SFO or recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO:

Name of Substantial Shareholders	Capacity/nature of interest	Number of Shares held	L/S/P <sup>(1)</sup>	Approximate Percentage of Shareholding in the Company <sup>(2)</sup>
FMR LLC <sup>(i)</sup>	Interest of corporation controlled by you	97,435,464	(L)	9.95%
Invesco Advisers, Inc. <sup>(iii)</sup>	Investment manager	81,677,890	(L)	8.34%
Invesco Developing Markets Fund <sup>(iii)</sup>	Person having a security interest in shares	72,447,310	(L)	7.39%
BAILLIE GIFFORD & CO <sup>(iii)</sup>	Investment manager	405,906 <sup>(3)</sup>	(L)	0.41%
Citigroup Inc. <sup>(iv)</sup>	Interest of corporation controlled by you	5,510,261 <sup>(3)</sup>	(L)	5.62%
	Person having a security interest in shares	500 <sup>(3)(4)</sup>	(L)	0.00%
	Interest of corporation controlled by you	31,314 <sup>(3)(4)</sup>	(L)	0.00%
	Interest of corporation controlled by you	4,202 <sup>(3)(4)</sup>	(S)	0.00%
JPMorgan Chase & Co.	Approved lending agent	5,200,946 <sup>(3)(4)</sup>	(P)	5.31%
	Interest of corporation controlled by you	27,802,555 <sup>(5)</sup>	(L)	2.84%
	Interest of corporation controlled by you	29,652,520 <sup>(5)</sup>	(S)	3.02%
	Investment manager	3,074,300 <sup>(5)</sup>	(L)	0.31%
	Person having a security interest in shares	6,856,970 <sup>(5)</sup>	(L)	0.70%
	Trustee	20,950 <sup>(5)</sup>	(L)	0.00%
	Approved lending agent	40,548,787 <sup>(5)</sup>	(P)	4.14%

Notes:

- (1) Long position (L)/ Short position (S)/ Lending pool (P)
- (2) These calculations are based on the total number of 979,087,430 Shares in issue as of December 31, 2022.
- (3) Following the Share Subdivision, the number of shares held before March 30, 2022 have been retrospectively adjusted to 10 times of its original ordinary shares held.
- (4) According to the corporate substantial shareholder notice regarding the relevant event dated September 28, 2020 submitted by Citigroup Inc. to Hong Kong Stock Exchange on October 5, 2020, an aggregated 5,232,760 Shares (long position), 4,202 Shares (short position), and 5,200,946 Shares (lending pool) of the Company are held by Citigroup Inc. indirectly through its certain subsidiaries. Among them, 5,080,573 Shares (long position) and 4,202 Shares (short position) are physically settled listed derivatives, and 137 Shares (long position) are cash settled unlisted derivatives.

# DIRECTORS' REPORT

- (5) According to the corporate substantial shareholder notice regarding the relevant event dated December 29, 2022 submitted by JPMorgan Chase & Co. to Hong Kong Stock Exchange on January 3, 2023, an aggregated 78,303,562 Shares (long position), 29,652,520 Shares (short position), and 40,548,787 Shares (lending pool) of the Company are held by JPMorgan Chase & Co. indirectly through its certain subsidiaries. Among them, 8,174,500 Shares (long position) and 1,649,160 Shares (short position) are cash settled unlisted derivatives.
- (i) According to the Schedule 13G/A filed by FMR LLC with the SEC on February 9, 2023 (<https://www.sec.gov/Archives/edgar/data/315066/000031506623002150/filing.txt>), as of December 31, 2022, it beneficially owned 91,917,195 ordinary shares of the Company, which accounted for 9.388% of the then issued share capital of the Company.
- (ii) According to the Schedule 13G filed by Invesco Ltd. with the SEC on February 10, 2023 ([https://www.sec.gov/Archives/edgar/data/914208/000091420823000246/SEC13G\\_Filing.htm](https://www.sec.gov/Archives/edgar/data/914208/000091420823000246/SEC13G_Filing.htm)), as of December 31, 2022, it beneficially owned 82,310,360 ordinary shares of the Company.
- (iii) According to the Schedule 13G filed by Baillie Gifford & Co with the SEC on July 5, 2022 (<https://www.sec.gov/Archives/edgar/data/1088875/000108887522000104/ZaiLab30062022.txt>), as of June 30, 2022, it beneficially owned 46,935,800 ordinary shares of the Company (which accounted for 4.79% of the then issued share capital of the Company).
- (iv) According to the Form 13F filed by Citigroup Inc with the SEC on August 10, 2022 ([https://www.sec.gov/Archives/edgar/data/831001/000083100122000127/xslForm13F\\_X01/CITIGROUP\\_13F\\_HR\\_INFOTABLE.xml](https://www.sec.gov/Archives/edgar/data/831001/000083100122000127/xslForm13F_X01/CITIGROUP_13F_HR_INFOTABLE.xml)), as of 30 June 2022, it beneficially owned 124,365 ADSs of the Company.
- (v) According to the Schedule 13G/A jointly filed by Qiming Corporate GP IV, Ltd., Qiming Managing Directors Fund IV, L.P., Qiming GP IV, L.P., Qiming Venture Partners IV, L.P., and QM11 Limited with the SEC on February 14, 2023 ([https://www.sec.gov/Archives/edgar/data/1603597/000095010323002283/dp188767\\_sc13ga-4.htm](https://www.sec.gov/Archives/edgar/data/1603597/000095010323002283/dp188767_sc13ga-4.htm)), as of December 31, 2022, QM 11 Limited beneficially owned 79,229,320 ordinary shares of the Company (after Share Subdivision), which accounted for 8.1% of the then issued share capital of the Company.

Save as disclosed above and to the best knowledge of the Directors, as of December 31, 2022, we are not aware of any other person (other than the Directors or the chief executive of the Company whose interests are set out in the section headed "DIRECTORS' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES AND DEBENTURES OF THE COMPANY OR ANY OF ITS ASSOCIATED CORPORATIONS" above) who had an interest or short position in the Shares or underlying Shares as recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO.

## EQUITY INCENTIVE PLANS

The Company has 3 equity incentive plans, namely the 2015 Plan, the 2017 Plan and the 2022 Plan. The 2022 Plan was adopted by the shareholders and took effect on June 27, 2022, the Primary Conversion Effective Date, and the Board determined that no new grants would be made under the 2015 Plan and the 2017 Plan thereafter. As at January 1, 2022, the 2022 Plan had not been adopted and the limit on the number of Shares which may be issued upon exercise of all outstanding options granted and yet to be exercised under the 2015 Plan and 2017 Plan was 208,210,639. As at December 31, 2022, the revised Chapter 17 of the HK Listing Rules has not come into effect, and the limit on the number of Shares which may be issued upon exercise of all outstanding options granted and yet to be exercised under the 2015 Plan, the 2017 Plan and the 2022 Plan was 202,544,809. During the Reporting Period, 61,440,310 Shares may be issued in respect of options and awards granted under the 2015 Plan, the 2017 Plan and the 2022 Plan, representing approximately 6.30% of the Shares in issue for the Reporting Period (dividing the number of Shares that may be issued in respect of options and awards granted by the weighted average number of shares in issue).

### 1. 2015 Equity Incentive Plan (the "2015 Plan")

The 2015 Plan was approved by the Board on March 5, 2015 and most recently amended with effect on April 10, 2016. The Board determined that no new grants would be made under the 2015 Plan after the dual-primary listing of the Company became effective on June 27, 2022.

# DIRECTORS' REPORT

As of January 1, 2022, 36,561,800 Shares were outstanding pursuant to options granted under the 2015 Plan, and as of December 31, 2022, 34,225,270 Shares were outstanding pursuant to options granted under the 2015 Plan. Details of the outstanding options under the 2015 Plan are set out below:

Name of grantee	Category of grantees	Date of grant	Vesting period <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	Exercise period <sup>(4)</sup>	Exercise (grant) price (in \$) <sup>(5)</sup>	Price on day prior to		Number of shares underlying the options		
						exercise during the Reporting Period (in \$) <sup>(6)</sup>	Outstanding as of January 1, 2022	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2022
<b>Directors and chief executive of the Company</b>										
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	10/22/2015	5 years	10 years	0.06	—	8,891,650	0	0	8,891,650
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	3/9/2016	5 years	10 years	0.12	—	6,043,760	0	0	6,043,760
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	8/25/2016	5 years	10 years	0.174	—	9,221,840	0	0	9,221,840
<b>Employee Participants (other than chief executive)</b>										
In aggregate	Employee Participants	3/5/2015	5 years	10 years	0.06	3	2,574,170	455,480	0	2,118,690
In aggregate	Employee Participants	10/22/2015	5 years	10 years	0.06	3.64	7,450,010	1,627,850	0	5,822,160
In aggregate	Employee Participants	3/9/2016	5 years	10 years	0.12	4.66	632,700	200,000	0	432,700
In aggregate	Employee Participants	8/25/2016	5 years	10 years	0.174	2.91	1,438,850	33,330	0	1,405,520
In aggregate	Employee Participants	8/25/2016	3 years	10 years	0.174	—	4,160	0	0	4,160
In aggregate	Employee Participants	12/6/2016	3 years	10 years	0.174	—	4,160	0	0	4,160
In aggregate	Employee Participants	5/12/2017	5 years	10 years	0.3	4.63	163,000	330	1,000	161,670
In aggregate	Employee Participants	5/12/2017	3 years	10 years	0.3	—	4,160	0	0	4,160
In aggregate	Employee Participants	5/12/2017	4 years	10 years	0.3	3.7	133,340	18,540	0	114,800
<b>Total</b>							<b>36,561,800</b>	<b>2,335,530</b>	<b>1,000</b>	<b>34,225,270</b>

## Notes:

- (1) Where the vesting period is 5 years, one-fifth of the options shall vest on each anniversary of the date of grant for the next five years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (2) Where the vesting period is 4 years, one-fourth of the options shall vest on each anniversary of the date of grant for the next four years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (3) Where the vesting period is 3 years, one-third of the options shall vest on each anniversary of the date of grant for the next three years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (4) The relevant portion of the options becomes exercisable upon vesting on each anniversary of the date of grant, with the validity period of the options being 10 years from the date of grant.
- (5) The stated exercise (grant) price was determined in good faith by the administrator of the 2015 Plan in the absence of an established market for the Shares.
- (6) The stated price was the weighted-average closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date on which the options were exercised during the Reporting Period.

# DIRECTORS' REPORT

## Purposes

The purposes of the 2015 Plan are to (1) attract and retain the best available personnel for positions of substantial responsibility; (2) provide additional incentive to employees, directors, and consultants; and (3) to promote the success of the Company's business.

## Eligible Participants

Management including officers, directors, employees, and individual advisors who render services to the Company may participate in the 2015 Plan.

## Maximum Number of Shares

The initial total number of shares available for issue under the 2015 Plan is 268,998,690 Shares (taking into account the Share Subdivision), which represents 27.47% of the issued shares of the Company as of the Latest Practicable Date. The Board determined that no new grants would be made under the 2015 Plan after the dual-primary listing of the Company became effective on June 27, 2022.

## Limit of Each Grantee

The 2015 Plan does not specify any limit on options granted to a grantee.

## Expiration of the 2015 Plan

Unless sooner terminated by the Board, the 2015 Plan will continue in effect for a term of 10 years from the later of (1) the effective date of the 2015 Plan, or (2) the earlier of the most recent Board or shareholder approval of an increase in the number of Shares reserved for issuance under the 2015 Plan, i.e. April 10, 2026.

## Exercise Period

At the time an option is granted, the administrator of the 2015 Plan will fix the period within which the option may be exercised. The term of each option granted under the 2015 Plan will be no more than 10 years from the date of grant.

## Consideration

No cash consideration is required to be paid by the grantees for the grant of options under the 2015 Plan.

# DIRECTORS' REPORT

## Exercise Price

The exercise price of each share option granted under the 2015 Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain incentive share options).

## 2. 2017 Equity Incentive Plan (the "2017 Plan")

The 2017 Plan was approved by the Board on August 7, 2017. The Board determined that no new grants would be made under the 2017 Plan after the dual-primary listing of the Company became effective on June 27, 2022.

As of January 1, 2022, 44,453,790 Shares were outstanding pursuant to options granted under the 2017 Plan, and as of December 31, 2022, 52,292,850 Shares were outstanding pursuant to options granted under the 2017 Plan. Details of the outstanding options under the 2017 Plan are set out below:

Name of grantee	Category of grantees	Date of grant	Vesting period <sup>(1) (2) (3)</sup>	Exercise period <sup>(4)</sup>	Exercise (grant) price (in \$) <sup>(5)</sup>	Price on day prior to exercise during the Reporting Period (in \$) <sup>(6)</sup>	Outstanding as of January 1, 2022	Number of shares underlying the options		
								Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2022
<b>Directors and chief executive of the Company</b>										
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	3/28/2018	5 years	10 years	2.09	—	3,500,000	0	0	3,500,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	3/8/2019	5 years	10 years	3.893	—	3,000,000	0	0	3,000,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	3/12/2020	5 years	10 years	4.494	—	2,500,000	0	0	2,500,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	4/1/2021	5 years	10 years	13.096	—	870,000	0	0	870,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	4/1/2022	5 years	10 years	4.547	—	0	0	0	2,820,000
<b>Employee Participants (other than chief executive)</b>										
In aggregate	Employee Participants	9/20/2017	3 years	10 years	1.8	—	75,000	0	0	75,000
In aggregate	Employee Participants	9/20/2017	5 years	10 years	1.8	3.54	409,520	1,660	0	407,860
In aggregate	Employee Participants	1/22/2018	5 years	10 years	2.374	3.64	533,400	103,000	10,000	420,400



# DIRECTORS' REPORT

Name of grantee	Category of grantees	Date of grant	Vesting period <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	Exercise period <sup>(4)</sup>	Number of shares underlying the options						
					Exercise (grant) price (in \$) <sup>(5)</sup>	Price on day prior to exercise during the Reporting Period (in \$) <sup>(6)</sup>		Outstanding as of January 1, 2022	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2022
						Exercise price	Exercise price				
In aggregate	Employee Participants	1/26/2018	5 years	10 years	2.458	—	—	370,000	0	0	370,000
In aggregate	Employee Participants	3/2/2018	5 years	10 years	2.184	—	—	3,700,000	0	0	3,700,000
In aggregate	Employee Participants	3/22/2018	5 years	10 years	2.074	—	—	1,300,000	0	0	1,300,000
In aggregate	Employee Participants	3/28/2018	5 years	10 years	2.09	—	—	600,000	0	0	600,000
In aggregate	Employee Participants	6/4/2018	5 years	10 years	2.38	—	—	3,450,000	0	0	3,450,000
In aggregate	Employee Participants	8/14/2018	5 years	10 years	2.193	4.46	—	505,000	10,000	0	495,000
In aggregate	Employee Participants	9/24/2018	5 years	10 years	1.892	4.08	—	4,200,000	2,200,000	2,000,000	0
In aggregate	Employee Participants	11/16/2018	5 years	10 years	1.799	—	—	300,000	0	0	300,000
In aggregate	Employee Participants	11/26/2018	5 years	10 years	1.76	3.8	—	1,078,000	175,000	70,000	833,000
In aggregate	Employee Participants	2/25/2019	3 years	10 years	2.912	—	—	50,000	0	0	50,000
In aggregate	Employee Participants	3/8/2019	5 years	10 years	2.775	4.62	—	1,122,000	184,000	162,000	776,000
In aggregate/	Employee Participants	3/27/2019	5 years	10 years	2.807	3.99	—	1,423,210	60,000	68,000	1,285,210
In aggregate	Employee Participants	6/28/2019	5 years	10 years	3.487	4.75	—	399,000	36,000	46,000	315,000
In aggregate	Employee Participants	9/30/2019	5 years	10 years	3.235	3.9	—	250,000	28,000	106,000	116,000
In aggregate	Employee Participants	12/31/2019	5 years	10 years	4.159	4.32	—	362,130	18,000	30,000	314,130
In aggregate	Employee Participants	10/14/2019	5 years	10 years	3.343	—	—	250,000	0	0	250,000
In aggregate	Employee Participants	10/7/2019	3 years	10 years	3.188	—	—	0	0	0	25,000
In aggregate	Employee Participants	3/12/2020	5 years	10 years	4.494	—	—	910,000	0	0	910,000
In aggregate	Employee Participants	3/31/2020	5 years	10 years	5.148	—	—	3,695,000	0	710,000	2,985,000
In aggregate	Employee Participants	6/30/2020	5 years	10 years	8.213	—	—	953,810	0	93,500	860,310
In aggregate	Employee Participants	8/17/2020	5 years	10 years	8.25	—	—	377,500	0	0	377,500
In aggregate	Employee Participants	9/21/2020	5 years	10 years	7.33	—	—	537,830	0	64,420	473,410
In aggregate	Employee Participants	12/1/2020	5 years	10 years	10.893	—	—	470,000	0	376,000	94,000
In aggregate	Employee Participants	12/21/2020	5 years	10 years	12.872	—	—	1,062,640	0	252,310	810,330
In aggregate	Employee Participants	5/1/2021	5 years	10 years	16.621	—	—	36,000	0	0	36,000
In aggregate	Employee Participants	3/1/2021	5 years	10 years	16.202	—	—	141,000	0	30,400	110,600
In aggregate	Employee Participants	4/1/2021	5 years	10 years	13.096	—	—	3,768,380	0	590,270	3,178,110
In aggregate	Employee Participants	6/1/2021	5 years	10 years	18.00	—	—	140,250	0	28,550	111,700
In aggregate	Employee Participants	7/1/2021	5 years	10 years	17.837	—	—	79,080	0	15,160	63,920
In aggregate	Employee Participants	8/1/2021	5 years	10 years	14.461	—	—	35,000	0	19,000	16,000
In aggregate	Employee Participants	9/1/2021	5 years	10 years	14.718	—	—	222,590	0	92,200	130,390
In aggregate	Employee Participants	10/1/2021	5 years	10 years	10.275	—	—	449,820	0	90,150	359,670
In aggregate	Employee Participants	11/1/2021	5 years	10 years	10.442	—	—	149,340	0	2,400	146,940
In aggregate	Employee Participants	11/1/2021	4 years	10 years	10.442	—	—	899,000	0	155,000	744,000
In aggregate	Employee Participants	12/1/2021	5 years	10 years	7.123	—	—	121,790	0	23,500	98,290
In aggregate	Employee Participants	12/1/2021	4 years	10 years	7.123	—	—	128,500	0	50,500	78,000
In aggregate	Employee Participants	12/30/2021	3 years	10 years	6.692	—	—	29,000	0	0	29,000
In aggregate	Employee Participants	1/1/2022	5 years	10 years	6.285	—	—	0	0	5,000	13,000
In aggregate	Employee Participants	2/1/2022	5 years	10 years	5.359	—	—	0	0	8,750	424,170

# DIRECTORS' REPORT

Name of grantee	Category of grantees	Date of grant	Vesting period <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>	Exercise period <sup>(4)</sup>	Exercise (grant) price (in \$) <sup>(5)</sup>	Number of shares underlying the options				
						Price on day prior to exercise during the Reporting Period (in \$) <sup>(6)</sup>	Outstanding as of January 1, 2022	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2022
In aggregate	Employee Participants	3/1/2022	5 years	10 years	5.255	—	0	0	10,500	497,890
In aggregate	Employee Participants	4/1/2022	5 years	10 years	4.547	—	0	0	2,100,400	11,117,990
In aggregate	Employee Participants	5/1/2022	5 years	10 years	3.955	—	0	0	8,750	567,790
In aggregate	Employee Participants	6/1/2022	5 years	10 years	2.95	—	0	0	0	286,240
<b>Total</b>							44,453,790	2,815,660	7,218,760	52,292,850

Details of options granted under the 2017 Plan during the Reporting Period are set out below:

Name of grantee	Category of grantees	Date of grant	Number of shares underlying the options	Vesting period <sup>(1)</sup>	Exercise period <sup>(4)</sup>	Exercise (grant) price (in \$) <sup>(5)</sup>	Fair value on day of grant during the Reporting Period (in \$) <sup>(7)</sup>	Price on day prior to grant during the Reporting Period (in \$) <sup>(8)</sup>
<b>Directors and chief executive of the Company</b>								
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	4/1/2022	2,820,000	5 years	10 years	4.547	2.842	4.398
<b>Employee Participants (other than chief executive)</b>								
In aggregate	Employee Participants	1/1/2022	18,000	5 years	10 years	6.285	3.84	6.285
In aggregate	Employee Participants	2/1/2022	432,920	5 years	10 years	5.359	3.295	4.967
In aggregate	Employee Participants	3/1/2022	508,390	5 years	10 years	5.255	3.224	5.47
In aggregate	Employee Participants	4/1/2022	13,218,390	5 years	10 years	4.547	2.842	4.398
In aggregate	Employee Participants	5/1/2022	576,540	5 years	10 years	3.955	2.497	3.996
In aggregate	Employee Participants	6/1/2022	286,240	5 years	10 years	2.95	1.863	2.91

Notes:

- (1) Where the vesting period is 5 years, one-fifth of the options shall vest on each anniversary of the date of grant for the next five years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (2) Where the vesting period is 4 years, one-fourth of the options shall vest on each anniversary of the date of grant for the next four years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (3) Where the vesting period is 3 years, one-third of the options shall vest on each anniversary of the date of grant for the next three years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.

