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

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended: December 31, 2021**

**Or**

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

**Commission file number: 001-38205**

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

| **Cayman Islands** | **98-1144595** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **4560 Jinke Road<br>Bldg. 1, Fourth Floor<br>Pudong<br>Shanghai, China** | |
| **(Address of principal executive offices)** | **201210<br>(Zip Code)** |

**+86 21 6163 2588**
**(Registrant's Telephone Number, Including Area Code)**

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **American Depositary Shares, each representing 1 Ordinary Share, par value $0.00006 per share** | **ZLAB** | **The Nasdaq Global Market** |
| **Ordinary Shares, par value $0.00006 per share*** | **9688** | **The Stock Exchange of Hong Kong Limited** |

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

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the ordinary shares, including in the form of American Depositary Shares ("ADSs"), each representing one ordinary share, held by non-affiliates of the registrant was approximately US$16.9 billion, based upon the closing price of the registrant's ADSs on the Nasdaq Global Market of US$176.99 on June 30, 2021.

As of February 28, 2022, 96,408,743 ordinary shares, par value $0.00006 per share, were outstanding, of which 71,043,133 ordinary shares were held in the form of ADSs.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2021. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Zai Lab Limited**
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**Forward-Looking Statements**

This Annual Report on Form 10-K contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potentially,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions, and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the risk factors discussed in the “Risk Factors” section of this Annual Report on Form 10-K. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Annual Report on Form 10-K, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

**Note on Company—Usage of Terms**

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Greater China” refer to mainland China, Hong Kong Special Administrative Region (“HKSAR” or “Hong Kong”), Macau Special Administrative Region (“Macau SAR” or “Macau”), and Taiwan, collectively; and references in this Annual Report on Form 10-K to “Zai Lab,” the “Company,” “we,” “us,” and “our” refer to Zai Lab Limited, a holding company, and its subsidiaries, on a consolidated basis; and references to “Zai Lab Limited” refer to Zai Lab Limited, a holding company. Zai Lab Limited is the entity in which investors are purchasing their interest.

Our operating subsidiaries comprise of Zai Lab (Hong Kong) Limited, domiciled in Hong Kong; Zai Auto Immune (Hong Kong) Limited, domiciled in Hong Kong; Zai Anti Infectives (Hong Kong) Limited, domiciled in Hong Kong; Zai Lab (Shanghai) Co., Ltd., domiciled in mainland China; Zai Lab International Trading (Shanghai) Co., Ltd., domiciled in mainland China; Zai Lab (Suzhou) Co., Ltd., domiciled in mainland China; Zai Biopharmaceutical (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab Trading (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab (Taiwan) Limited, domiciled in Taiwan; Zai Lab (AUST) Pty., Ltd., domiciled in Australia; Zai Lab (US) LLC, domiciled in the United States. Additionally, as of the date of this Annual Report on Form 10-K, Zai Auto Immune (Hong Kong) Limited and Zai Anti Infectives (Hong Kong) Limited have non-substantial business operations.

**Disclosures Relating to Our Chinese Operations**

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

Zai Lab Limited is not a Chinese operating company, but a holding company incorporated in the Cayman Islands. As a holding company, we conduct a substantial portion of our operations through wholly owned subsidiaries based in mainland China. Investors will not hold direct investments in our Chinese operating

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

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

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

For more information on these risks, and other risks relating to our ADSs, and ordinary shares, see the risk factors discussed in the "Risk Factors" section of this Annual Report on Form 10-K.

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

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

As of the date of this Annual Report on Form 10-K, we are not required to obtain approval or prior permission from the China Securities Regulatory Commission, or CSRC, or any other Chinese regulatory authority under the Chinese laws, and regulations currently in effect to issue securities to foreign investors. However, the CSRC recently released for public comment draft rules titled Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments), or the Draft Rules. If the Draft Rules are adopted in its current form, we would likely be required to submit filings to the CSRC in connection with the future issuance of our equity securities to foreign investors. For more details, see "Governmental 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. We are also required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them.