## DIRECTORS' REPORT

- (4) The relevant portion of the options becomes exercisable upon vesting on each anniversary of the date of grant, with the validity period of the options being 10 years from the date of grant.
- (5) The stated exercise (grant) price was the closing price as quoted on Nasdaq, divided by 10, on the date of grant.
- (6) The stated price was the weighted-average closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date on which the options were exercised during the Reporting Period.
- (7) The stated value was the fair value of options at the date of grant determined on the basis of the Black-Scholes option valuation model.
- (8) The stated price was the closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date of grant.

As of December 31, 2022, the Company had conditionally granted certain share awards under the 2017 Plan. The share awards include restricted share units ("RSUs"), performance-based restricted share units ("PSUs") and restricted shares ("RSAs").

As of January 1, 2022, 9,567,360 Shares were unvested pursuant to the awards granted under the 2017 Plan, and as of December 31, 2022, 30,142,500 Shares were unvested under the 2017 Plan. Details of the unvested share awards under the 2017 Plan are set out below:

Name of grantee	Category of grantees	Type of award	Date of grant	Vesting period <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup> <sup>(4)</sup> <sup>(5)</sup> <sup>(6)</sup>	Price on day prior to vesting during the Reporting Period (in \$) <sup>(7)</sup>	Number of shares underlying the awards				
						Unvested as of January 1, 2022	Vested during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Unvested as of December 31, 2022	
<b>Directors and chief executive of the Company</b>										
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	PSU	12/1/2021	(1)	—	631,750	0	0	0	631,750
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	RSU	4/1/2021	5 years	4.4	170,000	34,000	0	0	136,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	RSU	4/1/2022	5 years	—	0	0	0	0	540,000
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	RSU	6/25/2022	4 years	—	0	0	0	0	2,352,000
Dr. Kai-Xian Chen	Independent non-executive director	RSA	1/1/2021	1 year	6.29	38,520	38,520	0	0	0
Dr. Kai-Xian Chen	Independent non-executive director	RSA	1/1/2022	1 year	—	0	0	0	0	77,630
Dr. John Diekman	Independent non-executive director	RSA	1/1/2021	1 year	6.29	38,520	38,520	0	0	0
Dr. John Diekman	Independent non-executive director	RSA	1/1/2022	1 year	—	0	0	0	0	77,630
Mr. William Lis	Independent non-executive director	RSA	1/1/2021	1 year	6.29	38,520	38,520	0	0	0

# DIRECTORS' REPORT

Name of grantee	Category of grantees	Type of award	Date of grant	Vesting period <sup>(1) (2) (3) (4) (5) (6)</sup>	Price on day prior to vesting during the Reporting Period (in \$) <sup>(7)</sup>	Number of shares underlying the awards			
						Unvested as of January 1, 2022	Vested during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Unvested as of December 31, 2022
Mr. William Lis	Independent non-executive director	RSA	1/1/2022	1 year	—	0	0	0	77,630
Mr. Leon O. Moulder, Jr.	Independent non-executive director	RSA	1/1/2021	1 year	6.29	38,520	38,520	0	0
Mr. Leon O. Moulder, Jr.	Independent non-executive director	RSA	1/1/2022	1 year	—	0	0	0	77,630
Mr. Peter Wirth	Independent non-executive director	RSA	1/1/2021	1 year	6.29	38,520	38,520	0	0
Mr. Peter Wirth	Independent non-executive director	RSA	1/1/2022	1 year	—	0	0	0	77,630
Mr. Scott W. Morrison	Independent non-executive director	RSA	10/13/2021	3 years	2.91	73,450	24,480	0	48,970
Richard Gaynor, M.D.	Independent non-executive director	RSA	11/19/2021	3 years	3.5	89,120	29,700	0	59,420
<b>Employee Participants (other than chief executive)</b>									
In aggregate	Employee Participants	RSA	3/2/2018	5 years	5.26	400,000	200,000	0	200,000
In aggregate	Employee Participants	RSA	6/4/2018	5 years	3.04	500,000	250,000	0	250,000
In aggregate	Employee Participants	RSA	9/24/2018	5 years	0	800,000	0	800,000	0
In aggregate	Employee Participants	PSU	12/1/2021	(1)	0	1,684,650	0	491,360	1,193,290
In aggregate	Employee Participants	RSU	8/14/2018	5 years	4.42	120,000	60,000	0	60,000
In aggregate	Employee Participants	RSU	11/26/2018	5 years	3.17	278,000	127,000	36,000	115,000
In aggregate	Employee Participants	RSU	3/8/2019	5 years	3.72	240,000	80,000	60,000	100,000
In aggregate	Employee Participants	RSU	3/27/2019	5 years	4.23	36,000	12,000	0	24,000
In aggregate	Employee Participants	RSU	9/30/2019	5 years	0	54,000	0	54,000	0
In aggregate	Employee Participants	RSU	12/31/2019	5 years	3.07	36,000	12,000	0	24,000
In aggregate	Employee Participants	RSU	3/31/2020	5 years	4.55	96,000	24,000	72,000	0
In aggregate	Employee Participants	RSU	6/30/2020	5 years	3.46	244,000	61,000	0	183,000
In aggregate	Employee Participants	RSU	8/17/2020	5 years	4.56	194,000	48,500	0	145,500
In aggregate	Employee Participants	RSU	12/1/2020	5 years	0	240,000	0	240,000	0
In aggregate	Employee Participants	RSU	12/21/2020	5 years	3.03	64,000	14,000	8,000	42,000
In aggregate	Employee Participants	RSU	12/21/2021	(6)	3.07	150,000	150,000	0	0
In aggregate	Employee Participants	RSU	3/1/2021	5 years	5.47	31,000	6,200	800	24,000
In aggregate	Employee Participants	RSU	4/1/2021	5 years	4.4	1,616,500	314,850	202,450	1,097,700
In aggregate	Employee Participants	RSU	5/1/2021	5 years	4.00	33,000	6,600	6,400	20,000
In aggregate	Employee Participants	RSU	6/1/2021	5 years	2.91	86,250	17,250	18,600	50,400
In aggregate	Employee Participants	RSU	7/1/2021	5 years	3.47	172,750	34,140	8,720	129,890

# DIRECTORS' REPORT

Name of grantee	Category of grantees	Type of award	Date of grant	Vesting period <sup>(1) (2) (3) (4) (5) (6)</sup>	Price on day prior to vesting during the Reporting Period (in \$) <sup>(7)</sup>	Number of shares underlying the awards			
						Unvested as of January 1, 2022	Vested during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Unvested as of December 31, 2022
In aggregate	Employee Participants	RSU	8/1/2021	5 years	4.05	141,530	27,900	12,000	101,630
In aggregate	Employee Participants	RSU	9/1/2021	5 years	4.62	326,930	59,710	93,050	174,170
In aggregate	Employee Participants	RSU	10/1/2021	5 years	3.42	322,100	47,960	83,500	190,640
In aggregate	Employee Participants	RSU	11/1/2021	5 years	2.23	90,550	17,510	3,000	70,040
In aggregate	Employee Participants	RSU	11/1/2021	4 years	2.25	356,400	74,070	60,000	222,330
In aggregate	Employee Participants	RSU	12/1/2021	4 years	3.86	50,700	7,800	19,400	23,500
In aggregate	Employee Participants	RSU	12/1/2021	5 years	3.86	46,080	7,410	9,000	29,670
In aggregate	Employee Participants	RSU	1/1/2022	5 years	—	0	0	3,500	10,500
In aggregate	Employee Participants	RSU	2/1/2022	5 years	—	0	0	7,130	181,110
In aggregate	Employee Participants	RSU	3/1/2022	5 years	—	0	0	24,000	250,910
In aggregate	Employee Participants	RSU	4/1/2022	5 years	—	0	0	648,920	3,723,560
In aggregate	Employee Participants	RSU	5/1/2022	5 years	—	0	0	8,500	252,410
In aggregate	Employee Participants	RSU	6/1/2022	5 years	—	0	0	2,000	143,260
In aggregate	Employee Participants	RSU	6/25/2022	4 years	—	0	0	1,870,500	16,953,700
<b>Total</b>						9,567,360	1,940,680	4,842,830	30,142,500

Details of share awards granted under the 2017 Plan during the Reporting Period are set out below:

Name of grantee	Category of grantees	Date of grant	Type of award	Number of shares underlying the awards	Vesting period <sup>(2) (3) (5)</sup>	Fair value on day of grant during the Reporting Period (in \$) <sup>(6)</sup>	Price on day prior to grant during the Reporting Period (in \$) <sup>(6)</sup>
<b>Directors and chief executive of the Company</b>							
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	4/1/2022	RSU	540,000	5 years	4.547	4.398
Dr. Samantha Du	Executive Director, Chairperson and Chief Executive Officer	6/25/2022	RSU	2,352,000	4 years	3.433	3.422
Dr. Kai-Xian Chen	Independent non-executive director	1/1/2022	RSA	77,630	1 year	6.285	6.285
Dr. John Diekman	Independent non-executive director	1/1/2022	RSA	77,630	1 year	6.285	6.285
Mr. William Lis	Independent non-executive director	1/1/2022	RSA	77,630	1 year	6.285	6.285
Mr. Leon O. Moulder, Jr.	Independent non-executive director	1/1/2022	RSA	77,630	1 year	6.285	6.285
Mr. Peter Wirth	Independent non-executive director	1/1/2022	RSA	77,630	1 year	6.285	6.285

# DIRECTORS' REPORT

Name of grantee	Category of grantees	Date of grant	Type of award	Number of shares underlying the awards	Vesting period <sup>(2)(3)(5)</sup>	Fair value on day of grant during the Reporting Period (in \$) <sup>(8)</sup>	Price on day prior to grant during the Reporting Period (in \$) <sup>(9)</sup>
<b>Employee Participants (other than chief executive)</b>							
In aggregate	Employee Participants	1/1/2022	RSU	14,000	5 years	6.285	6.285
In aggregate	Employee Participants	2/1/2022	RSU	188,240	5 years	5.359	4.967
In aggregate	Employee Participants	3/1/2022	RSU	274,910	5 years	5.255	5.47
In aggregate	Employee Participants	4/1/2022	RSU	4,372,480	5 years	4.547	4.398
In aggregate	Employee Participants	5/1/2022	RSU	260,910	5 years	3.955	3.996
In aggregate	Employee Participants	6/1/2022	RSU	145,260	5 years	2.95	2.91
In aggregate	Employee Participants	6/25/2022	RSU	18,824,200	4 years	3.433	3.422

## Notes:

- (1) Vesting of PSUs is directly linked to achieving milestone goals. Up to 100% of the PSUs can be earned for maximum performance; 50% for threshold performance; 0% for below threshold performance. Any unearned awards at the end of the performance period from December 1, 2021 to December 31, 2025 will be forfeited.
- (2) Where the vesting period is 5 years, one-fifth of the RSUs shall vest on each anniversary of the date of grant for the next five years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (3) Where the vesting period is 4 years, one-fourth of the RSUs shall vest on each anniversary of the date of grant for the next four years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (4) Where the vesting period is 3 years, such RSAs shall vest ratably over 3 years on the anniversary of the date of grant, subject to continued service as a member of the Board through such date.
- (5) Where the vesting period is 1 year, such RSAs shall vest in full on the first anniversary of the date of grant, subject to continued service as a member of the Board through such date.
- (6) 50% of the one-time equity award vested immediately and the other 50% vested on Dec 31, 2022.
- (7) The stated price was the weighted-average closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date on which the applicable share awards were vested during the Reporting Period.
- (8) The stated value was the fair value of applicable share awards at the date of grant determined on the basis of the Black-Scholes option valuation model.
- (9) The stated price was the closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date of grant.

## Purposes

The purposes of the 2017 Plan are to attract, retain, and reward key employees and directors of, and consultants and advisors to, the Company and its subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of the Company, and to align their interests with the interests of the Company's shareholders.

# DIRECTORS' REPORT

## Types of awards

The 2017 Plan provides for the grant of share options, SARs, restricted and unrestricted shares, and share units, performance awards, and other awards that are convertible into or otherwise based on our Shares. Dividend equivalents may also be provided in connection with awards under the 2017 Plan.

## Stock options and SARs

The Administrator may grant share options, including ISOs, and SARs. A share option is a right entitling the holder to acquire shares upon payment of the applicable exercise price. An SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price of each share option, and the base value of each SAR, granted under the 2017 Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, share options and SARs granted under the 2017 Plan may not be repriced or substituted for with new share options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any share options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each share option and SAR will have a maximum term of not more than 10 years from the date of grant (or 5 years, in the case of certain ISOs).

## Restricted and unrestricted shares and share units

The Administrator may grant awards of shares, share units, restricted shares, and restricted share units. A share unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted share unit is a share unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted shares are shares that are subject to restrictions requiring that they be redelivered or offered for sale to the Company if specified conditions are not satisfied.

## Performance awards

The Administrator may grant performance awards, which are awards subject to performance criteria.

## Other stock-based awards

The Administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as it determines.

# DIRECTORS' REPORT

## Substitute awards

The Administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of the 2017 Plan.

## Eligible Participants

The Compensation Committee of the Board shall select participants of the 2017 Plan from among key employees and directors of, and consultants and advisors to, the Company. Eligibility for stock options intended to be incentive stock options (as defined under Section 422 of the Internal Revenue Code of the United States (the "Code")) is limited to employees of the Company or certain affiliates. Eligibility for stock options, other than incentive stock options, and stock appreciation rights is limited to individuals who are providing direct services on the date of grant of the award to the Company or certain affiliates.

## Maximum Number of Shares

The initial total number of shares available for issue under the 2017 Plan is 115,459,670 Shares (taking into account the Share Subdivision), which represents 11.79% of the issued shares of the Company as of the Latest Practicable Date. The Board determined that no new grants would be made under the 2017 Plan after the dual-primary listing of the Company became effective on June 27, 2022.

## Limit of Each Grantee

The total number of Shares underlying the share options that may be granted to a grantee under the 2017 Plan within a calendar year shall not exceed 577,298 Shares. In addition, the maximum grant date fair value of awards granted under the 2017 Plan to any non-employee director of the Company in respect of his or her service as a director with respect to any calendar year may not exceed \$500,000, assuming maximum payout.

## Expiration of the 2017 Plan

According to the terms of the 2017 Plan, no awards may be made after 10 years from the date of adoption of the 2017 Plan, provided that the Board determined that no new grants would be made under the 2017 Plan after the Primary Conversion Effective Date.



# DIRECTORS' REPORT

## Exercise Period

The Compensation Committee of the Board determines the terms of all options and awards granted under the 2017 Plan, including the time or times an option or award vests or becomes exercisable, the terms on which an option or award remains exercisable, and the effect of termination of a participant's employment or service on an option or award. The Compensation Committee of the Board may at any time accelerate the vesting or exercisability of an option or award. The maximum term of share options must not exceed 10 years from the date of grant.

## Consideration

No cash consideration is required to be paid by the grantees for the grant of options or awards under the 2017 Plan.

## Exercise Price

The exercise price of each share option granted under the 2017 Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain incentive share options).

### **3. 2022 Equity Incentive Plan (the "2022 Plan")**

The 2022 Plan was approved at the Company's 2022 annual general meeting of shareholders on June 22, 2022. Under the 2022 Plan, the Compensation Committee of the Board may award share options, share appreciation rights, restricted shares, restricted share units, performance-based awards, unrestricted shares, and cash-based awards subject to such conditions and restrictions as it may determine. The Compensation Committee of the Board may also grant dividend equivalent rights that entitle the recipient to receive credits for dividends that would be paid if the recipient held a specified number of ordinary shares. The equity-based incentive tools used in the 2022 Plan are substantially similar to those in the 2017 Plan, as the 2022 Plan is intended by the Company to replace the 2017 Plan upon the Primary Conversion Effective Date.

## DIRECTORS' REPORT

During the Reporting Period, the Company conditionally granted certain options under the 2022 Plan. As of December 31, 2022, 4,663,300 Shares were outstanding pursuant to the options granted under the 2022 Plan. The options granted under the 2022 Plan during the Reporting Period remain unvested. Details of the options granted under the 2022 Plan are as follows:

Name of grantee	Category of grantees	Date of grant	Vesting period <sup>(1)</sup>	Exercise period <sup>(2)</sup>	Exercise (grant) price (in \$) <sup>(3)</sup>	Number of shares underlying the options							
						Fair value on day of grant during the Reporting Period (in \$) <sup>(4)</sup>	Price on day prior to grant during the Reporting Period (in \$) <sup>(5)</sup>	Price on day prior to exercise during the Reporting Period (in \$) <sup>(6)</sup>	Outstanding as of January 1, 2022 <sup>(7)</sup>	Granted during the Reporting Period	Exercised during the Reporting Period <sup>(8)</sup>	Cancelled/Lapsed during the Reporting Period	Outstanding as of December 31, 2022
<b>Employee Participants (other than chief executive)</b>													
In aggregate	Employee Participants	8/15/2022	5 years	10 years	4.578	2.885	4.417	—	—	1,445,720	—	22,270	1,423,450
In aggregate	Employee Participants	9/12/2022	5 years	10 years	5.169	3.296	4.88	—	—	26,440	—	0	26,440
In aggregate	Employee Participants	10/3/2022	5 years	10 years	3.672	2.153	3.42	—	—	162,500	—	0	162,500
In aggregate	Employee Participants	11/14/2022	5 years	10 years	3.695	2.379	3.776	—	—	1,105,910	—	0	1,105,910
In aggregate	Employee Participants	12/12/2022	5 years	10 years	3.518	2.256	3.54	—	—	108,000	—	0	108,000
In aggregate	Employee Participants	12/30/2022	5 years	10 years	3.07	1.977	3.063	—	—	1,837,000	—	0	1,837,000
<b>Total</b>										4,685,570	0	22,270	4,663,300

Notes:

- (1) Where the vesting period is 5 years, one-fifth of the options shall vest on each anniversary of the date of grant for the next five years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (2) The relevant portion of the options becomes exercisable upon vesting on each anniversary of the date of grant, with the validity period of the options being 10 years from the date of grant.
- (3) The stated exercise (grant) price represents the higher of (i) the closing price of the ADSs, divided by 10, on the date of grant, and (ii) the average closing price of the ADSs, divided by 10, for the five Nasdaq trading days immediately preceding the date of grant.
- (4) The stated value was the fair value of options at the date of grant determined on the basis of the Black-Scholes option valuation model.
- (5) The stated price was the closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date of grant.

# DIRECTORS' REPORT

(6) No options were vested and became exercisable in 2022, and therefore there was no exercise of options under the 2022 Plan during the Reporting Period.

(7) N/A since the 2022 Plan became effective on June 27, 2022.

During the Reporting Period, the Company granted certain RSUs under the 2022 Plan. As of December 31, 2022, 3,291,390 Shares were unvested pursuant to the awards granted under the 2022 Plan. Details of the awards granted under the 2022 Plan are as follows:

Name of grantee	Category of grantees	Type of award	Date of grant	Vesting period <sup>(1) (2)</sup>	Fair value on day of grant during the Reporting Period (in \$) <sup>(3)</sup>	Price on day prior to grant during the Reporting Period (in \$) <sup>(4)</sup>	Price on day prior to vesting during the Reporting Period (in \$) <sup>(5)</sup>	Unvested as of January 1, 2022	Granted during the Reporting Period	Number of shares underlying the awards		
										Vested during the Reporting Period	Cancelled/Lapsed during the Reporting Period	Unvested as of December 31, 2022
<b>Employee Participants (other than chief executive)</b>												
In aggregate	Employees	RSU	8/15/2022	5 years	4.578	4.417	—	—	944,550	0	11,500	933,050
	Participants											
In aggregate	Employee	RSU	9/12/2022	5 years	5.169	4.88	—	—	16,090	0	0	16,090
	Participants											
In aggregate	Employee	RSU	10/3/2022	5 years	3.428	3.42	—	—	124,000	0	0	124,000
	Participants											
In aggregate	Employee	RSU	11/14/2022	5 years	3.695	3.776	—	—	653,250	0	0	653,250
	Participants											
In aggregate	Employee	RSU	12/12/2022	5 years	3.518	3.54	—	—	305,000	0	0	305,000
	Participants											
In aggregate	Employee	RSU	12/30/2022	5 years	3.07	3.063	—	—	1,050,000	0	0	1,050,000
	Participants											
In aggregate	Employee	RSU	12/30/2022	1 year	3.07	3.063	—	—	210,000	0	0	210,000
	Participants											
<b>Total</b>									3,302,890	0	11,500	3,291,390

## Notes:

- (1) Where the vesting period is 5 years, one-fifth of the RSUs shall vest on each anniversary of the date of grant for the next five years, in each case, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (2) Where the vesting period is 1 year, such RSUs shall vest in full on the first anniversary of the date of grant, subject to the grantee's continued employment relationship with the Company on such vesting dates.
- (3) The stated value was the fair value of options at the date of grant determined on the basis of the Black-Scholes option valuation model.
- (4) The stated price was the closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date of grant.
- (5) The stated price was the closing price as quoted on Nasdaq, divided by 10, on the trading day immediately prior to the date of grant.

# DIRECTORS' REPORT

## Purposes

The purposes of the 2022 Plan are to attract, retain, and reward key employees and directors of, and consultants and advisors to, the Company and its subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of the Company, and to align their interests with the interests of the Company's shareholders.

## Eligible Participants

The Compensation Committee of the Board shall select participants of the 2022 Plan from among key employees and directors of, and consultants and advisors to, the Company. Eligibility for stock options intended to be incentive stock options (as defined under Section 422 of the Code) is limited to employees of the Company or certain affiliates. Eligibility for share options, other than incentive stock options, and stock appreciation rights is limited to individuals who are providing direct services on the date of grant of the award to the Company or certain affiliates.

## Maximum Number of Shares

The initial total number of shares available for issue under the 2022 Plan is 97,908,743 Shares, which represents 10% of the issued shares of the Company as of June 22, 2022 and 10% of the issued shares of the Company as of the Latest Practicable Date.

## Limit of Each Grantee

Unless approved by the Company's shareholders, the total number of Shares issued and to be issued upon the exercise of share options granted and to be granted under the 2022 Plan and any other plan of the Company to any person within any 12-month period shall not exceed 1% of the Shares in issue at the date of any grant. In addition, the maximum grant date value of awards granted to any non-employee director in any calendar year, assuming a maximum payout, may not exceed, in the case of newly appointed non-employee director, \$750,000 in the first year of his/her appointment, or otherwise \$500,000 (subject to applicable laws).

## Expiration of the 2022 Plan

Unless sooner terminated by the Board, the term of the 2022 Plan will expire 10 years from the date of adoption, i.e., on April 20, 2032.

## Exercise Period

The Compensation Committee of the Board determines the terms of all awards granted under the 2022 Plan, including the time or times an award vests or becomes exercisable, the terms on which an award remains exercisable, and the effect of termination of a participant's employment or service on an award. The Compensation Committee of the Board may at any time accelerate the vesting or exercisability of an award. The maximum term of share options must not exceed 10 years from the date of grant.

# DIRECTORS' REPORT

## Consideration

No cash consideration is required to be paid by the grantees for the grant of options or awards under the 2022 Plan.

## Exercise Price

The exercise price of each share option granted under the 2022 Plan shall be no less than the fair market value of a share on the date of grant (110% in the case of certain incentive share options).

## PRE-EMPTIVE RIGHTS

There are no provisions for pre-emptive rights under our Articles or the laws of the Cayman Islands that would oblige the Company to offer new Shares on a pro-rata basis to existing shareholders.

## TAX RELIEF AND EXEMPTION

The Directors are not aware of any tax relief or exemption available to shareholders by reason of their holding of the Company's securities.

## CORPORATE GOVERNANCE

The Company's corporate governance practices are based on the principles and code provisions set forth in the Corporate Governance Code as set out in Appendix 14 of the HK Listing Rules.

Pursuant to code provision C.2.1 of the CG Code, companies listed on the Hong Kong Stock Exchange are expected to comply with, but may choose to deviate from, the requirement that the responsibilities of the Chairperson and the Chief Executive Officer should be segregated and should not be performed by the same individual. Dr. Samantha Du currently serves as our Chairperson and Chief Executive Officer. The Board believes that Dr. Samantha Du is the director best suited to serve as Chairperson. Dr. Samantha Du has an extensive understanding of our business and industry, is adept at identifying strategic opportunities, promoting the effective execution of those strategic initiatives, and facilitating the flow of information between management and the Board. In July 2022, the Board further enhanced our corporate governance by appointing Dr. John Diekman to be lead independent director. As lead independent director, Dr. John Diekman will, among other things, lead meetings of the Board when the Chairperson is not present, serve as liaison between the Chairperson and independent directors, have the authority to call meetings of the independent directors, and, if requested by a significant portion of our shareholders, be available for consultation and direct communication. While the roles of Chairperson of the Board and Chief Executive officer are combined, the Board believes that the balance of power and authority on the Board will not be impaired due to this arrangement. The Board will continue to review the corporate governance structure and practices from time to time and shall make changes the Board considers appropriate.

Except as disclosed above, from the Primary Conversion Effective Date and up to the Latest Practicable Date, the Company has complied with the code provisions set out in Part 2 of the CG Code.

The Board will continue to periodically review and monitor its corporate governance practices for compliance with the CG Code and maintain a high standard of corporate governance practices of the Company. Details about the corporate governance practices adopted by the Company are set out in the "Corporate Governance Report" contained in this annual report.

### **PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES**

During the Reporting Period, the Company did not purchase, sell, or redeem any of the Company's securities listed on the Hong Kong Stock Exchange.

### **AUDIT COMMITTEE REVIEW OF FINANCIAL STATEMENTS**

The Audit Committee of the Board oversees the accounting and financial reporting processes of the Company and the audits of the Company's financial statements, including but not limited to assisting the Board in its oversight of the integrity of the consolidated financial statements of the Company, the Company's compliance program, and the Company's risk management and internal control over financial reporting. As of the Latest Practicable Date, the Audit Committee currently consists of three members, namely Mr. Scott W. Morrison, Dr. John Diekman, and Mr. Peter Wirth, all of whom are independent Directors. Mr. Scott W. Morrison is the chairman of the Audit Committee.

The Audit Committee has reviewed the consolidated financial statements and annual results of the Company for the year ended December 31, 2022. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal controls with members of senior management and the external auditor of the Company, KPMG LLP. The consolidated financial statements included in this annual report have been audited by KPMG LLP.

### **CONTINUING DISCLOSURE OBLIGATIONS PURSUANT TO THE HK LISTING RULES**

The Company does not have any disclosure obligations under Rules 13.20, 13.21, and 13.22 of the HK Listing Rules.

### **PUBLIC FLOAT**

As at the Latest Practicable Date and based on the information that is publicly available to the Company and to the knowledge of the Directors of the Company, the Company has maintained the minimum public float required by the Hong Kong Stock Exchange.

# DIRECTORS' REPORT

## CHANGE IN AUDITORS

Deloitte Touche Tohmatsu Certified Public Accountants LLP and Deloitte Touche Tohmatsu served as our auditor for the financial statements included in our 2021 Annual Report.

In April 2022, the Audit Committee of the Board approved the engagement of KPMG LLP, an independent registered public accounting firm registered with the PCAOB in the United States, as our independent registered public accounting firm for the fiscal year ending December 31, 2022. On May 25, 2022, the Company received the requisite approvals from the Hong Kong Stock Exchange and the Financial Reporting Council of Hong Kong for this engagement, and on May 31, 2022, the Company and KPMG LLP signed an engagement letter, and the appointment became effective on the same date. KPMG LLP is engaged to audit our annual consolidated financial statements filed with the SEC and our internal control over financial reporting in accordance with the Securities Exchange Act of 1934, as amended, and to audit our consolidated financial statements filed in the annual reports prepared in accordance with the HK Listing Rules.

Since our transition to primary listing status on the Hong Kong Stock Exchange, there has been no change in auditors of the Company in 2022, save as disclosed hereinabove.

The consolidated financial statements of the Company for the fiscal year ended December 31, 2022 were audited by KPMG LLP, who shall retire and, being eligible, offer itself for re-appointment.

Upon the recommendation of the Audit Committee, the Board recommends shareholder approval at the 2023 annual general meeting of shareholders of the Company of the appointment of KPMG LLP and KPMG as our independent registered public accounting firms and auditors for the fiscal year ending December 31, 2023. KPMG LLP will be responsible for auditing our consolidated financial statements for the year ending December 31, 2023 filed with the SEC and the effectiveness of our internal control over financial reporting as of December 31, 2023 in accordance with the Exchange Act, and KPMG will be responsible for auditing our consolidated financial statements for the year ending December 31, 2023 filed in the annual report prepared in accordance with the HK Listing Rules.

On behalf of the Board

**Zai Lab Limited**

Dr. Samantha Du

*Director, Chairperson, and Chief Executive Officer*

Shanghai

April 21, 2023

# CORPORATE GOVERNANCE REPORT

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The Board is pleased to present the corporate governance report for the Company for the Reporting Period.

## CORPORATE GOVERNANCE PRACTICES

We seek to implement and follow corporate governance practices in line with best practices in our industry. The Board has adopted Corporate Governance Guidelines, which are available on our website at <https://ir.zailaboratory.com/corporate-governance/highlights>. The Board periodically reviews and updates these Guidelines, as deemed appropriate, such as in consideration of evolving legal and regulatory requirements and corporate governance best practices.

Our corporate governance practices include the following:

- Each of our directors is independent, except for the Chairperson who also serves as our Chief Executive Officer;
- Since July 2022, the Board has had a lead independent director to, among other things, lead meetings of the Board when the Chairperson is not present, serve as liaison between the Chairperson and independent directors, and preside over executive sessions of our independent directors;
- Our directors are elected annually;
- The Audit, Nominating and Corporate Governance, Compensation, and Commercial Committees are comprised solely of independent directors;
- Each of the Board Committees operates pursuant to a written charter that has been approved by the Board and is available on our website;
- Independent directors meet regularly without management;
- The Company provides new directors with a director orientation program to help familiarize them with our business, policies, and procedures and makes available to directors continuing education programs;
- The Board and Committees are provided access to senior management as well as independent advisors as necessary to perform their duties and, for Committees, in accordance with their respective charters;
- The Board and Board committees conduct an annual self-evaluation; and
- The Board periodically reviews the Company's succession planning.

The Company's corporate governance practices are based on the principles and code provisions set forth in the CG Code which are applicable to the Company.



# CORPORATE GOVERNANCE REPORT

Pursuant to code provision C.2.1 of the CG Code, companies listed on the Hong Kong Stock Exchange are expected to comply with, but may choose to deviate from, the requirement that the responsibilities of the Chairperson and the Chief Executive Officer should be segregated and should not be performed by the same individual. Dr. Samantha Du currently serves as our Chairperson and Chief Executive Officer. The Board believes that Dr. Samantha Du is the director best suited to serve as Chairperson, including due to her extensive understanding of our business and industry and her ability to identify strategic opportunities, promote the effective execution of strategic initiatives, and facilitate the flow of information between management and the Board. The Board believes that the balance of power and authority on the Board will not be impaired due to this arrangement. The Board will review the corporate governance structure and practices from time to time and shall make changes the Board considers appropriate.

Except as disclosed above, from the Primary Conversion Effective Date to the Latest Practicable Date, the Company has complied with the provisions set out in the CG Code.

The Board will continue to periodically review and monitor its corporate governance practices for compliance with the CG Code and maintain a high standard of corporate governance practices of the Company.

## MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted its own insider dealing policies on terms no less exacting than those in the Model Code regarding director dealings in the securities of the Company.

Having made specific enquiry of all the Directors, all the Directors confirmed that they have complied with the required standards set forth in the Company's insider dealing policies during the Reporting Period.

## BOARD OF DIRECTORS

The Board currently comprises ten members, consisting of one executive Director and nine independent Directors.

During the period from the Primary Conversion Effective Date and up to the Latest Practicable Date, unless otherwise noted, the Board comprised the following Directors:

### Executive Director

Dr. Samantha Du (*Chairperson and Chief Executive Officer*)

## Independent Directors

Dr. Kai-Xian Chen  
Dr. John Diekman (*appointed as Lead Independent Director on July 22, 2022*)  
Ms. Nisa Leung  
Mr. William Lis  
Mr. Leon O. Moulder, Jr.  
Mr. Peter Wirth  
Mr. Scott W. Morrison  
Richard Gaynor, M.D.  
Mr. Michel Vounatsos (*appointed on January 7, 2023*)

The biographical details of the Directors are set out in the section headed “Directors and Senior Management” of this annual report. None of the members of the Board is related to one another.

## INDEPENDENT DIRECTORS

To enhance our corporate governance while the roles of Chairperson of the Board and Chief Executive Officer are combined, the Board has appointed Dr. John Diekman as the Lead Independent Director. The Lead Independent Director’s authority and responsibilities include, but are not limited to, leading meetings when the Chairperson is not present or is conflicted; serving as a liaison between the Chairperson and the independent Directors; having the authority to call meetings of the independent directors; and, if requested by a significant portion of our shareholders, being available for consultation and direct communication.

Throughout the period from the Primary Conversion Effective Date to December 31, 2022, the Board at all times met the requirements of the HK Listing Rules relating to the appointment of at least three independent Directors, who are considered “independent non-executive directors” for the purpose of Rule 3.10 of the HK Listing Rules, representing at least one-third of the Board, with one possessing appropriate professional qualifications or accounting or related financial management expertise.

The Board has received from each of the independent Directors a written annual confirmation of his or her independence pursuant to Rule 3.13 of the HK Listing Rules and considers each of them to be independent.

## APPOINTMENT AND RE-ELECTION OF DIRECTORS

Our Sixth Restated Articles provide that commencing at, and following on from, the annual general meeting of the Company in 2022, each Director shall be elected annually for terms expiring at the next annual general meeting of the Company, at which he or she may be eligible for re-election, until his or her earlier death, resignation or removal.

# CORPORATE GOVERNANCE REPORT

## RESPONSIBILITIES, ACCOUNTABILITIES AND CONTRIBUTIONS OF THE BOARD AND MANAGEMENT

The Board oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. The Board performs this oversight role by using several different levels of review. In connection with its review of our operations and corporate functions, the Board addresses the primary risks associated with those operations and corporate functions. In addition, the Board reviews the risks associated with our business strategies periodically throughout the year.

Each of the Board committees also oversees risk management within its areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. For example, the Audit Committee oversees the operation of our enterprise risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to the Board regarding these activities. The Audit Committee also oversees risks related to our financial reporting, compliance with applicable laws and regulations, and our IT systems, processes, and data. In connection with its risk management role, the Audit Committee meets privately with representatives from our independent registered public accounting firms and receives regular reporting from management, including our Chief Financial Officer and Chief Compliance Officer. Our Chief Financial Officer is responsible for identifying, evaluating, and implementing risk management controls and methodologies to address financial reporting risks, and our Chief Compliance Officer is responsible for enterprise risk management program more broadly. The Compensation Committee considers risks related to our compensation policies and practices, and the Commercial Committee oversees risks related to our commercial programs.

## COMMITTEES OF THE BOARD

As of the Latest Practicable Date, the Board has five standing committees: the Audit Committee, the Compensation Committee, the Nominating and Corporate Governance Committee, the Research and Development Committee, and the Commercial Committee. The Company's Chief Executive Officer and Chairperson participates as a member of the Research and Development Committee. Otherwise, all of the standing committees are comprised solely of independent directors. These committees perform important functions on behalf of the Board and meet regularly. All of our committees operate in accordance with written charters, which were approved by the Board and are available on the websites of the Company and the Hong Kong Stock Exchange.

The membership of each committee as of the Latest Practicable Date, a brief description of their primary responsibilities, and the number of meetings held during the Reporting Period are included below.

### Audit Committee

The Audit Committee currently consists of three members, namely Scott Morrison, John Diekman, and Peter Wirth, all of whom are independent directors. Mr. Morrison, being Chair of the Audit Committee, is appropriately qualified as required under Rules 3.10(2) and 3.21 of the HK Listing Rules.

# CORPORATE GOVERNANCE REPORT

The Audit Committee's responsibilities include:

- Overseeing the integrity of our consolidated financial statements;
- Overseeing our compliance with legal and regulatory requirements;
- Overseeing the qualifications, independence, and performance of our independent auditor;
- Overseeing the performance of the Company's internal audit function, including reviewing the internal audit department's responsibilities, budget, staffing, and any recommended changes in the planned scope of the internal audit with the independent auditor and management;
- Deciding whether to appoint, retain, or terminate our independent auditors and approving all audit, permitted non-audit, tax, and other services, if any, and the fees for and terms of such services, to be provided by our independent auditor;
- Reviewing and discussing with management and the independent auditor our annual and quarterly and interim financial statements and related disclosures as well as significant financial reporting judgments and critical accounting policies and practices used by us;
- Overseeing our controls and procedures, including: (i) reviewing the adequacy of our internal control over financial reporting; (ii) establishing policies and procedures for the receipt and retention of financial and accounting-related complaints and concerns; (iii) establishing and implementing policies and procedures for the review and approval or disapproval of proposed related party transactions and reviewing all related party transactions for potential conflict of interest situations and approving all such transactions, if deemed appropriate;
- Overseeing our enterprise risk management and related guidelines and policies;
- Overseeing the integrity of our information technology systems, processes, and data and reviewing and discussing with management and the internal auditor the adequacy of security for our IT systems, processes, and data;
- Recommending, based upon the Audit Committee's review and discussions with management and the independent auditor, whether our annual audited financial statements should be included in our Annual Report on Form 10-K filed with the SEC and our annual report and annual results announcement filed with the Hong Kong Stock Exchange;
- Preparing the Audit Committee report and other disclosures required by SEC rules to be included in our annual proxy statement; and
- Reviewing our earnings releases and unaudited financial statements to be included in our quarterly and interim filings with the SEC and Hong Kong Stock Exchange, as applicable.

# CORPORATE GOVERNANCE REPORT

The Audit Committee held nine meetings in 2022. During the Reporting Period, the Audit Committee reviewed, among others, the consolidated financial statements and annual results of the Company for the year ended December 31, 2022, and the unaudited consolidated financial statements and interim results of the Company for the six months ended June 30, 2022. The Audit Committee also discussed matters with respect to the accounting policies and practices adopted by the Company and internal controls with members of senior management and the external auditor of the Company, KPMG LLP.

## Compensation Committee

Peter Wirth, John Diekman, and Leon O. Moulder, Jr. currently serve on the Compensation Committee, which is chaired by Peter Wirth. The Compensation Committee's responsibilities include:

- Reviewing the corporate goals and objectives relevant to the compensation of our Chairperson and Chief Executive Officer, evaluating the performance of our Chairperson and Chief Executive Officer in light of such corporate goals and objectives and recommending to the Board for approval of our Chairperson and Chief Executive Officer's compensation based on that evaluation;
- Reviewing and approving the compensation of our other executive officers;
- Approving our long-term compensation strategy for employees and directors and determining the types of shares and other compensation plans to be used by us and our affiliates;
- Overseeing the administration of our equity incentive plans and approving equity compensation awards pursuant to our equity incentive plans;
- Reviewing and making recommendations to the Board with respect to director compensation;
- Overseeing the management of risks relating to our executive compensation and overall compensation and benefits strategies, plans, arrangements, practices, and policies;
- Evaluating and assessing legal counsel, compensation consultants, and other advisors in accordance with the applicable requirements in the Nasdaq listing rules;
- Retaining and approving the compensation of any outside advisors to the Compensation Committee;
- Preparing the compensation committee report required by SEC rules to be included in our annual proxy statement or Annual Report on Form 10-K; and
- Reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K.

The Compensation Committee held five meetings in 2022 to carry out, among other things, the work summarized above.

# CORPORATE GOVERNANCE REPORT

## Nominating and Corporate Governance Committee

Leon O. Moulder, Jr., John Diekman, and William Lis currently serve on the Nominating and Corporate Governance Committee, which is chaired by Leon O. Moulder, Jr. The Nominating and Corporate Governance Committee's responsibilities include:

- Identifying and recommending candidates for membership of the Board and committees to the Board in accordance with criteria approved by the Board;
- Recommending to the Board or to the appropriate committee thereto processes for annual evaluation of the performance of the Board, the Chairperson of the Board, the Chief Executive Officer, and appropriate committees of the Board;
- Reviewing our practices and policies with respect to the Board and the functions, duties, and composition of the committees thereto;
- Developing and recommending to the Board a set of corporate governance principles and reviewing the principles on an annual basis, or more frequently if appropriate;
- Overseeing the maintenance and presentation of the Board or management's plans for succession to our senior management positions; and
- Overseeing the Company's environmental, social, and governance ("ESG") strategy, commitments, goals, and activities.

The Nominating and Corporate Governance Committee held four meetings in 2022 to carry out, among other things, the work summarized above.

## Research and Development Committee

Richard Gaynor, Kai-Xian Chen, Samantha Du, William Lis, and Michel Vounatsos currently serve on the Research and Development Committee, which is chaired by Richard Gaynor. The Research and Development Committee's responsibilities include:

- Reviewing and discussing with management our strategic research and development objectives, goals, and priorities, identifying opportunities for further research and development projects, and assessing, informing, and recommending to the Board such strategies and opportunities that it deems suitable for the Company;
- Overseeing, assessing, and, where applicable, approving any ongoing Company research and development programs; and
- Providing feedback and advice to the Board regarding our ongoing research and development programs and activities.

The Research and Development Committee held eight meetings in 2022 to carry out, among other things, the work summarized above.