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

For more information on these required permissions, see risk factors discussed in the "Risk Factors" section of this Annual Report on Form 10-K.

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

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

**Summary of Significant Risk Factors**

The following is a summary of significant risk factors and uncertainties that may affect our business, which are discussed in more detail below in "Part I—Item 1A—Risk Factors" included in this Annual Report on Form 10-K:

- The uncertainties in the Chinese legal system could materially and adversely affect us;
- Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares and/or our ADSs;
- The Chinese government may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs and ordinary shares, including potentially making those ADSs or ordinary shares worthless;
- The audit report included in this Annual Report on Form 10-K was prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection, we may be subject to additional Nasdaq listing criteria or other penalties and our ADSs may be delisted from the U.S. stock market;
- Proceedings brought by the SEC against China-based accounting firms could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act;
- Compliance with China's Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, and any other future laws and regulations may entail significant

expenses and could materially affect our business. Our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, materially and adversely impacting our operating results;

- The economic, political and social conditions in mainland China, as well as governmental policies, could affect the business environment and financial markets in mainland China, our ability to operate our business, our liquidity and our access to capital;
- If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our ADSs or ordinary shares may decline in value or become worthless;
- The approval of, filing or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures.
- We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation;
- Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies effectively;
- We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business;
- Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us;
- Chinese regulations establish complex procedures for some acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China;
- Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which may result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third-party contract manufacturers;
- Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations;
- It may be difficult for overseas regulators to conduct investigations or collect evidence within mainland China;
- If we are classified as a Chinese resident enterprise for Chinese income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders;
- We and our shareholders face uncertainties in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises;
- Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations;
- Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, or CFIUS, which may delay or block a transaction from closing;

- Changes in United States and international trade policies and relations, particularly with regard to mainland China, may adversely impact our business and operating results;
- It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts;
- We may be subject to fines due to the lack of registration of our leases;
- Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business;
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future. To date, we have not generated sufficient revenue from product sales to cover corresponding expenses, and we may never achieve or sustain profitability;
- We are invested in the commercial success of our four approved products and our ability to generate product revenues in the near future is highly dependent on the commercial success of each of those products;
- We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates and our business could be substantially harmed;
- If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us;
- If we fail to maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired; and
- Other risks and uncertainties, including those listed under “Part I—Item 1A—Risk Factors”.

These factors should not be construed as exhaustive, and should be read with the other cautionary statements, and other information in this Annual Report on Form 10-K, and our other filings with the SEC.

# PART I

## Item 1. Business

### Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are focused on developing and commercializing therapies that address medical conditions with unmet needs in 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 vision is to become a leading global biopharmaceutical company discovering, developing, and commercializing products to extend, and improve the lives of patients worldwide.

Since the Company's founding in 2014, we have taken steps to execute our strategy to become a fully integrated global biopharmaceutical company with substantial research and development, business development, and commercialization capabilities. To date, we have:

- received approval for and commercialized four products (ZEJULA, Optune, QINLOCK and NUZYRA);
- expanded our pipeline to increase our product candidates under development from four in 2015 to 28 today in oncology, autoimmune disorders, infectious diseases, and neuroscience, including 12 programs in late-stage clinical development;
- partnered with established biopharmaceutical and leading healthcare companies such as GlaxoSmithKline (GSK), Novocure, argenx, Turning Point, Deciphera, Karuna, Blueprint, MacroGenics, Cullinan, and Amgen 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 in mainland China through its inclusion on the National Reimbursement Drug List (NRDL);
- built a commercial organization of approximately 945 employees;
- increased our research and development team to approximately 788 employees;
- assembled a leadership team of seasoned industry veterans with extensive pharmaceutical research, development, and commercialization experience in both global and Chinese biopharmaceutical companies;
- advanced our in-house discovery pipeline and capabilities targeting global markets;
- built out our facilities in China to support our regulatory, clinical, manufacturing, and commercial infrastructure in eleven locations across Greater China and the United States;
- acquired land-use rights for 50,851 square meters of land in Suzhou for the purpose of constructing and operating a manufacturing site and research center; and
- expanded our U.S. footprint by opening a research facility in the San Francisco Bay area and a new corporate office in Cambridge, Massachusetts.