# CORPORATE GOVERNANCE REPORT

## Commercial Committee

Michel Vounatsos, William Lis, and Leon O. Moulder, Jr. currently serve on the Commercial Committee, which is chaired by Michel Vounatsos. The Commercial Committee's responsibilities include:

- Overseeing our commercialization strategy including reviewing and discussing with management our product commercialization plans and efforts and competitiveness of our commercial programs;
- Overseeing commercial risk management, including reviewing and discussing with management our risk assessment and risk management policies and procedures relating to commercial programs;
- Reviewing the organization, implementation, and effectiveness of our compliance programs with respect to commercial programs and activities and the adequacy of the resources for those programs; and
- Providing feedback and advice to the Board regarding commercial performance goals, the capabilities and performance of our commercial personnel.

The Commercial Committee was established on January 7, 2023 and thus no meetings were held in 2022.

## BOARD DIVERSITY POLICY

The Company's Board Diversity Policy, which is available on our website at <https://ir.zailaboratory.com/corporate-governance/highlights>, sets out the Company's approach to promote diversity on the Board. The Company sees increasing diversity at the Board level as an important element in supporting its development and the attainment of its strategic objectives and its sustainable development. All Board appointments will be based on meritocracy, and candidates will be considered against appropriate criteria, which have been approved by the Board, having due regard for the benefits of diversity on the Board.

Pursuant to the Board Diversity Policy, the Nominating and Corporate Governance Committee will report annually on the Board's composition, including with respect to diversity and other director qualifications and characteristics, and will monitor and evaluate the implementation of the Board Diversity Policy.

In reviewing the Board's composition, the Nominating and Corporate Governance Committee considers, among other characteristics, experiences, perspectives, and viewpoints as well as diversity with respect to gender, age, culture, ethnicity and nationality. The ultimate decision on whether to recommend a director candidate for approval will be based on merit and the expected contributions that the proposed candidates will bring to the Board.

The Nominating and Corporate Governance Committee will review and reassess the adequacy of this Policy, as appropriate. The Nominating and Corporate Governance Committee will recommend any proposed changes to the Board for consideration and approval.

# CORPORATE GOVERNANCE REPORT

The below chart provides information on each of our director's voluntary, self-identified characteristics.

**Board Diversity Matrix (as of April 1, 2023)**

<b>Board Size:</b>		
Total Number of Directors	10	
	<b>Female</b>	<b>Male</b>
<b>Gender Identity</b>		
Directors	2	8
<b>Demographic Background</b>		
Asian	2	1
White	0	6
Did not disclose demographic background	0	1

Twenty percent of the Board's directors are female, including the Chairperson of the Board who also serves as the Company's Chief Executive Officer. The Board will continue to consider gender diversity as an important factor when evaluating the suitability of future director candidates in light of the needs of the Board at that time. The Company is of the view that gender diversity in respect of the Board has been achieved.

Our commitment to diversity is reflected in the composition of our workforce. As of December 31, 2022, approximately 59% are female, and 55% of all our management positions (including junior, middle, and top management) are held by women. Accordingly, the Company considers that gender diversity is also achieved in its workforce generally.

## NOMINATION POLICY

As set forth in the Nominating and Corporate Governance Committee Charter, the Corporate Governance Guidelines and the Board Diversity Policy, the Nominating and Corporate Governance Committee will periodically review the size of the Board and recommend any proposed changes to the Board. The Nominating and Corporate Governance Committee is responsible for reviewing, on an annual basis, the qualification criteria for the Board as a whole and its individual members.

In evaluating the suitability of individual candidates (both new candidates and current Board members), the Nominating and Corporate Governance Committee, in recommending candidates to the Board, and the Board, in nominating and recommending candidates to the Company's shareholders for election (and, in the case of vacancies, appointing) such candidates, will take into account many factors, including:

- personal and professional integrity, character, reputation and business judgment;
- qualifications, skills, expertise, experience, and educational background;
- diversity across multiple dimensions, including diversity in experiences, perspectives, and skills as well as diversity with respect to gender, age, culture, ethnicity and nationality;
- dedication and time availability in light of other commitments;
- any actual or perceived conflicts of interest; and
- any other relevant factors that the Committee deems appropriate in the context of the needs of the Board and the overall diversity and composition of the Board.



# CORPORATE GOVERNANCE REPORT

With respect to the above, the Nominating and Corporate Governance Committee and the Board will also consider the candidate's ability to make independent analytical inquiries, general understanding of marketing, finance and other elements relevant to the success of a publicly traded company in today's business environment, experience in the Company's industry, understanding of the Company's business on a technical level, other board service and educational and professional background. Each director nominee must also possess fundamental qualities of intelligence, honesty, good judgment, ethics and integrity, fairness and responsibility. The Board will evaluate each individual in the context of the Board as a whole, with the objective of assembling a group that can best perpetuate the success of the business and represent shareholder interests. In determining whether to recommend a director for re-election, the Nominating and Corporate Governance Committee should also consider the director's past attendance at meetings and participation in and contributions to the activities of the Board.

Shareholder(s) may request the Company to convene an extraordinary general meeting for the purpose of nominating a person pursuant to the section titled "General Meetings" of the Company's Sixth Amended and Restated Articles of Association.

After the publication of the notice of the general meeting by the Company, if a shareholder wishes to propose a person (the "Candidate") for election as a director of the Company at the general meeting, he/she shall lodge a written notice (the "Notice") to: Zai Lab Limited, 314 Main Street, 4th Floor, Suite 100 Cambridge, MA 02142 USA, Attention: Corporate Secretary, with a copy forwarded to the registered office of the Company. The Notice (i) must include the personal information of the Candidate as required by Rule 13.51(2) of the HK Listing Rules; and (ii) must be signed by the shareholder concerned and signed by the Candidate indicating his/her willingness to be elected and consent to the publication of his/her personal information. The period for lodgement of the Notice shall be a period commencing on the day after the dispatch of the notice of such meeting and end on the earlier of (i) seven (7) days after the date of such Notice, or (ii) seven (7) days prior to the date of such meeting (or such other period, being a period of not less than seven (7) days, commencing no earlier than the day of dispatch of the notice of such meeting and ending no later than seven (7) days prior to the date appointed for such meeting, as may be determined by the Directors from time to time). In order to allow the Company's shareholders to have sufficient time to consider the proposal of election of the Candidate as a director of the Company, shareholders who wish to make the proposal are urged to submit and lodge the Notice as early as practicable before the relevant general meeting. Please refer to the Company's Sixth Amended and Restated Articles of Association for further details of the procedures involved.

## CORPORATE GOVERNANCE FUNCTION

The Board is responsible for performing the functions set out in code provision A.2.1 of the CG Code.

The Board has reviewed and monitored the training and continuous professional development of directors and senior management; reviewed practices on the Company's compliance with legal and regulatory requirements; developed and reviewed code of conduct applicable to employees and directors; and reviewed the Company's compliance with the CG Code and disclosure in the Corporate Governance Report.

# CORPORATE GOVERNANCE REPORT

## BOARD MEETINGS, COMMITTEE MEETINGS AND SHAREHOLDER MEETINGS

The attendance records of each Director at Board meetings, committee meetings and shareholder meetings during the Reporting Period are set out below.<sup>(1)</sup>

Name of director	Attendance/Number of Meeting(s)						
	Board	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee	Research and Development Committee	Shareholder Meetings	
						EGM March 28	AGM June 22
<b>Executive Director:</b>							
Dr. Samantha Du <sup>(1)</sup>	5/5	N/A	N/A	N/A	8/8	Yes	Yes
<b>Independent Directors:</b>							
Dr. Kai-Xian Chen	5/5	N/A	5/5	N/A	8/8	No	No
Dr. John Diekman <sup>(2)</sup>	5/5	9/9	N/A	4/4	N/A	No	Yes
Richard Gaynor, M.D.	5/5	N/A	N/A	N/A	8/8	No	Yes
Ms. Nisa Leung	5/5	N/A	4/5	N/A	N/A	No	No
Mr. William Lis	5/5	N/A	N/A	4/4	8/8	No	Yes
Mr. Scott W. Morrison <sup>(3)</sup>	5/5	9/9	N/A	N/A	N/A	No	Yes
Mr. Leon O. Moulder, Jr.	5/5	N/A	N/A	4/4	N/A	No	Yes
Mr. Peter Wirth <sup>(4)</sup>	5/5	9/9	5/5	N/A	N/A	No	Yes
Mr. Michel Vounatsos <sup>(5)</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes:

- (1) Dr. Samantha Du attended 1 Compensation Committee meeting and 1 Nominating & Corporate Governance Committee meeting, respectively, as a non-member guest.
- (2) Dr. John Diekman was appointed to the Compensation Committee after the last committee meeting in 2022 and thus had no attendance requirement in 2022, and attended 2 R&D Committee meetings as a non-member guest.
- (3) Mr. Scott Morrison attended 1 R&D Committee meeting as a non-member guest.
- (4) Mr. Peter Wirth attended 4 R&D Committee meetings as a non-member guest.
- (5) Mr. Michel Vounatsos was appointed as an independent director of the Company, chairperson of the Commercial Committee and a member of the Research and Development Committee with effect from January 7, 2023.
- (6) Following the establishment of the Commercial Committee on January 7, 2023 being chaired by Mr. Michel Vounatsos, an independent director of the Company, Mr. William Lis and Mr. Leon O. Moulder, Jr., independent directors of the Company, were appointed as members of the Commercial Committee with effect from January 13, 2023.

# CORPORATE GOVERNANCE REPORT

## **DIRECTORS' RESPONSIBILITY IN RESPECT OF THE FINANCIAL STATEMENTS**

The Directors acknowledge their responsibility for supervising management's preparation of the financial statements of the Company for the Reporting Period.

The Directors of the Company are responsible for the oversight of the consolidated financial statements for the Reporting Period that give a true and fair view in accordance with U.S. generally accepted accounting principles and the disclosure requirements of the Hong Kong Companies Ordinance, and for such internal control as the directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. During the Reporting Period, the Audit Committee of the Board oversees the accounting and financial reporting processes of the Company and the audits of the Company's financial statements, including but not limited to assisting the Board in its oversight of the integrity of the consolidated financial statements of the Company, the Company's compliance program, and the Company's risk management and internal control over financial reporting.

The Directors are not aware of any material uncertainties relating to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern.

## **CONTINUOUS PROFESSIONAL DEVELOPMENT OF DIRECTORS**

The Directors intend to keep abreast of their responsibilities as directors of the Company and of the conduct, business activities and development of the Company.

The Company arranges a formal and comprehensive induction to a newly appointed Director so that the Director has a proper understanding of the Company's operations and business and is fully aware of the director's responsibilities under the HK Listing Rules and SFO, and other legal and regulatory requirements.

The Company arranges trainings to provide Directors with updates on latest development and changes in the HK Listing Rules and other relevant legal and regulatory requirements from time to time. The Directors are also provided with regular updates on the Company's performance, position and prospects to enable the Board as a whole and each Director to discharge his or her duties. The Company also encourages the Directors to attend relevant training courses provided by legal advisors and/or any appropriate institutions.

For the Reporting Period, all Directors participated in continuing professional development regarding their duties and responsibilities as a director of a listed company which included reading materials and/or attending training.

Effective January 7, 2023, Mr. Michel Vounatsos was appointed to the Board. Mr. Michel Vounatsos has been appropriately trained as to Hong Kong law, on directors' duties, responsibilities and obligations under the HK Listing Rules and the SFO.

## AUDITORS' REMUNERATION

The fees paid or payable in relation to audit and non-audit services for the year ended December 31, 2022 provided by KPMG LLP and its affiliates, and for the year ended December 31, 2021 provided by Deloitte Touche Tohmatsu Certified Public Accountants LLP, Deloitte Touche Tohmatsu, and their affiliates (in thousands), were as follows:

	Year Ended December 31,	
	2022	2021
	US\$'000	US\$'000
Audit Fees <sup>(1)</sup>	4,716	1,150
Tax Fees	—	88
Total	4,716	1,238

(1) Audit fees consist of fees for the audit of our consolidated financial statements, reviews of our interim financial statements, and the audit of the effectiveness of our internal control over financial reporting. Audit fees also include services that are normally provided in connection with statutory and regulatory filings.

(2) KPMG LLP and its affiliates did not provide any tax or other non-audit services in 2022.

## CONNECTED TRANSACTIONS AND CONTINUING CONNECTED TRANSACTIONS

During the Reporting Period, the Company has not entered into any connected transaction or continuing connected transaction which should be disclosed pursuant to the requirements of Rule 14A.71 of the HK Listing Rules.

## RELATED PARTY TRANSACTION

The related party transaction disclosed in Note 16 to the consolidated financial statements does not constitute a connected transaction or continuing connected transaction subject to independent shareholders' approval, annual review and all disclosure requirements in Chapter 14A of the HK Listing Rules.

## RISK MANAGEMENT AND INTERNAL CONTROLS

During the Reporting Period, we have conducted an annual review of the effectiveness of our risk management and internal control systems, which we consider to be effective and adequate. Such review covers the adequacy of resources, staff qualifications and experience, training programs and budget of the issuer's accounting, internal audit, financial reporting functions, as well as those relating to the issuer's ESG performance and reporting, and the matters covered in code provision D.2.3 of the CG Code. For more details about the Company's risk management and internal control systems, please refer to the sub-section entitled "RISK MANAGEMENT" under the "Business" section in this annual report and the section headed "Responsibilities, Accountabilities and Contributions of the Board and Management" in this Corporate Governance Report.

# CORPORATE GOVERNANCE REPORT

## Procedures and Internal Controls for the Handling and Dissemination of Inside Information

The Company follows the requirements of the SFO and the HK Listing Rules and ensures that inside information is disclosed to the public as soon as reasonably practicable unless the information falls within any of the safe harbours of the SFO. Before such disclosure, the information should be kept strictly confidential. In addition, the Company adopted the policy of disclosing relevant information only to appropriate staff within the Company or to its professional advisers who have a need to know such information.

## COMPANY SECRETARY

The Company has appointed Mr. F. Ty Edmondson and Ms. Nelly Au-Yeung as joint company secretaries of the Company, with effect from June 27, 2022. Mr. Edmondson has extensive experience in legal and compliance matters but presently may not possess all of the qualifications under Rules 3.28 and 8.17 of the HK Listing Rules, and may not be able to solely fulfill the requirements of the HK Listing Rules. Therefore, the Company has appointed Ms. Au-Yeung as one of the joint company secretaries of the Company. Ms. Au-Yeung is currently a Senior Manager of Tricor Services Limited, a global professional services provider specializing in integrated business, corporate and investor services. Ms. Au-Yeung is a chartered secretary, an associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute (formerly known as The Institute of Chartered Secretaries and Administrators). Ms. Au-Yeung has around 10 years of experience in the corporate secretarial field and is currently the company secretary of Anton Oilfield Service Group (Stock Code: 3337). Ms. Au-Yeung holds a Bachelor of Arts in Economics and Finance from Hong Kong Shue Yan University and obtained a Master of Corporate Governance from The Hong Kong Polytechnic University. Ms. Au-Yeung, who fully meets the requirements stipulated under Note 1 to Rule 3.28 and Rule 8.17 of the HK Listing Rules, acts as the other joint company secretary to provide assistance to Mr. Edmondson for an initial period of three years from the Primary Conversion Effective Date to enable Mr. Edmondson to acquire the “relevant experience” under Note 2 to Rule 3.28 of the HK Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the HK Listing Rules.

The Company’s principal business activities are primarily outside of Hong Kong. The Company believes that it would be in the best interests of the Company and the corporate governance of the Company to have as its joint company secretary a person such as Mr. Edmondson, who is an employee of the Company and the Chief Legal Officer and who has day-to-day knowledge of the Company’s affairs. Mr. Edmondson has the necessary nexus to the Board and close working relationships with management of the Company in order to perform the function of a joint company secretary and to take necessary actions in an effective and efficient manner.

## SHAREHOLDERS’ RIGHTS

### Convening of Extraordinary General Meetings by Shareholders

Pursuant to Articles 57 and 58 of our Sixth Amended and Restated Articles of Association, an extraordinary general meeting of our Company shall be convened on a members’ requisition put forth by our shareholders holding at the date of deposit of the requisition not less than one-tenth of the share capital of the Company as at that date carries the right of voting at general meetings of the Company. The requisition must state the objects of the meeting and must be signed by the requisitionists and deposited at the principal place of business of the Company (with a copy forwarded to the registered office), and may consist of several documents in like form each signed by one or more requisitionists. If the Directors do not within 21 calendar days from the date of the deposit of the requisition duly proceed to convene a general meeting to be held within a further 21 calendar days, the requisitionists, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a general meeting, but any meeting so convened shall not be held after the expiration of three months after the expiration of the second said 21 calendar days.

# CORPORATE GOVERNANCE REPORT

## Putting Forward Proposals at General Meetings

Shareholders may present proper proposals for inclusion in our proxy statement and for consideration at our next annual general meeting of shareholders by submitting their proposals in writing to us in a timely manner. In order to be considered for inclusion in the proxy statement for the 2024 annual general meeting of shareholders, shareholder proposals must be received at our principal executive offices no later than December 30, 2023, and must otherwise comply with the requirements of the Exchange Act. If we do not receive notice of the proposal at our principal executive offices prior to such date, such proposal will be considered untimely for purposes of the Exchange Act. Any other shareholder proposal for the 2024 annual general meeting of shareholders which is submitted outside the processes of Exchange Act shall be considered untimely unless received by the Company in writing no later than March 14, 2024. A copy of all notices of proposals by shareholders should be sent to Chief Legal Officer & Corporate Secretary, Zai Lab Limited, 314 Main Street, Fourth Floor, Suite 100, Cambridge, MA 02142.

## Putting Forward Enquiries to the Board and Contact Details

The Board provides every shareholder the ability to communicate with the Board, as a whole, and with individual directors on the Board through an established process for shareholder communication. For a shareholder communication directed to the Board as a whole, shareholders may send such communication to the attention of our Corporate Secretary via regular mail or expedited delivery service to: Zai Lab Limited, 314 Main Street, Fourth Floor, Suite 100, Cambridge, MA 02142, Attention: Board c/o Corporate Secretary.

For a shareholder communication directed to an individual director in his or her capacity as a member of the Board, shareholders may send such communication to the attention of the individual director via Regular Mail or Expedited Delivery Service to: Zai Lab Limited, 314 Main Street, Fourth Floor, Suite 100, Cambridge, MA 02142, Attention: [Name of Individual Director].

Communications will be distributed to the Board, or to any individual director or directors as deemed appropriate, depending on the facts and circumstances outlined in the communications. Items that are unrelated to the duties and responsibilities of the Board may be excluded, such as junk mail and mass mailings, resumes and other forms of job inquiries, surveys, and solicitations or advertisements.

## COMMUNICATION WITH SHAREHOLDERS AND INVESTOR RELATIONS

The Company considers that effective communication with shareholders is essential for enhancing investor relations and investor understanding of the Company's business performance and strategies. The Company endeavors to maintain an on-going dialogue with shareholders and in particular, through annual general meetings and extraordinary general meetings. The Company provides the shareholders with relevant information on the resolution(s) proposed at a general meeting in a timely manner in accordance with the HK Listing Rules, to provide information that the Company deems reasonably necessary to enable the shareholders to make an informed decision on the proposed resolution(s). Shareholders are encouraged to participate in general meetings. At the forthcoming 2023 annual general meeting, Directors (or their delegates as appropriate) will be available in person or via teleconference to meet shareholders and answer their enquiries.

The Company has in place a Shareholder Communication Policy. The Board has reviewed the implementation and effectiveness of the Company's Shareholder Communication Policy during the Reporting Period and considered that the policy was able to facilitate an open and on-going communication with the shareholders on fair disclosure basis.

# CORPORATE GOVERNANCE REPORT

## CHANGES IN CONSTITUTIONAL DOCUMENTS

A proposal was made to amend the Fifth Amended and Restated Memorandum of Association adopted by a special resolution passed on September 4, 2020, and the Fifth Amended and Restated Articles of Association adopted by a special resolution passed on June 24, 2021 (collectively the “Fifth Restated Articles”) at the annual general meeting held on June 22, 2022. The details of the amendments are set out in our definitive proxy statement/circular dated May 3, 2022 (Shanghai and Hong Kong Time), which was published on the websites of the Hong Kong Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company, including the key changes summarized below. Such amendments were approved by our Shareholders at the annual general meeting held on June 22, 2022.

The Sixth Amended and Restated Memorandum and Articles of Association adopted by a special resolution passed on June 22, 2022 (the “Sixth Restated Articles”), which became effective on June 27, 2022, upon completion of the Company’s conversion to dual-primary listing on the Main Board of Hong Kong Stock Exchange, include the following key changes to the Fifth Restated Articles:

### Special Resolution — Article 1

The Fifth Restated Articles was amended and restated to vary the definition of a Special Resolution to specifically make reference to, and include, instances flagged in the Sixth Restated Articles that require the increased voting threshold (from two-thirds to three-fourths of the votes cast on a proposal) of a “Super-Majority Resolution” (as defined below). This amendment is made in compliance with the Companies Act (Revised) of the Cayman Islands, which provides at Section 60(1)(a) that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that any such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution.

### Variation of Rights Attaching to Shares — Article 23

The Fifth Restated Articles was amended and restated to increase the voting threshold for the variation of rights attaching to any class or series of shares by written consent from two-thirds of the issued shares to three-fourths of the voting rights of the holders of that class or series, and that such variation of rights can also be approved by a not less than three-fourth of our shareholders (“Super-Majority Resolution”), who, as being entitled to do so, vote at a general meeting, the quorum of which is not less than an aggregate of one-third of the issued shares of the relevant class. This amendment is made in compliance with paragraph 15 of Appendix 3 of the HK Listing Rules, which provides that a super-majority vote of the issuer’s members of the class to which the rights are attached shall be required to approve a change to those rights. For the purpose of this HK Listing Rule, a “super-majority vote” means at least three-fourths of the voting rights of the members holding shares in that class present and voting in person or by proxy at a separate general meeting of members of the class where the quorum for such meeting shall be holders of at least one third of the issued shares of the class.



## **Quorum — Article 24(b)**

The Fifth Restated Articles was amended and restated to increase the necessary quorum to hold a general meeting of holders of one class or series of shares or to demand a poll at such a general meeting from one or more persons holding or representing at least one-tenth of the issued shares of that class or series to one or more persons holding or representing at least one-third of the issued shares of that class or series. This amendment is made in compliance with paragraph 15 of Appendix 3 of the HK Listing Rules, which provides that a super-majority vote of the issuer's members of the class to which the rights are attached shall be required to approve a change to those rights and which a quorum for such meeting shall be holders of at least one third of the issued shares of that class. If this Proposal is approved, language relating to the right of members to demand a poll within Article 24(b) will also be removed (as explained below).

## **Shareholder Right to Speak at General Meeting — Articles 52–54, 58, 71**

The Fifth Restated Articles was amended and restated to explicitly specify that each shareholder of the Company entitled to attend or vote at a general meeting shall also have the right to speak at the general meeting. This amendment is made in compliance with paragraph 14(3) of Appendix 3 of the HK Listing Rules, which provides that members must have the right to speak at a general meeting; and vote at a general meeting except where a member is required, by the HK Listing Rules, to abstain from voting to approve the matter under consideration.

## **General Meetings — Article 56(a)**

The Fifth Restated Articles was amended and restated to provide that the annual general meeting of the Company shall occur within 6 months after the end of the Company's financial year (or such longer period as the relevant stock exchange may authorize). This amendment is made in compliance with paragraph 14(1) of Appendix 3 of the HK Listing Rules, which provides that an issuer must hold a general meeting for each financial year as its annual general meeting and generally, an issuer must hold its annual general meeting within six months after the end of its financial year.

## **Notice of General Meetings — Article 58**

The Fifth Restated Articles was amended and restated to provide that the notice period for any extraordinary general meeting of the Company will be at least 14 calendar days and the notice period for any annual general meeting of the Company will be at least 21 calendar days. This amendment is made in compliance with paragraph 14(2) of Appendix 3 of the HK Listing Rules.

## **Voting by poll at General Meetings — Articles 24(b), 66–69, 77 and 78**

The Fifth Restated Articles was amended and restated to provide that voting on a resolution at a general meeting shall be decided by poll, rather than a show of hands, save for matters that the Chairperson of the meeting may, in good faith, deem to be matters that are purely administrative or procedural and were not on the agenda of the meeting or any supplementary circular to members, and therefore may put such matter to vote by a show of hands. These amendments are made in compliance with Rule 13.39(4) of the HK Listing Rules.



# CORPORATE GOVERNANCE REPORT

## **Clearing Houses — Article 81A**

The Fifth Restated Articles was amended and restated to provide that the Hong Kong Securities Clearing Company Limited (“HKSCC”) will be entitled to appoint proxies or corporate representatives to attend the Company’s general meetings and creditors meetings and such proxies or corporate representatives will enjoy rights equivalent to the rights of other shareholders of the Company, and that, where applicable law prohibits HKSCC from appointing proxies or corporate representatives, the Company will use its best efforts to make necessary arrangements with HKSCC to ensure that Hong Kong investors holding shares through HKSCC enjoy the right to vote, attend and speak at general meetings. This amendment is made in compliance with paragraph 19 of Appendix 3 of the HK Listing Rules, which provides that HKSCC must be entitled to appoint proxies or corporate representatives to attend the issuer’s general meetings and creditors meetings and those proxies/corporate representatives must enjoy rights equivalent to the rights of other shareholders, including the right to speak and vote.

## **Directors — Article 82(d)**

The Fifth Restated Articles was amended and restated to specify within this Article that directors appointed by ordinary resolution to fill a casual vacancy on the board or as an addition to the existing board will hold office until the first annual general meeting of the Company after his appointment and will then be eligible for re-election at that meeting. This amendment is made in compliance with paragraph 4(2) of Appendix 3 of the HK Listing Rules, which provides that any person appointed by the directors to fill a casual vacancy on or as an addition to the board shall hold office only until the first annual general meeting of the issuer after his appointment, and shall then be eligible for re-election.

## **Proceedings of Directors — Article 103(a)**

The Fifth Restated Articles was amended and restated to provide that at least 14 calendar days’ notice shall be given to all directors and their respective alternates for regular board meetings. This amendment is made in compliance with Code Provision C.5.3 of Appendix 14 of the HK Listing Rules, which provides that notice of at least 14 days should be given of a regular board meeting to give all directors an opportunity to attend. For all other board meetings, reasonable notice should be given.

## **Proceedings of Directors — Article 108**

The Fifth Restated Articles was amended and restated to specify that a Director’s vote with respect to any matter that he may be interested in shall be subject to the relevant rules of the designated stock exchange.

## **Audit — Article 134**

The Fifth Restated Articles was amended and restated to provide that the appointment and removal of an auditor of the Company shall be approved by a majority of the shareholders of the Company or other body that is independent of the Board in accordance with the HK Listing Rules, that the removal of an auditor of the Company before the expiration of its period of office shall require the approval of an ordinary resolution, and that the remuneration of the auditor of the Company shall be approved by a majority of the shareholders of the Company or other body that is independent of the Board. This amendment is made in compliance with paragraph 17 of Appendix 3 of the HK Listing Rules, which provides that the appointment, removal and remuneration of auditors must be approved by a majority of the issuer's members or other body that is independent of the board of directors.

## **Information — Article 150**

The Fifth Restated Articles was amended and restated to provide that any branch Register of Members maintained in Hong Kong shall be open for inspection by a shareholder of the Company without charge, and shall be open to such other persons on payment of a fee as the Board may determine, subject to certain limitations, and that the Company may be permitted to close the branch Register of Members on terms equivalent to Section 632 of Companies Ordinance (Cap. 622 of the Laws of Hong Kong). This amendment is made in compliance with paragraph 20 of Appendix 3 of the HK Listing Rules, which provides that the branch register of members in Hong Kong shall be open for inspection by members but the issuer may be permitted to close the register on terms equivalent to section 632 of the Companies Ordinance (Cap. 622 of the Laws of Hong Kong).

## **Winding Up — Article 155**

The Fifth Restated Articles was amended and restated to provide that the Company may be wound up voluntarily if the shareholders of the Company at any general meeting so resolve by Super-Majority Resolution. This amendment is made in compliance with paragraph 21 of Appendix 3 of the HK Listing Rules, which provides that a super-majority vote of the issuer's members in a general meeting shall be required to approve a voluntary winding up of an issuer.

## **Amendment to Memorandum and Articles — Article 155**

The Fifth Restated Articles was amended and restated to provide that the Company's memorandum of association and articles of association may be altered or amended, or the name of the Company may be changed, if the shareholders of the Company at any general meeting so resolve by Super-Majority Resolution. This amendment is made in compliance with paragraph 16 of Appendix 3 of the HK Listing Rules, which provides that a super-majority vote of the issuer's members in a general meeting shall be required to approve changes to an issuer's constitutional documents. For the purpose of this HK Listing Rule, a "super-majority vote" means at least three-fourth of the voting rights of the members present and voting in person or by proxy at the general meeting.

# INDEPENDENT AUDITOR'S REPORT

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## **To the Shareholders and Board of Directors of Zai Lab Limited**

### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheet of Zai Lab Limited and subsidiaries (the "Company") as of December 31, 2022, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2022, and the related notes and schedule listed in the Schedule I (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, 2022 and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The consolidated financial statements of the Company as of and for the year ended December 31, 2021, were audited by other auditors in accordance with Hong Kong Standards on Auditing whose report dated March 1, 2022, expressed an unmodified opinion on those statements.

## **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 audit. We are a public accounting firm registered with the U.S. Public Company Accounting Oversight Board ("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 U.S. 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 the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

# INDEPENDENT AUDITOR'S REPORT

## 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, the Company recorded \$62.9 million in accounts payable and \$65.8 million in other current liabilities, 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 projects 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 and accrued liability 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 the reporting date 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.

New York, New York

March 31, 2023

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED BALANCE SHEETS

(\$ in thousands except for number of shares and per share data)

	Notes	December 31,	
		2022	2021
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	3	1,008,470	964,100
Short-term investments	5	—	445,000
Accounts receivable (net of allowance for credit loss of \$11 as of December 31, 2022 and 2021, respectively)	6	39,963	47,474
Notes receivable		8,608	7,335
Inventories, net	7	31,621	18,951
Prepayments and other current assets		35,674	18,021
<b>Total current assets</b>		<b>1,124,336</b>	1,500,881
Restricted cash, non-current	4	803	803
Long-term investments (including the fair value measured investment of \$6,431 and \$15,383 as of December 31, 2022 and 2021, respectively)	8	6,431	15,605
Prepayments for equipment		1,396	989
Property and equipment, net	9	57,863	43,102
Operating lease right-of-use assets	10	19,512	14,189
Land use rights, net		6,892	7,811
Intangible assets, net		1,511	1,848
Long-term deposits		1,396	870
Value added tax recoverable		—	23,858
<b>Total assets</b>		<b>1,220,140</b>	1,609,956
<b>Liabilities and shareholders' equity</b>			
<b>Current liabilities</b>			
Accounts payable	11	65,974	126,163
Current operating lease liabilities	10	7,050	5,927
Other current liabilities	14	66,818	60,811
<b>Total current liabilities</b>		<b>139,842</b>	192,901
Deferred income		21,360	27,486
Non-current operating lease liabilities	10	13,343	9,613
<b>Total liabilities</b>		<b>174,545</b>	230,000

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED BALANCE SHEETS (CONTINUED)

(\$ in thousands except for number of shares and per share data) (Continued)

	December 31,	
	2022	2021
<b>Commitments and contingencies (Note 22)</b>		
<b>Shareholders' equity</b>		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized, 962,455,850 and 955,363,980 shares issued as of December 31, 2022 and 2021, respectively; 960,219,570 and 954,981,050 shares issued and outstanding as of December 31, 2022 and 2021, respectively)	6	6
Additional paid-in capital	<b>2,893,120</b>	2,825,948
Accumulated deficit	<b>(1,861,360)</b>	(1,418,074)
Accumulated other comprehensive income (loss)	<b>25,685</b>	(23,645)
Treasury stock (at cost, 2,236,280 and 382,930 shares as of December 31, 2022 and 2021, respectively)	<b>(11,856)</b>	(4,279)
<b>Total shareholders' equity</b>	<b>1,045,595</b>	1,379,956
<b>Total liabilities and shareholders' equity</b>	<b>1,220,140</b>	1,609,956

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

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENTS OF OPERATIONS

(\$ in thousands except for number of shares and per share data)

	Notes	Year ended December 31,	
		2022	2021
Revenues			
Product revenue, net	12	<b>212,672</b>	144,105
Collaboration revenue	12	<b>2,368</b>	207
Total revenues		<b>215,040</b>	144,312
Expenses			
Cost of sales		<b>(74,018)</b>	(52,239)
Research and development		<b>(286,408)</b>	(573,306)
Selling, general and administrative		<b>(258,971)</b>	(218,831)
Loss from operations		<b>(404,357)</b>	(700,064)
Interest income		<b>14,582</b>	2,190
Interest expenses		—	—
Foreign currency (loss) gain		<b>(56,403)</b>	4,661
Other income (expenses), net	19	<b>3,113</b>	(10,201)
Loss before income tax and share of loss from equity method investment		<b>(443,065)</b>	(703,414)
Income tax expense	13	—	—
Share of loss from equity method investment		<b>(221)</b>	(1,057)
Net loss		<b>(443,286)</b>	(704,471)
Loss per share — basic and diluted	15	<b>(0.46)</b>	(0.76)
Weighted-average shares used in calculating net loss per ordinary share — basic and diluted		<b>958,067,140</b>	929,921,120
Loss per American Depositary Shares (“ADS”) — basic and diluted		<b>(4.63)</b>	(7.58)
Weighted-average ADSs used in calculating net loss per ADS — basic and diluted		<b>95,806,714</b>	92,992,112

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

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

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

*(\$ in thousands)*

	Year ended December 31,	
	2022	2021
Net loss	<b>(443,286)</b>	(704,471)
Other comprehensive income (loss), net of tax of nil:		
Foreign currency translation adjustments	<b>49,330</b>	(9,121)
Comprehensive loss	<b>(393,956)</b>	(713,592)

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



# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(\$ in thousands except for number of shares and per share data)

	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 December 31, 2020	878,110,260	5	1,897,467	(713,603)	(14,524)	—	—	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	2,054,500	0	0	—	—	—	—	—
Exercise of shares option	12,353,400	0	7,417	—	—	—	—	7,417
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of \$839	57,164,000	1	818,035	—	—	—	—	818,036
Issuance of ordinary shares in connection with collaboration and license arrangement (Note 18)	5,681,820	0	62,250	—	—	—	—	62,250
Issuance cost adjustment for secondary listing	—	—	65	—	—	—	—	65
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(382,930)	(4,279)	(4,279)
Share-based compensation	—	—	40,714	—	—	—	—	40,714
Net loss	—	—	—	(704,471)	—	—	—	(704,471)
Foreign currency translation	—	—	—	—	(9,121)	—	—	(9,121)
Balance at December 31, 2021	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956
Issuance of ordinary shares upon vesting of restricted shares	1,940,680	0	0	—	—	—	—	—
Exercise of shares option	5,151,190	0	5,870	—	—	—	—	5,870
Receipt of employees' shares 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

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

"0" in above table means less than \$1,000.

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(\$ in thousands)

	Year ended December 31,	
	2022	2021
<b>Cash flows from operating activities</b>		
Net loss	(443,286)	(704,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss	1	10
Inventory write-down	477	1,368
Depreciation and amortization expenses	8,227	6,487
Amortization of deferred income	(2,602)	(521)
Share-based compensation	61,302	40,714
Non-cash research and development expenses	—	62,250
Share of loss from equity method investment	221	1,057
Loss from fair value changes of equity investment with readily determinable fair value	8,952	14,617
Loss (gain) on disposal of property and equipment	560	29
Non-cash lease expenses	8,350	6,119
Foreign currency remeasurement loss (gain)	56,403	(10,679)
Changes in operating assets and liabilities:		
Accounts receivable	4,330	(42,319)
Notes receivable	(1,976)	(7,335)
Inventories	(15,382)	(7,174)
Prepayments and other current assets	(19,258)	(7,086)
Long-term deposits	(527)	(8)
Value added tax recoverable	22,781	(1,717)
Accounts payable	(53,773)	63,522
Other current liabilities	7,392	30,142
Operating lease liabilities	(8,455)	(5,385)
Deferred income	(1,379)	11,149
Net cash used in operating activities	(367,642)	(549,231)
<b>Cash flows from investing activities</b>		
Purchases of short-term investments	(260,274)	(445,000)
Proceeds from maturity of short-term investments	705,274	743,902
Purchases of investment in equity investee	—	(30,000)
Purchases of property and equipment	(24,585)	(18,295)
Proceeds from disposal of property and equipment	—	3
Purchases of intangible assets	(399)	(653)
Net cash provided by investing activities	420,016	249,957

# CONSOLIDATED FINANCIAL STATEMENTS

## CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(\$ in thousands) (Continued)

	Year ended December 31,	
	2022	2021
<b>Cash flows from financing activities</b>		
Proceeds from exercises of stock options	5,870	7,417
Proceeds from issuance of ordinary shares upon public offerings	—	818,875
Payment of public offering costs	—	(1,837)
Employee taxes paid related to settlement of equity awards	(7,600)	(4,253)
Net cash (used in) provided by financing activities	(1,730)	820,202
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(6,274)	1,116
Net increase in cash, cash equivalents and restricted cash	44,370	522,044
Cash, cash equivalents and restricted cash — beginning of the year	964,903	442,859
Cash, cash equivalents and restricted cash — end of the year	1,009,273	964,903
<b>Supplemental disclosure on non-cash investing and financing activities</b>		
Payables for purchase of property and equipment	5,269	2,568
Payables for purchase of intangible assets	163	191
Payables for treasury stock	2	26
Right-of-use asset acquired under operating leases	14,801	2,183
Receivables for disposal of property and equipment	64	—
<b>Supplemental disclosure of cash flow information</b>		
Cash and cash equivalents	1,008,470	964,100
Restricted cash, non-current	803	803
Total cash and cash equivalents and restricted cash	1,009,273	964,903

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

# CONSOLIDATED FINANCIAL STATEMENTS

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### 1. ORGANIZATION AND PRINCIPAL ACTIVITIES

Zai Lab Limited was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Act of the Cayman Islands (as amended). Zai Lab Limited and its subsidiaries are focused on discovering, developing, and commercializing products and product candidates that address medical conditions with significant unmet needs, including in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience.

The Company's principal operations and geographic markets are in Greater China (mainland China, Hong Kong, Macau, and Taiwan). The Company has a substantial presence in Greater China and the United States.

As of December 31, 2022, Zai Lab Limited had the following 16 subsidiaries:

Name of Company	Place of Incorporation	Particulars of Issued/ Paid-in Capital	Percentage of Ownership	Principal Activities and Place of Operation
Zai Lab (Hong Kong) Limited	Hong Kong	HK\$1	100%	Operating company for business development and R&D activities and commercialization of innovative medicines and device; Hong Kong
ZLIP Holding Limited	Cayman Islands	HK\$1	100%	Investment holding
ZL Capital Limited	British Virgin Islands	\$1	100%	Investment holding
ZL China Holding Two Limited	Hong Kong	HK\$1	100%	Investment holding
Zai Anti Infectives Limited	Cayman Islands	\$1	100%	Investment holding
Zai Auto Immune Limited	Cayman Islands	\$1	100%	Investment holding
Zai Lab (Shanghai) Co., Ltd.	Mainland China*	\$416,500,000	100%	Development and commercialization of innovative medicines and devices; mainland China
Zai Lab (AUST) Pty. Ltd.	Australia	Australian dollar ("A\$")100	100%	Clinical trial activities; Australia
Zai Lab (Suzhou) Co., Ltd.	Mainland China*	Chinese Renminbi ("RMB") 166,500,000	100%	Development and commercialization of innovative medicines; mainland China

# CONSOLIDATED FINANCIAL STATEMENTS

## 1. ORGANIZATION AND PRINCIPAL ACTIVITIES (CONTINUED)

Name of Company	Place of Incorporation	Particulars of Issued/ Paid-in Capital	Percentage of Ownership	Principal Activities and Place of Operation
Zai Biopharmaceutical (Suzhou) Co., Ltd.	Mainland China*	\$15,000,000	100%	Development and commercialization of innovative medicines; mainland China
Zai Lab (US) LLC	United States	\$1	100%	Operating company for business development, R&D activities and certain business activities, including legal, compliance and communication functions of the Company; United States
Zai Lab International Trading (Shanghai) Co., Ltd.	Mainland China*	RMB1,000,000	100%	Commercialization of innovative medicines and devices; mainland China
Zai Auto Immune (Hong Kong) Limited	Hong Kong	HK\$100	100%	Operating company for business development and R&D activities; Hong Kong
Zai Anti Infectives (Hong Kong) Limited	Hong Kong	HK\$100	100%	No substantial business activities
Zai Lab (Taiwan) Limited	Taiwan	Taiwan dollar ("TWD") 1,000,000	100%	Commercialization of innovative medicines and devices; Taiwan
Zai Lab Trading (Suzhou) Co., Ltd.	Mainland China*	RMB1,000,000	100%	Commercialization of innovative medicines and devices; mainland China

\* Limited liability company established in mainland China.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### (a) Basis of presentation

The consolidated financial statements have been prepared in accordance with U.S. GAAP. Significant accounting policies followed by the Company in the preparation of the accompanying consolidated financial statements are summarized below.

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

In 2022, the Company began to separately present foreign currency (loss) gain on our consolidated statements of operations. This amount was previously included in other income (expense), net. Additionally, the Company began to provide a breakdown of other income (expense), net in Note 19. The Company also began to separately present the amount of foreign currency remeasurement loss (gain) on our consolidated statements of cash flows. This amount was previously included in changes in other current liabilities. This change did not have any impact on net cash used in operating activities. Corresponding amounts in the prior periods of the consolidated financial statements have been presented to conform to the current period presentation.