We are committed to our goal of becoming a leading global biopharmaceutical company focused on discovering, developing, and commercializing products to extend and improve the lives of patients worldwide. We intend to continue to pursue a strategy of growth and development by: (i) expanding our product candidate pipeline through global collaborations and corporate development activities; (ii) capitalizing on commercial

opportunities for our approved products; and (iii) investing in our global pipeline by advancing our internally discovered novel therapeutics. We also plan to expand our collaborations with leading academic institutions in both the United States and Greater China. We believe that this strategy, supported by the above actions we have taken and other actions we plan to take, will bring us closer to achieving our goal of becoming a leading global biopharmaceutical company.

Dividends and Other Distributions

Zai Lab Limited is a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. If any of our Chinese subsidiaries incur debt on their own behalf in the future, the instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from our Chinese subsidiaries to our subsidiaries located in or outside of mainland China. In addition, as of the date of this Annual Report on Form 10-K, 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 $366.5 million in capital contributions via twenty-four separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2021 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 the risk factors discussed in the "Risk Factors" section of this Annual Report on Form 10-K 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 commercial products:

| Product | Indications | Regulatory Status | Commercial Rights | Partner |
|---|---|---|---|---|
| Zejula niraparib | 1st line ovarian cancer maintenance treatment<br>Platinum sensitive relapsed ovarian cancer maintenance treatment | Launched in mainland China, Hong Kong, and Macau | mainland China, Hong Kong, and Macau | GSK |
| OPTUNE | Newly diagnosed glioblastoma multiforme (GBM)<br>Recurrent GBM | Launched in mainland China, Hong Kong, and Macau | mainland China, Hong Kong, Macau, and Taiwan | Novocure |
| QINLOCK | 4th line gastrointestinal stromal tumors (GIST) | Launched in mainland China, Hong Kong, and Taiwan | mainland China, Hong Kong, Macau, and Taiwan | Deciphera |
| NUZYRA (omadacycline) | Acute bacterial skin and skin structure infections (ABSSSI)<br>Community-acquired bacterial pneumonia (CABP) | Launched in mainland China | mainland China, Hong Kong, Macau, and Taiwan | Paratek |

***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 both 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 sensitive to ZEJULA. In the maintenance setting, ZEJULA does not require the addition of radiation or chemotherapies to kill tumor cells.

In September 2016, we entered into 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. We have the exclusive right to develop and commercialize ZEJULA in the licensed territories for all potential indications except prostate cancer. For further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements—GSK.”

ZEJULA was first approved in March 2017 by the United States Food and Drug Administration (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. 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.

The European Medicines Agency (EMA) approved ZEJULA in November 2017 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. Additionally, ZEJULA was approved by the EMA in October 2020 as 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.

As maintenance therapy, ZEJULA is for women who have had prior chemotherapy treatment but are expected to see their cancer return. ZEJULA is intended to avoid or slow a recurrence of the cancer if it is in remission after prior treatment. A platinum-sensitive cancer is one that responded to initial platinum-based chemotherapy and remained in remission post-chemotherapy for more than six months.

***Market Opportunity and Competition***

We 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. We launched ZEJULA in mainland China in January 2020 after approval in December 2019 by the NMPA as a second-line 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. ZEJULA is the only PARP inhibitor approved by the FDA, the EMA and the NMPA for first- and second-line maintenance treatment for women with platinum-responsive advanced ovarian cancer regardless of biomarker status, such as BRCA mutations.