### (b) Principles of consolidation

The consolidated financial statements include the financial statements of the Company. 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, judgements, 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 to the appropriate financial reporting period based on the progress of the research and development projects, fair value of share-based compensation expenses, recoverability of deferred tax assets, and a lack of marketability discount of the ordinary shares issued in connection with license and collaboration arrangements (Note 18). 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (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 Chinese mainland subsidiaries determined their functional currency to be the RMB. The Company’s Australia subsidiary determined its functional currency to be the A\$. The Company’s Taiwan subsidiary determined its functional currency to be the 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 changes in shareholders’ equity.

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

Non-monetary assets and liabilities are remeasured 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (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. In addition, the Company records accounts receivable arising from its collaborative agreements. 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 is 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, 2022 and 2021.

### (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 sales in the period that the decline in value is first identified.

### (j) Prepayments for equipment

The prepayments for equipment purchase are recorded in long-term prepayments considering the prepayments are all related to property and equipment.



# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (k) Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. 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.

### (l) Leases

The Company leases facilities for its offices, research and development center, and manufacturing facilities in mainland China, Hong Kong, and the United States. On January 1, 2019, the Company adopted ASC 842, Leases 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 re-evaluated 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.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (l) Leases (Continued)

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.

### (m) 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 balance sheet, which is amortized over the remaining lease term.

In 2019, the Company acquired land use rights for a term of 30 years from the local Bureau of Land and Resources in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou.

### (n) Long-term deposits

Long-term deposits represent amounts paid in connection with the Company's long-term lease agreements.

### (o) Value added tax recoverable

Value added tax recoverable relates to amounts paid by the Company for purchases. The amounts were expected to be deducted from future value added tax payables arising on the Company's future revenues.

### (p) Intangible assets

Intangible assets mainly consist of externally purchased software which are amortized over three to five years on a straight-line basis. Amortization expenses for both 2022 and 2021 were \$0.5 million. Amortization expenses of the Company's intangible assets are expected to be approximately \$0.6 million, \$0.5 million, \$0.3 million, \$0.1 million, insignificant amount, and nil for 2023, 2024, 2025, 2026, 2027, and thereafter, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (q) 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 any amount of impairment based on the difference between the carrying value and the estimated fair value of the impaired asset group. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. Impairment of the Company's long-lived assets was not material for 2022 and 2021.

### (r) Fair value measurements

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

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

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

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

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

ASC 820 describes three main approaches 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 \$6.4 million and \$15.4 million as of December 31, 2022 and 2021, respectively. The unrealized gains and losses from fair value changes are recognized in other income (expenses), net in the consolidated statements of operations.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (r) Fair value measurements (Continued)

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

### (s) 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 sales mainly consists of the acquisition cost of products, the manufacturing cost of products, royalty fees, and sales-based milestone payments.

The Company has applied the practical expedients under ASC 606 with regard to assessment of 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. The Company’s product revenues were mainly generated from the sale of ZEJULA (niraparib), Optune (Tumor Treating Fields), QINLOCK (ripretinib), and NUZYRA (Omadacycline) to customers.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (s) Revenue recognition (Continued)

In mainland China, the Company sells the 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 are recorded as a reduction of revenue, if any. 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 was recognized at the amount to which the Company expected to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

The Company didn't recognize any contract assets and contract liabilities as of December 31, 2022 and 2021.

### (t) 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 pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (u) 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 of exclusive development rights of 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 contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), investigators, and clinical trial sites that conduct our 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 and have no alternative future uses.

The Company has acquired rights to develop and commercialize 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 did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, and the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. 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. If the conditions enabling capitalization of development costs as an asset have not yet been met, all development expenditures are recognized in profit or loss when incurred.

### (v) Deferred income

Deferred income mainly consists of deferred income from government grants, the American Depositary Receipt ("ADR") Program Agreement with ADR depository bank (the "DB") in July 2017, and the upfront payments received from Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd. ("Huizheng", a direct wholly owned subsidiary of Hanhui Pharmaceutical Co., Ltd. ("Hanhui")).

Government grants consist of cash subsidies received by the Company's subsidiaries in mainland China from local governments. Grants received as incentives for conducting business in certain local districts with no performance obligation or other restriction as to the use are recognized when cash is received. The Company included \$11.5 million and \$4.1 million of cash grants in other income for 2022 and 2021, respectively. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Company may be required to refund the subsidy. The Company recorded \$0.9 million and \$2.4 million of cash grants in deferred income as of December 31, 2022 and 2021, respectively, which will be recognized when the government specified performance obligation is satisfied.

According to the ADR Program Agreement, the Company has the right to receive reimbursements for using DB's services, subject to the compliance by the Company with the terms of the agreement. The Company performed a detailed assessment of the requirements and recognizes the reimbursements it expects to be entitled to over the five-year contract term as other income. The Company recorded \$0.2 million and \$0.3 million in other income for 2022 and 2021, respectively. The Company recorded nil and \$0.2 million in deferred income as of December 31, 2022 and 2021, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (v) Deferred income (Continued)

In March 2020, the Company entered into an exclusive promotion agreement with Huizheng. Under the terms of the agreement, the Company will leverage Hanhui's existing infrastructure to optimize an anticipated future commercial launch of NUZYRA in mainland China given that NUZYRA is a broad-spectrum antibiotic in both hospital and community care facilities. In exchange for the exclusive promotion rights in mainland China, Huizheng has agreed to pay the Company a non-creditable, upfront payment in the amount of RMB230.0 million. The Company received RMB90.0 million in April 2020 and received RMB70.0 million in February 2022. The Company assessed and determined to record the upfront payment as deferred income and amortize it over 10 years from the date when the income recognition criteria were met. In December 2021, the Company obtained regulatory approval for the commercialization of NUZYRA in mainland China which triggered the income recognition criteria, and therefore, the Company started to amortize the deferred income into collaboration revenue on a monthly basis. The Company recorded \$2.4 million and \$0.2 million in collaboration revenue for 2022 and 2021, respectively. The Company recorded \$20.5 million and \$24.9 million in deferred income as of December 31, 2022 and 2021, respectively.

### (w) 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.

### (x) 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").

Share-based awards are measured at grant date fair value using the Black-Scholes model. In accordance with ASC 718, the Company has elected to use the straight-line method to recognize compensation expense for share awards with graded vesting based on service conditions, subject to the minimum amount of cumulative compensation expense recognized is not less than the portion of the award vested to date. The Company recognized as 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.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

The Company determines the fair value of stock options granted to employees using the Black-Scholes option valuation model.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (y) 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. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

### (z) Earnings (loss) per share

Basic earnings (loss) per ordinary share is computed by dividing net income (loss) attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

Diluted earnings (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 earnings (loss) per share in the future. To calculate the number of shares for diluted earnings (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 earnings (loss) per share does not assume exercise or conversion of securities that would have an anti-dilutive effect.

### (aa) Segment information

In accordance with ASC 280, Segment Reporting, the Company's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Company as a whole and therefore, the Company has only one operating and reportable segment.



# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (ab) Concentration of risks

#### Concentration of Customers

The following customers accounted for 10% or more of revenue (\$ in thousands):

	Year ended December 31,	
	2022	2021
A	52,534	40,634

#### Concentration of Suppliers

The following suppliers accounted for 10% or more of research and development expenses and inventory purchases (\$ in thousands):

	Year ended December 31,	
	2022	2021
C	*	*
D	*	*
E	*	165,431
F	*	66,650

\* Represents less than 10% of research and development expenses and inventory purchases for the period.

#### Concentration of Credit Risk

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2022 and 2021, 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (ab) Concentration of risks (Continued)

#### Concentration of Credit Risk (Continued)

The following debtors accounted for 10% or more of accounts receivable balances (\$ in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
A	<b>9,342</b>	10,293
B	*	10,979

\* Represents less than 10% of accounts receivable as of the applicable date.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangements. The Company manages credit risk of accounts receivable through ongoing monitoring of the 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.

Certain accounts receivable balances may be settled in the form of notes receivable. As of December 31, 2022, 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 promissory notes to settle the receivables is at the Company's discretion, and this selection does not impact the agreed contractual purchase prices.

#### 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 of RMB316.8 million and RMB151.7 million, which were denominated in RMB, as of December 31, 2022 and 2021, respectively, representing 5% and 2% of cash and cash equivalents as of December 31, 2022 and 2021, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (ac) Recent accounting pronouncements

#### Adopted Accounting Standards

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

## 3. CASH AND CASH EQUIVALENTS

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

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash at bank and in hand	<b>1,007,423</b>	663,472
Cash equivalents (note (i))	<b>1,047</b>	300,628
	<b>1,008,470</b>	964,100
Denominated in:		
US\$	<b>957,824</b>	932,888
RMB (note (ii))	<b>45,486</b>	23,791
HK\$	<b>4,378</b>	6,674
A\$	<b>598</b>	475
TWD	<b>184</b>	272
	<b>1,008,470</b>	964,100

#### Notes:

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

# CONSOLIDATED FINANCIAL STATEMENTS

## 4. RESTRICTED CASH, NON-CURRENT

The Company's restricted cash balance was \$0.8 million as of both December 31, 2022 and 2021 and consisted of long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Company.

## 5. 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 nil as of December 31, 2022. The Company's short-term investments balance was \$445.0 million as of December 31, 2021 and consisted entirely of short-term held to maturity debt instruments with high credit ratings, which were determined to have remote risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of December 31, 2021.

## 6. ACCOUNTS RECEIVABLE

The following table presents the Company's accounts receivable as of December 31, 2022 and 2021 (\$ in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Accounts receivable	<b>39,974</b>	47,485
Impairment	<b>(11)</b>	(11)
Total	<b>39,963</b>	47,474

The Company's trading terms with its customers are mainly on credit and the credit period generally ranges from 40 to 90 days. The Company seeks to maintain strict control over its outstanding receivables and overdue balances are regularly reviewed. The Company does not hold any collateral or other credit enhancements over its accounts receivable balances. Accounts receivable are non-interest-bearing.

The following table presents an aging analysis of the accounts receivable, based on the invoice date (\$ in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Within 3 months	<b>39,953</b>	47,474
3 months to 6 months	<b>4</b>	—
6 months to 1 year	<b>6</b>	—
Total	<b>39,963</b>	47,474

# CONSOLIDATED FINANCIAL STATEMENTS

## 7. INVENTORIES, NET

The Company's net inventory balance was \$31.6 million and \$19.0 million as of December 31, 2022 and 2021, respectively, and mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline plc ("GSK"), for distribution in Hong Kong, from NovoCure Limited ("NovoCure") for distribution in Hong Kong and mainland China, and from Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong, mainland China, and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China.

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

	December 31,	
	2022	2021
Finished goods	12,156	5,632
Raw materials	19,029	13,231
Work in progress	436	88
Inventories	31,621	18,951

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. The Company recorded write-downs in cost of sales of \$0.5 million and \$1.4 million during the years ended December 31, 2022 and 2021, respectively.

## 8. LONG-TERM INVESTMENTS

In July 2021, the Company made an equity investment in MacroGenics Inc. ("MacroGenics"), a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer, in a private placement with total contributions of \$30,000 and obtained 958,467 newly issued common shares of MacroGenics at \$31.30 per share. 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 (expenses), net in the consolidated statements of operations. The equity investments with readily determinable fair value are measured using level 1 inputs and were \$6.4 million and \$15.4 million as of December 31, 2022 and 2021, respectively. The Company recognized a fair value loss of \$9.0 million and \$14.6 million for 2022 and 2021, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 9. PROPERTY AND EQUIPMENT, NET

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

	December 31,	
	2022	2021
Office equipment	977	836
Electronic equipment	7,416	5,036
Vehicles	202	220
Laboratory equipment	18,726	17,069
Manufacturing equipment	17,055	14,600
Leasehold improvements	11,300	10,432
Construction in progress	24,251	11,334
	<b>79,927</b>	59,527
Less: accumulated depreciation	<b>(22,064)</b>	(16,425)
Property and equipment, net	<b>57,863</b>	43,102

Depreciation expense was \$7.7 million and \$6.0 million for 2022 and 2021, respectively.

## 10. 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 seven 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,	
	2022	2021
Operating fixed lease cost	<b>8,774</b>	6,263

The following table presents operating cash flows related to leases (\$ in thousands):

	Year ended December 31,	
	2022	2021
Cash paid for amounts included in measurement of lease liabilities	<b>8,084</b>	5,840
Non-cash operating lease liabilities arising from obtaining operating right-of-use assets	<b>14,801</b>	2,183

# CONSOLIDATED FINANCIAL STATEMENTS

## 10. LEASES (CONTINUED)

The maturities of lease liabilities in accordance with ASC Topic 842, Leases in each of the next five years and thereafter were as follows (\$ in thousands):

	Year ended December 31,
2023	7,561
2024	6,184
2025	4,586
2026	1,734
2027	822
Thereafter	391
Total lease payments	21,278
Less: imputed interest	(885)
Present value of minimum operating lease payments	20,393

Weighted-average remaining lease terms and discount rates are as follows:

	December 31,	
	2022	2021
Weighted-average remaining lease term	2.6 years	4.2 years
Weighted-average discount rate	3.4%	2.3%

## 11. ACCOUNTS PAYABLE

The following table presents an aging analysis of the accounts payable, based on the invoice date (\$ in thousands):

	December 31,	
	2022	2021
Within 3 months	65,249	125,709
3 months to 6 months	132	416
6 months to 1 year	577	22
Over 1 year	16	16
Total	65,974	126,163

The accounts payable are non-interest-bearing and repayable within the normal operating cycle or on demand.

# CONSOLIDATED FINANCIAL STATEMENTS

## 12. REVENUE

### Product Revenue, Net

The Company's product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The table below presents the Company's net product sales (\$ in thousands):

	Year ended December 31,	
	2022	2021
Product revenue — gross	<b>234,009</b>	190,180
Less: Rebates and sales returns	<b>(21,337)</b>	(46,075)
Product revenue — net	<b>212,672</b>	144,105

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

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

	Year ended December 31,	
	2022	2021
ZEJULA	<b>145,194</b>	93,579
Optune	<b>47,321</b>	38,903
QINLOCK	<b>14,957</b>	11,620
NUZYRA	<b>5,200</b>	3
Total product revenue — net	<b>212,672</b>	144,105

### Collaboration Revenue

The Company's collaboration revenue was \$2.4 million and \$0.2 million for 2022 and 2021, respectively. Accounts receivable arising from the Company's collaborative arrangement were nil and \$11.0 million as of December 31, 2022 and 2021, respectively. The collaboration revenue was from the Company's exclusive promotion arrangement with Huizheng.



# CONSOLIDATED FINANCIAL STATEMENTS

## 13. 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 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK\$2 million will be taxed at 16.5%. For the years ended December 31, 2022 and 2021, 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 13. INCOME TAX (CONTINUED)

### People's Republic of China

Under the Enterprise Income Tax Law of the People's Republic of China (the "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 a HNTE certificate in 2018 and began to enjoy the preferential tax rate of 15% from 2018 to 2020 and further extended the certificate in 2021 effective for 2021 to 2023. 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 and all of its subsidiaries are in cumulative loss positions for the periods presented.

The following table presents loss (income) before income taxes (\$ in thousands):

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cayman Islands	<b>19,454</b>	28,401
British Virgin Islands	<b>2</b>	2
Mainland China	<b>290,056</b>	340,865
Hong Kong	<b>53,425</b>	243,400
United States	<b>79,620</b>	89,374
Australia	<b>(260)</b>	1,758
Taiwan	<b>989</b>	671
	<b>443,286</b>	704,471

Reconciliations of the differences between the Chinese statutory income tax rate and the Company's effective income tax rate are as follows:

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Statutory income tax rate	<b>25%</b>	25%
Share-based compensation	<b>(1.40%)</b>	(0.92%)
Research and development super deduction	<b>2.51%</b>	—%
Non-deductible expenses	<b>(2.31%)</b>	(5.78%)
Prior year tax filing adjustment	<b>6.33%</b>	1.50%
Effect of different tax rate of subsidiary operation in other jurisdictions	<b>(2.85%)</b>	(4.60%)
Preferential tax rate	<b>(6.26%)</b>	(4.30%)
Changes in valuation allowance	<b>(21.02%)</b>	(10.90%)
Effective income tax rate	<b>—%</b>	—%

# CONSOLIDATED FINANCIAL STATEMENTS

## 13. INCOME TAX (CONTINUED)

### People's Republic of China (Continued)

The following table presents the principal components of deferred tax assets and liabilities (\$ in thousands):

	Year ended December 31,	
	2022	2021
Deferred tax assets:		
Depreciation of property and equipment, net	98	108
Research and experimental capitalization	22,476	—
Share-based compensation	1,787	—
Accrued expenses	1,800	—
Government grants	189	496
Deferred revenue	3,378	3,733
Qualified donation	12,947	10,246
Net operating loss carry forwards	241,397	175,101
Less: valuation allowance	(284,072)	(189,684)
Deferred tax assets, net	—	—

The Company considers positive and negative evidence to determine whether some portion or all of the deferred tax assets will be more likely than not realized. This assessment considers, among other matters, the nature, frequency, and severity of recent losses and forecasts of future profitability. These assumptions require significant judgment, and the forecasts of future taxable income are consistent with the plans and estimates the Company is using to manage the underlying businesses. Valuation allowances are established for deferred tax assets based on a more likely than not threshold. 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 2022 and 2021, the Company determined that the deferred tax assets on temporary differences and net operating loss carry forwards were related to certain subsidiaries, for which the Company is not able to conclude that the future realization of those net operating loss carry forwards and other deferred tax assets are more likely than not. As such, it has fully provided valuation allowance for the deferred tax assets as of December 31, 2022 and 2021. As of December 31, 2022 and 2021, the Company had net operating losses of approximately \$1,483.2 million and \$1,089.7 million, respectively. As of December 31, 2022, net operating loss carryforwards related to the Company's subsidiaries in mainland China, Hong Kong, Taiwan, the United States, and Australia are \$1,225.9 million, \$43.9 million, \$1.5 million, \$208.1 million, and \$3.8 million, respectively. Net operating loss carryforwards in mainland China and Taiwan expire through 2032 and those in Hong Kong, the United States, and Australia do not expire.

# CONSOLIDATED FINANCIAL STATEMENTS

## 13. INCOME TAX (CONTINUED)

### People's Republic of China (Continued)

The following table presents that movement of the valuation allowance (\$ in thousands):

	<b>2022</b>	2021
Balance as of January 1,	<b>(189,684)</b>	(105,134)
Additions	<b>(94,388)</b>	(84,550)
Balance as of December 31,	<b>(284,072)</b>	(189,684)

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.

## 14. OTHER CURRENT LIABILITIES

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

	<b>December 31,</b>	
	<b>2022</b>	2021
Payroll	<b>31,689</b>	25,685
Accrued professional service fee	<b>4,080</b>	4,319
Payables for purchase of property and equipment	<b>5,269</b>	2,568
Accrued rebate to distributors	<b>8,443</b>	15,001
Tax payables	<b>13,283</b>	8,817
Others (i)	<b>4,054</b>	4,421
Total	<b>66,818</b>	60,811

- Others mainly include accrued travel and business-related expenses.

# CONSOLIDATED FINANCIAL STATEMENTS

## 15. 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,	
	2022	2021
Numerator:		
Net loss attributable to ordinary shareholders	<b>(443,286)</b>	(704,471)
Denominator:		
Weighted average number of ordinary shares — basic and diluted	<b>958,067,140</b>	929,921,120
Net loss per share-basic and diluted	<b>(0.46)</b>	(0.76)

As a result of the Company's net loss for the years ended December 31, 2022 and 2021, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	December 31,	
	2022	2021
Share options	<b>91,181,420</b>	81,015,590
Non-vested restricted shares	<b>33,433,890</b>	9,567,360

## 16. RELATED PARTY TRANSACTIONS

The Company incurred research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd. ("MEDx"), over which an immediate family member of our Chief Executive Officer and Chairperson of the Board held significant influence. The Company incurred development expenses with MEDx of \$0.4 million and \$0.7 million during the years ended December 31, 2022 and 2021, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 17. SHARE-BASED COMPENSATION

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

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

The options granted have a contractual term of ten years and generally vest ratably over a five-year period, with 20% of the awards vesting on each anniversary of the grant date, subject to continued employment 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 set forth in an agreement between the Company and the award holder.

Upon each settlement date of certain share-based awards, shares were withheld to cover the required withholding tax, which was based on the value of a share on the settlement date as determined by the applicable 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 17. SHARE-BASED COMPENSATION (CONTINUED)

### Stock Option Activity

The following table presents a summary of option activity and related information during the year ended December 31, 2022:

	Number of options	Weighted average exercise price (\$)	Weighted average remaining contractual term (years)	Aggregate intrinsic value (\$ in thousands)
Outstanding at December 31, 2021	81,015,590	2.79	5.98	339,570
Granted	22,571,050	4.37	—	—
Exercised	(5,151,190)	1.14	—	—
Forfeited	(7,254,030)	5.66	—	—
Outstanding at December 31, 2022	<b>91,181,420</b>	<b>3.05</b>	<b>5.89</b>	<b>115,969</b>
Vested and exercisable as of December 31, 2022	<b>54,682,520</b>	<b>1.48</b>	<b>4.22</b>	<b>112,582</b>

The aggregate intrinsic value of stock options exercised during 2022 and 2021 was \$14.3 million and \$170.4 million, respectively.

### Stock Option Valuation Assumptions

The following table presents the assumptions used to estimate the fair values of the share options granted:

	2022	2021
Risk-free rate of return	1.4%–4.0%	0.9%–1.4%
Expected term (in years)	6.5	6, 6.25 or 6.5
Estimated volatility rate	65%	65%
Expected dividend rate	0%	0%

# CONSOLIDATED FINANCIAL STATEMENTS

## 17. SHARE-BASED COMPENSATION (CONTINUED)

### Non-Vested Restricted Shares Activity

The following table summarized the Company's non-vested restricted share activity in 2022:

	Numbers of non-vested restricted shares	Weighted average remaining contractual term (years)	Aggregate intrinsic value (\$ in thousands)
Non-vested as of December 31, 2021	9,567,360	3.36	60,131
Granted	30,663,040	—	—
Vested	(1,940,680)	—	—
Forfeited	(4,855,830)	—	—
Non-vested as of December 31, 2022	<b>33,433,890</b>	<b>3.55</b>	<b>102,642</b>

### Stock-Based Compensation Expenses

Options granted are measured based on grant-date fair value estimated using the Black-Scholes option pricing model. The grant-date fair value of restricted shares is the fair value of the underlying stock on the award's grant date. Compensation expense is recognized over the vesting period of the applicable awards on a straight-line basis. The weighted-average grant-date fair value per share for options granted during 2022 and 2021 were \$2.74 and \$12.60 per share, respectively. The weighted-average grant-date fair value per share for restricted shares granted in 2022 and 2021 were \$3.71 and \$10.55 per share, respectively.

The following table presents the stock-based compensation expense which has been reported in the Company's consolidated statements of operations (\$ in thousands):

	Year ended December 31, 2022	2021
Selling, general and administrative	<b>38,118</b>	23,194
Research and development	<b>23,184</b>	17,520
Total	<b>61,302</b>	40,714

As of December 31, 2022, there was unrecognized share-based compensation expense related to unvested share options and unvested restricted shares of \$101.3 million and \$128.6 million, respectively, which the Company expects to recognize over a weighted-average period of 3.34 years and 3.59 years, respectively.



# CONSOLIDATED FINANCIAL STATEMENTS

## 18. 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 payments related to certain future development, regulatory, and sales-based milestones as well as tiered royalties on future sales of licensed products in the licensed territory. 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. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item when the Company become obligated to pay, which is generally in the same fiscal year of payment unless otherwise noted. The following is a description of the Company's significant license and collaboration agreements as of December 31, 2022.

### **License and Collaboration Agreement with GSK (Niraparib)**

In September 2016, the Company entered into a collaboration, development, and license agreement with Tesaro, Inc., 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, in mainland China, Hong Kong, and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer).

To date, the Company has made an upfront payment of \$15.0 million and has paid \$16.5 million development, regulatory, and sales-based milestones, including a \$1.0 million milestone payment accrued in 2020 and made in 2021, a \$4.0 million milestone payment made in 2022, and a \$3.5 million development milestone and \$8.0 million sales-based milestone paid in 2022, which were accrued in 2019 and 2021, respectively.

The Company may be required to pay an additional aggregate amount of up to \$28.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentages rates ranging from mid- to high-teens on annual net sales of the licensed products in the licensed territories.

### **License and Collaboration Agreement with Paratek Bermuda Ltd. ("Paratek") (Omadacycline)**

In April 2017, the Company entered into a license and collaboration agreement with Paratek, 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 (ZL-2401) as an active ingredient in Greater China in the field of all human therapeutic and preventative uses other than biodefense.

# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### License and Collaboration Agreement with Paratek Bermuda Ltd. (“Paratek”) (Omadacycline) (Continued)

To date, the Company has made an upfront payment of \$7.5 million and has paid \$14.0 million in development and regulatory milestone payments, including a \$5.0 million development milestone payment upon approval by the U.S. Food and Drug Administration (“FDA”) of a New Drug Application submission in 2018, a \$3.0 million development milestone payment upon submission of the first regulatory approval application for a licensed product in the People’s Republic of China paid in 2020, and a \$6.0 million development milestone upon regulatory approval of omadacycline for the treatment of adults with ABSSSI and CABP in the People’s Republic of China accrued in December 2021 and paid in 2022.

The Company may be required to pay an additional aggregate amount of up to \$40.5 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentages rates ranging from low- to mid-teens on annual net sales of 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 Therapeutics, Inc. (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.

To date, the Company has made an upfront payment of \$5.0 million and a milestone payment of \$2.0 million. 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 ranging from high-teens to low twenties on annual net sales of the licensed product 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 product outside of the licensed territory until the tenth (10th) anniversary of the first commercial sale of each such licensed product outside the licensed territory.

# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### **License and Collaboration Agreement with Entasis Therapeutics Holdings Inc. (“Entasis”) (SUL-DUR)**

In April 2018, the Company entered into a license and collaboration agreement with Entasis, pursuant to which it obtained an exclusive license under certain patents and know-how of Entasis to develop and commercialize products containing Entasis’ proprietary compounds known as durlobactam (ETX2514) and Sulbactam (ETX2514SUL) as an active ingredient 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’s rights to develop and commercialize the licensed products are limited to the lead product (Sulbactam) until such lead product receives initial FDA approval in the United States.

To date, the Company has made an upfront payment of \$5.0 million and two development milestone payments totaling \$7.0 million. The Company may be required to pay an additional aggregate amount of up to \$91.6 million in development and commercial 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 clinical trial of SUL-DUR outside of the territory.

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

### **License and Collaboration Agreement with Crescendo Biologics Ltd. (“Crescendo”) (ZL-1102)**

In May 2018, the Company entered into an agreement with Crescendo, pursuant to which the Company obtained an exclusive, worldwide license to develop, commercialize, and manufacture ZL-1102, a topical, innovative antibody VH domain therapeutic for all indications. Pursuant to the terms of the agreement, the Company will be responsible for conducting all regulatory filings, clinical studies, and commercialization activities, with both companies participating in a Joint Development Committee.

In October 2020, the Company and Crescendo entered into a supplemental license agreement, under which Crescendo granted to the Company a non-exclusive, worldwide license to use the Crescendo VH HLEs in connection with the development, commercialization, manufacture, and other exploitation of VH HLE licensed products.

To date, the Company has made two upfront fee payments totaling \$4.5 million, including a \$2.5 million payment in 2020, and three milestone payments totaling \$6.0 million, including a \$2.0 million payment in 2020 and a \$4.0 million payment in 2021. The Company may be required to pay an additional aggregate amount of up to \$298.1 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual global sales.

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

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### 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 Tumor Treating Fields products in all human therapeutic and preventative uses in the field of oncology in Greater China.

To date, the Company has made an upfront payment of \$15.0 million in 2018 and two milestone payments totaling \$10.0 million made in 2020. The Company may be required to pay an additional aggregate amount of up to \$68.0 million in development, 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. The Company will purchase licensed products exclusively from NovoCure at NovoCure's fully burdened manufacturing cost.

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

### License and Collaboration Agreements with MacroGenics (including Margetuximab and Tebotelimab)

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

To date, the Company has made an upfront payment of \$25.0 million and three milestone payments totaling \$9.0 million, including \$4.0 million paid in 2020 and \$5.0 million accrued in 2021 but paid in 2022. The Company may be required to pay an additional aggregate amount of up to \$84.0 million in development and regulatory milestones as well as certain royalties at tiered percentage rates ranging from low-teens to twenties on annual net sales of the licensed products in the licensed territory. The tebotelimab program was terminated in 2022, but the Company continue to collaborate with respect to the other licensed products.

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

# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### **License and Collaboration Agreements with MacroGenics (including Margetuximab and Tebotelimab) (Continued)**

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

To date, the Company has made an upfront payment of \$25.0 million in 2021. Further, on June 15, 2021, as partial consideration for the rights granted to us under this agreement, the Company entered into a stock purchase agreement with MacroGenics, pursuant to which the Company purchased from MacroGenics in a private placement an aggregate of 958,467 newly issued shares of common stock, par value \$0.01 per share, of MacroGenics, with a per share purchase price of \$31.30, for aggregate gross proceeds of approximately \$30.0 million. The Company may be required to pay an additional aggregate amount of up to \$1,386.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual net sales of specified products, subject to reduction under specified circumstances. The Company also has an option to convert the royalty arrangement for the lead research molecule to a global 50/50 profit and loss sharing arrangement by making a payment of approximately \$85.0 million.

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

### **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.

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### License and Collaboration Agreement with Deciphera (Ripretinib) (Continued)

To date, the Company has made an upfront payment of \$20.0 million and three milestone payments totaling \$12.0 million, including \$2.0 million paid in 2020 and \$5.0 million paid in 2021. 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.

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

### License and Collaboration Agreement with Incyte Corporation (“Incyte”) (Retifanlimab)

In July 2019, the Company entered into a collaboration and license agreement with Incyte, pursuant to which it obtained an exclusive license under certain patents and know-how of Incyte to develop and commercialize products containing retifanlimab (INCMGA012) as an active ingredient in the treatment, palliation, diagnosis, or prevention of diseases in the fields of hematology or oncology in humans in Greater China. The Company terminated this license agreement, in accordance with its terms, effective January 11, 2023.

### Collaboration Agreement with Regeneron Pharmaceuticals, Inc (“Regeneron”) (Odronextamab)

In April 2020, the Company entered into a collaboration agreement with Regeneron Ireland Designated Activity Company, an affiliate of Regeneron, pursuant to which it obtained oncology development and exclusive commercialization rights for products containing odronextamab as the sole active ingredient in Greater China. The Company also obtained a right of first negotiation for additional indications outside the field of cancer.

To date, the Company has made an upfront payment of \$30.0 million in 2020. The Company may be required to pay an additional aggregate amount of up to \$160.0 million in regulatory and sales-based milestones. Additionally, the Company will make payments to Regeneron based on annual net sales, such that Regeneron shares in a significant portion of any potential profits. The Company is also responsible for contributing to the global development costs of odronextamab for certain trials and will purchase odronextamab exclusively from Regeneron.

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

# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### **License Agreement with BMS (Formerly Turning Point Therapeutics Inc (“Turning Point”)) (Repotrectinib and TPX-0022)**

In July 2020, the Company entered into an exclusive license agreement with Turning Point (a company later acquired by 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.

To date, the Company has made an upfront payment of \$25.0 million in 2020 and three milestone payments in 2021 totaling \$5.0 million. The Company may be required to pay an additional aggregate amount of up to \$146.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from mid- to high-teens on annual net sales of the licensed product in the licensed territory.

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

In January 2021, the Company entered into an additional license agreement with Turning Point, which expanded their collaboration. Under the terms of this agreement, the Company obtained an exclusive license under certain patents and know-how to develop and commercialize products containing Turning Point’s product candidate, TPX-0022, as an active ingredient in all human therapeutic indications in Greater China.

To date, the Company has made an upfront payment of \$25.0 million. the Company may be required to pay an additional aggregate amount of up to \$336.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from mid-teen to low twenties on annual net sales of the licensed products in the licensed territory. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology product candidate discovered by the Company.

### **License Agreement with Taiho Pharmaceutical Co., Ltd. (“Taiho”) (formerly Cullinan Pearl Corp. (“Cullinan Pearl”)) (Zipalertinib, formerly CLN-081)**

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

# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### **License Agreement with Taiho Pharmaceutical Co., Ltd. (“Taiho”) (formerly Cullinan Pearl Corp. (“Cullinan Pearl”)) (Zipalertinib, formerly CLN-081) (Continued)**

To date, the Company has made an upfront payment of \$20.0 million, which was accrued in 2020 and paid in 2021. The Company may be required to pay an additional aggregate amount of up to \$211.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from high-single-digit to low-teens on annual net sales of the licensed product in the licensed territory. Cullinan Pearl received worldwide rights for CLN-081, excluding Japan, from Taiho in 2018. In June 2022, Taiho acquired Cullinan Pearl and obtained exclusive global rights to CLN-081 outside of the United States. In December 2022, the Company agreed with Taiho on the assignment of our license agreement with Cullinan Pearl to Taiho.

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

### **License Agreement with Takeda Pharmaceutical Company Limited (“Takeda”) (Simurosertib)**

In December 2020, the Company entered into an exclusive license agreement with Takeda. Under the terms of the license agreement, Takeda exclusively licensed to the Company the right to research, develop, and commercialize the licensed products in the licensed field during the term. To date, the Company has made an upfront payment of \$6.0 million to Takeda, which was accrued in 2020 and paid in 2021. This program was terminated in 2022.

### **Collaboration and License Agreement with argenx BV (“argenx”) (Efgartigimod)**

In January 2021, the Company entered into a collaboration and license agreement with argenx pursuant to which the Company received 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.

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 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. In addition, the Company made a \$75.0 million cash payment as a guarantee for non-creditable, non-refundable development cost-sharing payment in 2021.



# CONSOLIDATED FINANCIAL STATEMENTS

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### **Collaboration and License Agreement with argenx BV (“argenx”) (Efgartigimod) (Continued)**

The Company has made a milestone payment of \$25.0 million in 2022 which was accrued in the fourth quarter of 2021 related to the first regulatory approval for the licensed product by the FDA in December 2021.

The Company may be required to pay certain royalties at tiered percentages rates ranging from mid-teen to low-twenties on annual net sales of the licensed products in the licensed territory.

### **Collaboration and License Agreement with Mirati Therapeutics, Inc. (“Mirati”) (Adagrasib)**

In May 2021, the Company entered into a collaboration and license agreement with Mirati pursuant to which the Company obtained the right to research, develop, manufacture, and exclusively commercialize adagrasib in all indications in Greater China, with Mirati retaining exclusive rights for the development, manufacturing, and commercialization of adagrasib outside of Greater China and certain co-commercialization, manufacture, and development rights in Greater China.

To date, the Company has made an upfront payment of \$65.0 million to Mirati in 2021 and two development milestone payments totaling \$10.0 million in 2022. The Company may be required to pay an additional aggregate amount of up to \$263.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from high-teens to low-twenties on annual net sales of the licensed product in the licensed territory.

### **Collaboration and License Agreement with Blueprint Medicines Corporation (“Blueprint”) (BLU-945 and BLU-701)**

In November 2021, the Company entered into a collaboration and license agreement with Blueprint, pursuant to which the Company obtained rights to develop and exclusive commercialize BLU-701 and BLU-945 and BLU-701 and certain other forms thereof, including backup compounds, for the treatment of patients with EGFR-driven non-small cell lung cancer in Greater China.

To date, the Company has made an upfront payment of \$25.0 million in 2021. The Company may be required to pay an additional aggregate amount of up to \$590.0 million in clinical, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from the low- to mid-teens on annual net sales of the licensed products in the licensed territory. Blueprint deprioritized BLU-701 in 2022, but the Company continue to collaborate with respect to BLU-945.

The Company has the right to terminate this agreement after the second anniversary of the effective date by providing written notice of termination to Blueprint.

## 18. LICENSE AND COLLABORATION AGREEMENTS (CONTINUED)

### License Agreement with Karuna Therapeutics, Inc. (“Karuna”) (KarXT)

In November 2021, the Company entered into a license agreement with Karuna, pursuant to which the Company obtained an exclusive license to develop, manufacture, and commercialize KarXT (xanomeline-trospium) in Greater China.

To date, the Company has made an upfront payment of \$35.0 million in 2021 and two development milestone payments totaling \$10.0 million in 2022. The Company may be required to pay an additional aggregate amount of up to \$142.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of the licensed products in Greater China.

### Collaboration and License Agreement with Seagen Inc. (“Seagen”) (TIVDAK)

In September 2022, the Company entered into a collaboration and license agreement with Seagen, pursuant to which the Company and Seagen agreed to collaboratively develop and commercialize TIVDAK (tisotumab vedotin). Under the agreement, the Company obtained an exclusive license to develop and commercialize TIVDAK in Greater China.

To date, the Company has made an upfront payment of \$30.0 million in 2022. The Company may be required to pay an additional aggregate amount of up to \$263.0 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.

The agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The agreement contains 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, for certain bankruptcy events, and by Seagen upon a challenge of the licensed patent rights.

### Aggregate Potential Payments under License and Collaboration Agreements

As noted above, the Company has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Company is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management’s evaluation of the progress of each project noted above, as of December 31, 2022, the Company may be required to pay licensors an aggregate additional amount of up to approximately \$5,300.4 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentage rates on annual net sales. The development milestones, such as regulatory approval for the product candidates, may occur before the Company has commercialized the product or received any revenue from sales of such product candidate. These milestone payments are subject to uncertainties and contingencies and may not occur.

# CONSOLIDATED FINANCIAL STATEMENTS

## 19. OTHER INCOME (EXPENSES), NET

The following table presents other income (expenses), net (\$ in thousands):

	Year ended December 31,	
	2022	2021
Government grants	11,471	4,113
Loss on equity investments with readily determinable fair value	(8,952)	(14,617)
Others miscellaneous gain	594	303
Total	3,113	(10,201)

## 20. 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, 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 during the years ended December 31, 2022 and 2021 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 Chinese subsidiaries from transferring out funds in the form of dividends, loans, and advances. As of December 31, 2022 and 2021, amounts restricted are the paid-in capital of the Company's Chinese subsidiaries, which amounted to \$456.0 million and \$406.0 million, respectively.

# CONSOLIDATED FINANCIAL STATEMENTS

## 21. 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 China mainland 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 \$23.6 million and \$17.6 million for 2022 and 2021, 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. In 2022, the Company makes a matching contribution equal to 50% of the first 5% of the employee's elective contributions under the plan, up to 2.5% 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, was \$0.5 million in 2022 and was not material in 2021.

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 2022 and was not material in 2021.

There is no forfeiture of contribution related to any of the Company's employee defined contribution plans as described above.

## 22. COMMITMENTS AND CONTINGENCIES

### (a) Purchase Commitments

The Company's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statements were \$9.0 million as of December 31, 2022 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.

# CONSOLIDATED FINANCIAL STATEMENTS

## 22. COMMITMENTS AND CONTINGENCIES (CONTINUED)

### (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.

## 23. DIRECTOR AND CHIEF EXECUTIVE REMUNERATION

Director and chief executive remuneration for the years ended December 31, 2022 and 2021 are disclosed pursuant to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "HK Listing Rules"), section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance, and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation and are as follows (\$ in thousands):

	Year ended December 31,	
	2022	2021 (unaudited)
Fees	473	355
Other emoluments:		
Salaries, allowances and benefits in kind	861	1,262
Performance related and discretionary bonuses	832	1,108
Share-based compensation expenses*	12,438	10,601
Pension scheme contributions	6	11
	<b>14,137</b>	12,982
	<b>14,610</b>	13,337

\* The fair value of share-based compensation, which has been recognized in the consolidated statements of operations over the vesting period, was determined on the date of grant in accordance with ASC 718, Compensation-Stock Compensation under U.S. GAAP. Refer to Note 17 for additional information.

None of the Company's directors waived any emoluments during 2022 and 2021.

During 2022 and 2021, no emoluments were paid or payable by the Company to any of the Company's directors as an inducement to join or upon joining the Company or as compensation for loss of office.

# CONSOLIDATED FINANCIAL STATEMENTS

## 23. DIRECTOR AND CHIEF EXECUTIVE REMUNERATION (CONTINUED)

The remuneration of each director for the years ended December 31, 2022 and 2021 were as follows (\$ in thousands):

Year ended December 31, 2022	Fees	Salaries, allowances and benefits in kind	Performance related and discretionary bonuses	Share-based compensation expense	Pension scheme contributions	Total remuneration
<b>Executive director and chief executive</b>						
Dr. Samantha Du <sup>Note (i)</sup>	—	861	832	9,438	6	11,137
<b>Independent non-executive directors</b>						
Dr. Kai-Xian Chen	56	—	—	500	—	556
Dr. John Diekman	88	—	—	500	—	588
Ms. Nisa Leung	—	—	—	—	—	—
Mr. William Lis	61	—	—	500	—	561
Mr. Leon O. Moulder, Jr.	68	—	—	500	—	568
Mr. Peter Wirth	75	—	—	500	—	575
Mr. Scott W. Morrison	64	—	—	250	—	314
Mr. Richard Gaynor, M.D.	61	—	—	250	—	311

Year ended December 31, 2021 (Unaudited)	Fees	Salaries, allowances and benefits in kind	Performance related and discretionary bonuses	Share-based compensation expense	Pension scheme contributions	Total remuneration
<b>Executive director and chief executive</b>						
Dr. Samantha Du <sup>Note (i)</sup>	—	800	864	6,384	4	8,052
<b>Executive director</b>						
Mr. Tao Fu <sup>Note (i)(ii)</sup>	—	462	244	1,515	7	2,228
<b>Independent non-executive directors</b>						
Dr. Kai-Xian Chen	51	—	—	521	—	572
Dr. John Diekman	75	—	—	521	—	596
Ms. Nisa Leung	—	—	—	—	—	—
Mr. William Lis	66	—	—	521	—	587
Mr. Leon O. Moulder, Jr.	68	—	—	535	—	603
Mr. Peter Wirth	75	—	—	521	—	596
Mr. Scott W. Morrison	13	—	—	54	—	67
Mr. Richard Gaynor, M.D.	7	—	—	29	—	36

Notes:

- (i) The Company compensates its independent non-executive directors pursuant to its non-employee director compensation policy. Executive officers that also serve as directors, including Dr. Samantha Du and Mr. Tao Fu, are not compensated separately for their services to the Company as directors.
- (ii) Effective on May 7, 2021, the Board appointed Mr. Tao Fu as Chief Strategy Officer of the Company. Concurrent with this appointment, Mr. Tao Fu resigned from his positions as President and Chief Operating Officer of the Company and from his position as an executive director of the Company, effective immediately.