In May 2020, ZEJULA was recommended as a monotherapy in first-line maintenance treatment of women with platinum-responsive advanced ovarian cancer in the Ovarian Cancer PARP Inhibitor Clinical Guidelines published by Gynecological Oncology, Chinese Medical Association. In December 2020, ZEJULA was included in the updated National Reimbursement Drug List, or the 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. In December 2021, ZEJULA was included in the updated NRDL as a first-line maintenance treatment of adult patients with advanced ovarian cancer following a response to platinum-based chemotherapy. As of January 31, 2022, ZEJULA was listed in 44 regional customized commercial health insurance plans guided by provincial or municipal governments throughout mainland China, or supplemental insurance plans.

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 have completed several studies in Chinese patients with ovarian cancer. In November 2021, we announced positive topline results from the Phase III PRIME study of ZEJULA as maintenance therapy for Chinese patients with first-line platinum-responsive, advanced ovarian cancer, regardless of biomarker status. In September 2020, we announced the results from the Phase III NORA study that ZEJULA demonstrated a significant PFS benefit with an improved safety profile as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer, regardless of biomarker status.

***Optune (Tumor Treating Fields)***

Tumor Treating Fields (TTFields) is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and potentially causing cancer cell death. 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 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.

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. Optune is also approved or has a CE certificate for the treatment of GBM in the European Union, Japan and certain other countries.

In September 2018, we entered into an exclusive license agreement with Novocure to develop and commercialize Optune in Greater China in all human therapeutic and preventive uses in the field of oncology.

For further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements—Novocure.”

***Market Opportunity and Competition***

GBM, a malignant form of astrocytoma, is the most aggressive form of brain cancer. In mainland China during 2019, GBM represented about 47% of all newly diagnosed cases of brain cancer, with an estimated annual

incidence of 53,600 patients. 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 temozolomide for the treatment of patients with newly diagnosed GBM and also as a monotherapy for the treatment of patients with recurrent GBM. As of January 31, 2022, Optune was listed in 33 supplemental insurance plans. Enrollment into these regional reimbursement programs has improved and will improve access to Optune for many patients in need across mainland China.

In August 2020, we launched Optune Lua, a portable medical device that delivers TTFields for the treatment of unresectable, locally advanced or metastatic malignant pleural mesothelioma (MPM) in Hong Kong. MPM is a type of cancer that occurs in the thin layer of tissue in the torso covering internal organs. In May 2019, Novocure received FDA approval for 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. For details about our clinical development of TTFields, see the subsection “Our Oncology Pipeline-Tumor Treating Fields.”

***QINLOCK (ripretinib)***

QINLOCK, an orally administered kinase switch control inhibitor of the KIT and PDGFRA kinases, is approved in nine territories for the treatment of fourth-line advanced gastrointestinal stromal tumors (GIST), including the United States, the European Union, mainland China, Taiwan, and Hong Kong.

In June 2019, we obtained 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 further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements—Deciphera.”

***Market Opportunity and Competition***

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.

In July 2020, the NMPA accepted the NDA submission of QINLOCK for fourth-line advanced GIST. That same month, QINLOCK was approved, pursuant to the special Named Patient Program (NPP), by the Health Commission and Medical Products Administration of Hainan Province as the first Urgently Needed Drug that can be taken from the Bo’ao Pilot Zone by a designated patient. Under the NPP, patients may apply for permission to purchase a small amount of legally imported drugs that are not yet registered domestically (either inside or outside the Bo’ao Pilot Zone) and that address urgent medical needs in the Bo’ao Pilot Zone.

In August 2020, the NMPA granted Priority Review to the NDA submission for QINLOCK for the treatment of adult patients with advanced GIST who have received priority treatment with three or more kinase inhibitors. In March 2021, QINLOCK was approved by the NMPA. In February 2020, it was approved by the Hong Kong Department of Health for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib. In September 2021, the Taiwan Food and Drug Administration approved the NDA for QINLOCK for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. As of January 31, 2022, QINLOCK has been listed in 52 supplemental insurance plans since its commercial launch in mainland China in May 2021.