# CONSOLIDATED FINANCIAL STATEMENTS

## 24. FIVE HIGHEST PAID INDIVIDUALS

The five highest paid individuals for the years ended December 31, 2022 and 2021 included the following number of directors and chief executive (headcount):

	Year ended December 31,	
	2022	2021
		(unaudited)
Director and chief executive#	1	1
Neither director nor chief executive	4	4
	5	5

# Details of the remuneration of the Director and chief executive are set out in Note 23 above.

The aggregate of the emoluments in respect of the remaining individuals who are neither a director nor chief executive of the Company are as follows (\$ in thousands):

	Year ended December 31,	
	2022	2021
		(unaudited)
Salaries, allowances and benefits in kind	2,238	2,092
Performance related and discretionary bonuses	1,084	1,187
Share-based compensation expenses*	12,176	8,671
Pension scheme contributions	34	37
Inducement to join or upon joining the Company	—	300
	15,532	12,287

\* The fair value of share-based compensation, which has been recognized in the consolidated statements of operations over the vesting period, was determined on the date of grant in accordance with ASC 718, *Compensation — Stock Compensation* under U.S. GAAP. Refer to Note 17 for additional information.

# CONSOLIDATED FINANCIAL STATEMENTS

## 24. FIVE HIGHEST PAID INDIVIDUALS (CONTINUED)

The number of non-director and non-chief executive highest paid individuals whose remuneration fell within the following bands is as follows (headcount):

	2022	2021 (unaudited)
HK\$22,000,001 to HK\$22,500,000	—	1
HK\$23,500,001 to HK\$24,000,000	—	2
HK\$25,500,001 to HK\$26,000,000	—	1
HK\$26,500,001 to HK\$27,000,000	1	—
HK\$29,000,001 to HK\$29,500,000	1	—
HK\$29,500,001 to HK\$30,000,000	1	—
HK\$36,000,001 to HK\$36,500,000	1	—
	<b>4</b>	<b>4</b>

Share-based compensation amount is included in the above disclosures. The fair value of share-based compensation, which has been recognized in the consolidated statements of operations over the vesting period, was determined on the date of grant in accordance with ASC 718, *Compensation — Stock Compensation* under U.S. GAAP. Refer to Note 17 for additional information.

During 2022 and 2021, no emoluments were paid or payable by the Company to any of the five highest paid individuals of the Company as compensation for loss of office.

## 25. AUDITORS' REMUNERATION

The fees paid or payable by the Company in relation to audit services for the year ended December 31, 2022 and 2021 (unaudited) were \$4.7 million and \$1.2 million, respectively. The auditor's remuneration paid or payable by the Company in relation to non-audit services for the year ended December 31, 2022 and 2021 (unaudited) were nil and \$0.1 million, respectively.

## 26. DIVIDENDS

The Board did not recommend any final dividend for the years ended December 31, 2022 and 2021.



# FINANCIAL STATEMENTS SCHEDULE I — FINANCIAL INFORMATION OF PARENT COMPANY

## PARENT COMPANY CONSOLIDATED BALANCE SHEET

(\$ in thousands except for number of shares and per share data)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	944,649	591,842
Short-term investments	—	445,000
Prepayments and other current assets	10,203	2,364
Total current assets	954,852	1,039,206
Investment in subsidiaries	93,363	341,980
<b>Total assets</b>	<b>1,048,215</b>	<b>1,381,186</b>
<b>Liabilities and shareholders' equity</b>		
<b>Liabilities</b>		
Current liabilities:		
Other current liabilities	2,620	996
Total current liabilities	2,620	996
Deferred income	—	234
<b>Total liabilities</b>	<b>2,620</b>	<b>1,230</b>
<b>Shareholders' equity</b>		
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized, 962,455,850 and 955,363,980 shares issued as of December 31, 2022 and 2021, respectively; 960,219,570 and 954,981,050 shares issued and outstanding as of December 31, 2022 and 2021, respectively)		
	6	6
Additional paid-in capital	2,893,120	2,825,948
Accumulated deficit	(1,861,360)	(1,418,074)
Accumulated other comprehensive income (loss)	25,685	(23,645)
Treasury stock	(11,856)	(4,279)
<b>Total shareholders' equity</b>	<b>1,045,595</b>	<b>1,379,956</b>
<b>Total liabilities and shareholders' equity</b>	<b>1,048,215</b>	<b>1,381,186</b>

## FINANCIAL STATEMENTS SCHEDULE I — FINANCIAL INFORMATION OF PARENT COMPANY

### PARENT COMPANY STATEMENTS OF SHAREHOLDERS' EQUITY

(\$ in thousands except for number of shares and per share data)

	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 December 31, 2020	878,110,260	5	1,897,467	(713,603)	(14,524)	—	—	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	2,054,500	0	0	—	—	—	—	—
Exercise of shares option	12,353,400	0	7,417	—	—	—	—	7,417
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of \$839	57,164,000	1	818,035	—	—	—	—	818,036
Issuance of ordinary shares in connection with collaboration and license arrangement (Note 18)	5,681,820	0	62,250	—	—	—	—	62,250
Issuance cost adjustment for secondary listing	—	—	65	—	—	—	—	65
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(382,930)	(4,279)	(4,279)
Share-based compensation	—	—	40,714	—	—	—	—	40,714
Net loss	—	—	—	(704,471)	—	—	—	(704,471)
Foreign currency translation	—	—	—	—	(9,121)	—	—	(9,121)
<b>Balance at December 31, 2021</b>	<b>955,363,980</b>	<b>6</b>	<b>2,825,948</b>	<b>(1,418,074)</b>	<b>(23,645)</b>	<b>(382,930)</b>	<b>(4,279)</b>	<b>1,379,956</b>
Issuance of ordinary shares upon vesting of restricted shares	<b>1,940,680</b>	<b>0</b>	<b>0</b>	—	—	—	—	—
Exercise of shares option	<b>5,151,190</b>	<b>0</b>	<b>5,870</b>	—	—	—	—	<b>5,870</b>
Receipt of employees' shares 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
<b>Balance at December 31, 2022</b>	<b>962,455,850</b>	<b>6</b>	<b>2,893,120</b>	<b>(1,861,360)</b>	<b>25,685</b>	<b>(2,236,280)</b>	<b>(11,856)</b>	<b>1,045,595</b>

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

# FINANCIAL STATEMENTS SCHEDULE I — FINANCIAL INFORMATION OF PARENT COMPANY

## RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS

The consolidated financial statements of the Company are prepared in accordance with U.S. GAAP, which differ in certain respects from the International Financial Reporting Standards (“IFRS”). The following tables present the effect of material differences on the financial information of the Company prepared under U.S. GAAP and IFRS, as of and for the year ended December 31, 2022 and 2021 (the “Reconciliation Statements”).

The following information is extracted from the consolidated financial statements as of and for the year ended December 31, 2022, which were prepared for the purpose of these Reconciliation Statements in accordance with the accounting policies that are consistent with the recognition and measurement requirements of IFRS, and audited by KPMG, Certified Public Accountants.

### Reconciliation of consolidated statements of operations (\$ in thousands)

Consolidated statements of operations	Year ended December 31, 2022		
	IFRS adjustments		
	Amounts as reported under U.S. GAAP	Share-based compensation (note (i))	Amounts as reported under IFRS
Expenses			
Research and development	(286,408)	(4,726)	(291,134)
Selling, general and administrative	(258,971)	(10,644)	(269,615)
Net loss	(443,286)	(15,370)	(458,656)
Net loss attributable to ordinary shareholders	(443,286)	(15,370)	(458,656)

Consolidated statements of operations	Year ended December 31, 2021		
	IFRS adjustments		
	Amounts as reported under U.S. GAAP	Share-based compensation (note (i))	Amounts as reported under IFRS
Expenses			
Research and development	(573,306)	(6,436)	(579,742)
Selling, general and administrative	(218,831)	(7,014)	(225,845)
Net loss	(704,471)	(13,450)	(717,921)
Net loss attributable to ordinary shareholders	(704,471)	(13,450)	(717,921)

## FINANCIAL STATEMENTS SCHEDULE I — FINANCIAL INFORMATION OF PARENT COMPANY

### RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS (CONTINUED)

#### Reconciliation of consolidated balance sheets (\$ in thousands)

	As of December 31, 2022		
	IFRS adjustments		
	Amounts as reported under U.S. GAAP	Share-based compensation (note (i))	Amounts as reported under IFRS
<b>Consolidated balance sheets</b>			
Additional paid-in capital	2,893,120	46,070	2,939,190
Accumulated deficit	(1,861,360)	(46,070)	(1,907,430)
Total shareholders' equity	1,045,595	—	1,045,595

	As of December 31, 2021		
	IFRS adjustments		
	Amounts as reported under U.S. GAAP	Share-based compensation (note (i))	Amounts as reported under IFRS
<b>Consolidated balance sheets</b>			
Additional paid-in capital	2,825,948	30,700	2,856,648
Accumulated deficit	(1,418,074)	(30,700)	(1,448,774)
Total shareholders' equity	1,379,956	—	1,379,956

#### NOTES:

##### (i) Share-based compensation

Under U.S. GAAP, the Company has elected to use the straight-line method to recognize compensation expense for instruments granted to employees with graded vesting based on service conditions, subject to the minimum amount of cumulative compensation expense recognized is not less than the portion of the award vested to date.

Under IFRS, the graded vesting method must be applied to recognize compensation expense.

In addition, under U.S. GAAP, the Company has elected to recognize the effect of forfeitures as they occur, and previously recognized compensation cost is reversed in the period that the award is forfeited.

Under IFRS, the number of instruments that are expected to vest are estimated by the Company initially. Subsequently, these estimates are trued up for differences between the number of instruments expected to vest and the actual number of instruments vested.

# FINANCIAL STATEMENTS SCHEDULE I — FINANCIAL INFORMATION OF PARENT COMPANY

## NOTES: (CONTINUED)

### (i) Share-based compensation (Continued)

A difference of \$15.4 million arose between the amount of share-based compensation (included in research and development expenses, and selling, general and administrative expenses) recognized under U.S. GAAP and IFRS for the year ended December 31, 2022 (the difference was \$13.5 million for the year ended December 31, 2021).

The accumulated difference on share-based compensation recognized in accumulated deficit and additional paid in capital under U.S. GAAP and IFRS was \$46.1 million as of December 31, 2022 (the accumulated difference was \$30.7 million as of December 31, 2021).

### (ii) Leases

Under U.S. GAAP, as a lessee, the Company recognized a lease liability based on the present value of the total remaining lease payments, and a corresponding right of use asset. The amortization of the right-of-use assets and the interest expenses related to the lease liabilities are recorded together as a single total lease expense on a straight-line basis on the consolidated statements of operations.

Under IFRS, the amortization of the right-of-use assets is recognized on a straight-line basis while the interest expense related to the lease liabilities is recognized on the basis that the lease liabilities are measured at amortized cost. Compared to the U.S. GAAP, this changes the allocation and the total amount of expenses recognized for each period of the lease terms, and results in a higher total charge to profit or loss in the early years and a decreasing expense during the latter years of the lease terms. The amortization on the right-of-use assets and the interest expense on the lease liabilities are separately recorded on the consolidated statements of operations.

Based on the Company's assessment, the differences on leases recognized under U.S. GAAP and IFRS did not have material impact on the consolidated financial statements as of and for the years ended December 31, 2022 and 2021.

# DEFINITIONS

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“2015 Plan”	the 2015 Equity Incentive Plan approved by the Board on March 5, 2015 and most recently amended with effect on April 10, 2016
“2017 Plan”	the 2017 Equity Incentive Plan approved by the Board on August 7, 2017
“2022 Plan”	the 2022 Equity Incentive Plan approved by the Board and at the Company’s 2022 annual general meeting of shareholders on April 20, 2022 and June 22, 2022, respectively
“AACR”	American Association for Cancer Research
“ADS(s)”	American depositary share(s), each representing ten ordinary shares, on deposit with a U.S. banking institution selected by the Company and which are registered pursuant to a Form F-1
“affiliate(s)”	with respect to any specified person or any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Amended AML”	amendments to the PRC Anti-Monopoly Law, which was published by the SCNPC on June 24, 2022 and came into effect on August 1, 2022
“America Invents Act”	Leahy-Smith America Invents Act, which was signed into law in September 2011
“Arrangement”	Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned
“BLA”	Biologics License Application
“BMTPZ”	Hainan Bo’ao Lecheng International Medical Tourism Pilot Zone
“Board”	the board of directors of the Company
“CAC”	Cyberspace Administration of China
“CDE”	Center for Drug Evaluation of the NMPA
“CFIUS”	the Committee on Foreign Investment in the United States
“CG Code”	the Corporate Governance Code as set out in Appendix 14 of the HK Listing Rules
“chief executive”	has the meaning ascribed to it in the HK Listing Rules
“China”, “P.R. China” or the “PRC”	the People’s Republic of China
“CJEU”	Court of Justice of the European Union

## DEFINITIONS

“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented, or otherwise modified from time to time
“Company”, “we” or “us”	Zai Lab Limited, a company incorporated in the Cayman Islands with limited liability on March 28, 2013, and its subsidiaries from time to time
“Crescendo”	Crescendo Biologics Ltd.
“CSRC”	China Securities Regulatory Commission
“CTA”	clinical trial application
“Draft Management Regulations”	Regulations on Network Data Security Management (Draft for Comment)
“Deciphera”	Deciphera Pharmaceuticals, LLC
“Director(s)”	the director(s) of the Company
“DP”	drug product
“DS”	drug substance
“EEA”	European Economic Area
“EIT Law”	the Enterprise Income Tax Law of the People’s Republic of China
“EMA”	European Medicines Agency
“ESG”	Environmental, Social and Governance
“FCPA”	U.S. Foreign Corrupt Practices Act
“FDA”	U.S. Food and Drug Administration
“Fifth Restated Articles”	the Fifth Amended and Restated Memorandum of Association adopted by a special resolution passed on September 4, 2020, and the Fifth Amended and Restated Articles of Association adopted by a special resolution passed on June 24, 2021
“Five Prime”	Five Prime Therapeutics, Inc.
“GDPR”	General Data Protection Regulation
“Global Offering”	the global offering of the Company as described in the Prospectus
“GLP”	Good Laboratory Practices
“Greater China”	mainland China, Hong Kong, the Macau Special Administrative Region of the PRC, and Taiwan

## DEFINITIONS

“GSK”	GlaxoSmithKline plc
“Hanhui”	Hanhui Pharmaceutical Co., Ltd.
“HFCAA”	Holding Foreign Companies Accountable Act, as amended
“HGRAC”	Human Genetic Resources Administration Office of China
“HIPAA”	the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations
“HK dollar” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“HK Listing Rules”	the Rules governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented, or otherwise modified from time to time
“HKMA”	Hong Kong Monetary Authority
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong Share Register”	a branch register of members in Hong Kong on which our ordinary shares that are traded on the Hong Kong Stock Exchange are registered
“Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Huizheng”	Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.
“Internal Revenue Code”	the Internal Revenue Code of 1986, as amended
“IRA”	the Inflation Reduction Act
“Latest Practicable Date”	April 21, 2023, being latest practicable date prior to the issue of this annual report
“M&A Rules”	the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors
“MAA”	marketing authorization application
“MLPS”	multi-level protection scheme
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 of the HK Listing Rules
“Nasdaq”	Nasdaq Global Market
“NDA”	new drug application



## DEFINITIONS

“New Arrangement”	the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region
“NHTA”	National Healthcare Security Administration of the People’s Republic of China
“NMPA”	National Medical Products Administration of the People’s Republic of China
“NovoCure”	NovoCure Ltd.
“NRDL”	National Reimbursement Drug List
“ordinary share(s)”	ordinary share(s) in the authorized share capital of the Company with a par value of \$0.000006 per share (or \$0.00006 per share where “before Share Subdivision” is indicated)
“Paratek”	Paratek Pharmaceuticals, Inc.
“PBOC”	People’s Bank of China
“PCAOB”	U.S. Public Company Accounting Oversight Board
“PFIC”	a passive foreign investment company
“Primary Conversion Effective Date”	the date on which the Company’s voluntary conversion from secondary listing status to primary listing on the Hong Kong Stock Exchange became effective, i.e., June 27, 2022
“Prospectus”	the prospectus of the Company dated September 17, 2020
“PSUs”	performance-based restricted share units
“R&D”	research and development
“Reporting Period”	the year ended December 31, 2022
“RMB” or “Renminbi”	Renminbi, the lawful currency of PRC
“RSAs”	restricted shares
“RSUs”	restricted share units
“SAFE”	State Administration of Foreign Exchange of China
“SAT”	State Taxation Administration of the People’s Republic of China
“SCNPC”	Standing Committee of the National People’s Congress
“SEC”	U.S. Securities and Exchange Commission

## DEFINITIONS

“Securities Act”	the Securities Act of 1933, as amended
“Security Assessment Measures”	Measures on Security Assessment of Cross-Border Data Transfer
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented, or otherwise modified from time to time
“Share(s)”	ordinary share(s), or ADS(s) represented by such number of ordinary shares
“Shareholder(s)”	holder(s) of the Share(s)
“Share Subdivision”	the subdivision of each of the Company’s issued and unissued ordinary shares into ten ordinary shares effective as of March 30, 2022
“Sixth Restated Articles”	the Sixth Amended and Restated Memorandum and Articles of Association adopted by a special resolution passed on June 22, 2022
“subsidiary(ies)”	has the meaning ascribed to it thereto in section 15 of the Companies Ordinance
“substantial shareholder”	has the meaning ascribed to it in the HK Listing Rules
“supplemental insurance plans”	regional customized commercial health insurance plans guided by provincial or municipal governments
“Takeda”	Takeda Pharmaceutical Company Limited
“United States” or “U.S.”	the United States of America, its territories, its possessions, and all areas subject to its jurisdiction
“U.S. dollars”, “US\$”, or “\$”	United States dollars, the lawful currency of the United States
“U.S. GAAP”	United States generally accepted accounting principles
“USPTO”	United States Patent and Trademark Office

# GLOSSARY OF TECHNICAL TERMS

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“ABSSSI”	acute bacterial skin and skin structure infections
“ADC”	antibody drug conjugate
“ADCC”	antibody-dependent cellular cytotoxicity
“ADCP”	antibody-dependent cellular phagocytosis
“anti-AchR”	anti-acetylcholine receptor
“bemarituzumab FPA144-004 Study”	bemarituzumab (FPA144) in combination with FOLFOX in front-line gastric and gastroesophageal cancer
“CABP”	community-acquired bacterial pneumonia
“CI”	confidence interval
“CIDP”	chronic inflammatory demyelinating polyneuropathy
“CNS”	central nervous system
“cORR”	confirmed objective response rate
“CRAB”	carbapenem-resistant Acinetobacter baumannii
“CRABC”	CRAB-calcoaceticus
“CRC”	colorectal cancer
“DCR”	disease control rate
“DLBCL”	diffuse large B-cell lymphoma
“DOR”	duration of response
“EGFR”	epidermal growth factor receptor
“FcRn”	neonatal Fc receptor

## GLOSSARY OF TECHNICAL TERMS

“FL”	follicular lymphoma
“GBM”	glioblastoma multiforme
“GEJ”	gastroesophageal junction
“GI”	gastrointestinal
“GIST”	gastrointestinal stromal tumors
“gMG”	generalized myasthenia gravis
“HER2”	human epidermal growth factor receptor 2
“HRD”	homologous recombination deficiency
“IC”	intracranial
“IgG”	immunoglobulin G
“ITP”	immune thrombocytopenia
“mDOR”	median duration of response
“MDR”	multidrug-resistant
“mFOLFOX6”	modified FOLFOX6
“MMAE”	monomethyl auristatin E
“mOS”	median overall survival
“mPFS”	median progression-free survival
“MPM”	malignant pleural mesothelioma
“NSCLC”	non-small cell lung cancer

## GLOSSARY OF TECHNICAL TERMS

“ORR”	objective response rate
“OS”	overall survival
“PANSS”	positive and negative syndrome scale
“PARP”	poly (ADP-ribose) polymerase
“R/R”	relapsed/refractory
“SC”	subcutaneous
“SUL-DUR”	Sulbactam/durlobactam
“TKI”	tyrosine kinase inhibitor
“TMZ”	temozolomide
“TRAEs”	treatment-related adverse events
“TTFields”	Tumor Treating Fields

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