In November 2021, Deciphera announced top-line results from the INTRIGUE Phase III clinical study of QINLOCK in patients with GIST previously treated with imatinib. The study did not meet the primary endpoint of improved progression-free survival compared with the standard of care in second-line GIST, sunitinib. We do not anticipate that the INTRIGUE study results will have a material effect on the current operations of the Company. We have received the CTA approval for the registrational study of QINLOCK in patients with second-line GIST in mainland China. The study is ongoing.

**NUZYRA (omadacycline)**

NUZYRA is a broad-spectrum antibiotic in a new class of tetracycline derivatives known as aminomethylcyclines. NUZYRA is primarily being developed by our partner Paratek Pharmaceuticals, Inc., or Paratek, for acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) in both the hospital and community settings. 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. Our partner, Paratek, launched NUZYRA in the United States in February 2019.

In April 2017, we obtained 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 further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements—Paratek.”

***Market Opportunity and Competition***

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. We believe that NUZYRA’s potential use in multiple settings, including the emergency room, hospital and community care facilities, provides a significant benefit to patients as an empiric monotherapy. In 2015, the estimated incidences of ABSSSI and CABP in mainland China were 2.8 million patients and 16.5 million patients, respectively.

We completed the technology transfer for NUZYRA in November 2017 to enable us to prepare for the manufacture of both oral tablets and intravenous injections of NUZYRA.

In December 2021, the NMPA approved the NDA for NUZYRA for the treatment of CABP and ABSSSI. NUZYRA was approved as a Category 1 innovative drug by the NMPA and is locally manufactured in mainland China. NUZYRA was launched in late December 2021.

We continue to explore use of omadacycline, including the oral only administration, for the treatment of adults with CABP and ABSSSI. We plan to discuss the scope of any and all post-approval commitments (PAC) studies with the regulators prior to the expiry of market authorization.

## Our Pipeline of Product Candidates

The following table summarizes the status of our clinical pipeline assets as of February 28, 2022:

| Product Candidates | Description | Phase I | Phase II | Pivotal: Phase Ib / Phase II | Pivotal: Phase III | Commercial Rights |
|---|---|---|---|---|---|---|
| **Oncology** | | | | | | |
| **ZEJULA** | **PARP** | Other solid tumors*[1] | | | | Mainland China, HK, Macau |
| **Tumor Treating Fields** | | MPM – *Approved in the United States* | | | | Greater China |
| | | NSCLC | | | | |
| | | NSCLC brain metastases | | | | |
| | | Pancreatic | | | | |
| | | Ovarian* | | | | |
| | | Gastric[2] | | | | |
| | | Liver* | | | | |
| **MARGENZA** | **HER2** | Breast cancer[3] – *Approved in the United States* | | | | |
| **Adagrasib** | **KRAS G12C** | NSCLC (mono/combo)*[4] – *NDA accepted in the United States* | | | | |
| | | Colorectal cancer (mono/combo)*[4] | | | | |
| **Odronextamab** | **CD20xCD3** | B-NHL[5] | | | | |
| **Repotrectinib** | **ROS1, TRK** | ROS1+ NSCLC, NTRK+ solid tumors | | | | |
| **Bemarituzumab** | **FGFR2b** | Gastric cancer/GEJ* | | | | |
| **CLN-081** | **EGFR Ex20ins** | NSCLC*[6] | | | | |
| **TPX-0022** | **MET** | Gastric cancer, NSCLC* | | | | |
| **Retifanlimab** | **PD-1** | NSCLC | | | | |
| | | MSI-high endometrial cancer | | | | |
| **BLU-945** | **EGFR triple mutant** | NSCLC* | | | | |
| **BLU-701** | **EGFR double mutant** | NSCLC* | | | | |
| **Simurosertib** | **CDC7** | Multiple tumors | | | | Global |
| **ZL-1201** | **CD47** | Multiple tumors | | | | |
| **ZL-1211** | **Claudin18.2** | Multiple tumors | | | | |
| **Autoimmune Diseases** | | | | | | |
| **Efgartigimod** | **FcRn** | MG – *Approved in the United States and Japan* | | | | Greater China |
| | | ITP | | | | |
| | | PV | | | | |
| | | CIDP | | | | |
| | | Bullous pemphigoid* | | | | |
| | | Myositis* | | | | |
| **ZL-1102** | **IL-17** | Psoriasis[7] | | | | Global |
| **Infectious Diseases** | | | | | | |
| **Omadacycline** | | ABSSSI, CABP (oral only)* – *Approved in the United States* | | | | Greater China |
| **Sulbactam-Durlobactam** | | Carbapenem-resistant *Acinetobacter* infections | | | | Asia Pacific[8] |
| **Neuroscience** | | | | | | |
| **KarXT** | | Schizophrenia (psychosis)* | | | | Greater China |
| | | Schizophrenia (psychosis in adults with an inadequate response to SOC)* | | | | |
| | | Schizophrenia (negative & cognitive symptoms)* | | | | |
| | | Alzheimer's disease psychosis* | | | | |

Note: *Greater China trial in preparation or under planning; (1) Reflects ongoing trials run by GSK, including a Phase III trial in NSCLC; (2) Phase II pilot China-only trial; (3) NDA acceptance of MARGENZA (margetuximab) in pretreated metastatic HER2-positive breast cancer in China by the NMPA in January 2022; (4) Includes multiple mono or combo therapies; NDA of adagrasib in pretreated KRAS-G12C-mutated NSCLC by the FDA in February 2022; (5) Global Phase II potentially pivotal trial; (6) Global Phase I/IIa potentially pivotal trial; (7) Achieved proof of concept in Phase Ib study in October 2021; (8) Includes Greater China, South Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan. **This Table illustrates our clinical pipeline assets, including their various stages of development, which are described more fully elsewhere in this Annual Report on Form 10-K. For completeness, please read this Table in conjunction with the remainder of this Report.**

Abbreviations: Greater China = mainland China, Hong Kong, Macau, Taiwan; HK = Hong Kong; I/O = immune-oncology; MPM = malignant pleural mesothelioma; NSCLC = non-small cell lung cancer; B-NHL = B-cell non-Hodgkin lymphoma; GEJ = gastroesophageal junction; MG = myasthenia gravis; ITP = immune thrombocytopenia; PV = pemphigus vulgaris; CIDP = chronic inflammatory demyelinating polyneuropathy; ABSSSI = acute bacterial skin and skin structure infections; CABP = community-acquired bacterial pneumonia; SOC = standard of care.

**Our Oncology Pipeline**

***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 further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—GSK."

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

***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 further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements – Novocure."

Novocure continues to test TTFields against a broad range of solid tumor types. We have enrolled or intend to enroll patients in Greater China in the various global trials for TTFields.

In January 2020, we enrolled the first patient in a Phase II pilot clinical trial evaluating the safety and efficacy of TTFields in combination with chemotherapy as a first-line treatment in patients with gastric adenocarcinoma, a type of gastric cancer. 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.

We are participating in the PANOVA-3 Phase III pivotal trial of TTFields for pancreatic cancer, and the first patient in Greater China in this clinical trial was treated in January 2022. 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 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. We have completed Chinese patient enrollment in December 2021. Lung cancer consists of NSCLC in approximately 85% of cases and small cell lung cancer (SCLC) in approximately 15% of cases. 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%.

In December 2021, we submitted to the NMPA a Marketing Authorization Application (MAA) for Optune Lua for MPM, which is under administrative review.

We are also considering participating in a clinical trial of TTFields that includes ovarian cancer. Ovarian cancer is one of the most common gynecologic cancers in mainland China. Since early symptoms of ovarian cancer are not specific to the disease and are difficult to detect, approximately 70% of women are diagnosed with ovarian cancer when the disease is already at an advanced stage, when prognosis is poor. Despite high response rates to platinum-based chemotherapy in the front-line setting, approximately 85% of patients will experience disease recurrence.

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. The designation offers Novocure an opportunity to interact with FDA experts through several program options to address regulatory topics efficiently as they arise during the premarket review phase and allows for prioritized review of regulatory submissions.

In October 2021, Novocure announced that the last patient had been enrolled in the global Phase III pivotal INNOVATE-3 trial for the treatment of recurrent ovarian cancer. In that same month, we and Novocure announced that the final patient had been enrolled in the Phase II pilot trial of TTFields in combination with chemotherapy as a first-line treatment in patients with gastric adenocarcinoma. Final data collection is expected in 2022.

In November 2021, Novocure announced the release of updated data from the Phase II pilot 2-THE-TOP trial testing the safety and efficacy of Tumor Treating Fields (TTFields) together with pembrolizumab and temozolomide for the treatment of adult patients with newly diagnosed GBM.

***MARGENZA™ (margetuximab-cmkb)***

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

In November 2018, we entered into an exclusive license agreement, the MacroGenics Agreement, with MacroGenics, Inc., or MacroGenics, to develop and commercialize MARGENZA in Greater China in all human fields of use. For further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements – MacroGenics.”

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 patients with pretreated 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.

Based on a review of the clinical data and the changing treatment landscape, we have decided to no longer participate in Cohort B of the Phase II/III MAHOGANY study, which is a MacroGenics-sponsored global Phase II/III clinical trial designed to evaluate margetuximab in combination with retifanlimab or tebotelimab, with or without chemotherapy, as a potential first-line treatment for patients with advanced or metastatic HER2+ gastric and GEJ cancer. In November 2021, MacroGenics previously announced a decision to discontinue enrollment of Cohort A of the MAHOGANY study.

***Adagrasib***

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

In June 2021, Mirati announced that the FDA granted Breakthrough Therapy Designation to adagrasib for the potential treatment of patients with NSCLC who harbor the KRAS G12C mutation following prior systemic therapy.

In September 2021, our partner, Mirati, announced positive topline results from the potentially registrational Phase II KRYSTAL-1 study evaluating adagrasib in a patient cohort with advanced NSCLC harboring the KRAS G12C mutation following prior systemic therapy. Adagrasib 600mg BID demonstrated an objective response rate (ORR) of 43% and a disease control rate of 80%, based on central independent review as of June 15, 2021. The median follow-up was nine months. The safety and tolerability profile was consistent with previously reported findings for adagrasib in patients with advanced NSCLC. In that same month, Mirati announced results from a cohort of the Phase I/II KRYSTAL-1 study evaluating adagrasib at the 600mg BID dose as both monotherapy and in combination with cetuximab in patients with heavily pretreated colorectal cancer harboring a KRAS G12C mutation. Results showed that adagrasib alone and with cetuximab demonstrated significant clinical activity and broad disease control in these patients.

In November 2021, Mirati announced that preliminary results from the Phase Ib cohort of the KRYSTAL-1 study evaluating adagrasib plus pembrolizumab in eight patients with KRAS G12C-mutated first-line NSCLC support moving forward with a 400 mg BID dose of adagrasib with full dose pembrolizumab, which will be evaluated in the ongoing Phase II KRYSTAL-7 study.

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 G12C 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-G12C-mutated GI cancers evaluated in this cohort, adagrasib was well-tolerated, with a manageable safety profile.

In February 2022, Mirati announced that the FDA accepted the NDA for *adagrasib* for the treatment of patients with NSCLC harboring the KRAS G12C mutation who have received at least one prior systemic therapy. The Prescription Drug User Fee Action (PDUFA) date for adagrasib is December 14, 2022.

***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.

In April 2020, we entered into a collaboration agreement with Regeneron Ireland Designated Activity Company, an affiliate of Regeneron Pharmaceuticals, Inc., or Regeneron, pursuant to which we obtained the development rights and exclusive commercialization rights to odronextamab for oncology in Greater China. For further details of this collaboration, see “Overview of Our Material License and Strategic Collaboration Agreements—Regeneron.” In December 2020, Regeneron announced that it was pausing new enrollment of patients with B-cell non-Hodgkin lymphomas in its trials for odronextamab in compliance with an FDA partial clinical hold requesting that Regeneron amend the trial protocols in order to further reduce the incidence of [3]Grade 3 cytokine release syndrome (CRS) during step-up dosing. Enrolled patients who were deriving clinical benefit from odronextamab were able to continue treatment following re-consent. In May 2021, Regeneron announced that the partial clinical hold on odronextamab had been lifted. In October 2021, we announced that the first patient was treated in the Greater China portion of the potentially registrational, global study of odronextamab monotherapy being conducted by our partner Regeneron and us in patients with B-NHL.

We have received China Trial Application (CTA) approval in mainland China for, and have joined, the open-label, multi-center, global, potentially registrational Phase II program evaluating the efficacy and safety of odronextamab in several disease-specific cohorts, including patients with R/R FL and DLBCL.

***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 -pretreated cancer patients.

In July 2020, we entered into an exclusive license agreement with Turning Point Therapeutics, or Turning Point, to develop and commercialize repotrectinib in Greater China in all human therapeutic indications. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—Turning Point."

The FDA has granted two Breakthrough Therapy designations 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; and
- Patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI.

The FDA has granted four Fast-Track designations for:

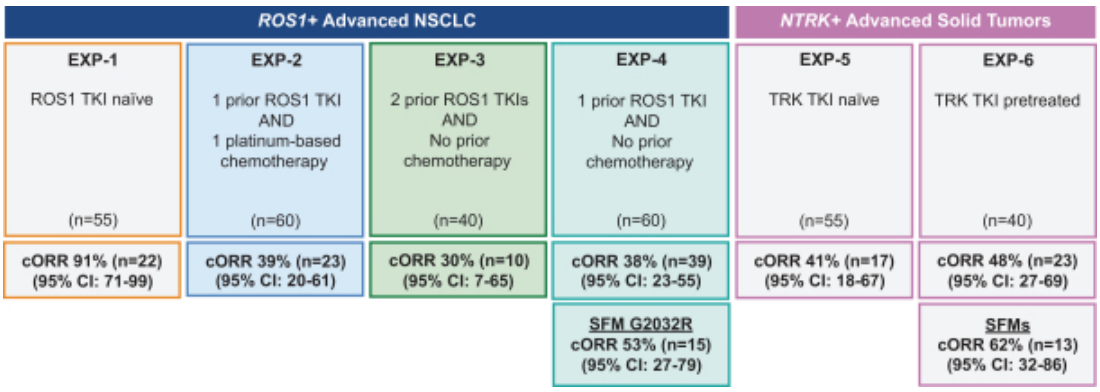
- Patients with ROS1-positive advanced NSCLC who have not been previously treated with a ROS1 TKI;
- Patients with ROS1-positive advanced NSCLC who have been previously treated with one prior line of platinum-based chemotherapy and one prior ROS1 TKI;
- Patients with ROS1-positive advanced NSCLC pretreated 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.

In August 2021, Turning Point announced the initiation of the first cohort of its Phase Ib/II TRIDENT-2 combination study of repotrectinib in combination with the MEK-inhibitor trametinib in KRAS G12D-mutated advanced solid tumors.

In October 2021, Turning Point provided early clinical data from the NTRK-positive TKI-naïve and TKI-pretreated advanced solid tumor cohorts (EXP-5 and EXP-6) of the ongoing TRIDENT-1 Phase I/II study of its lead drug candidate repotrectinib. In that same month, Turning Point provided a clinical data update from the ongoing TRIDENT-1 study. Repotrectinib demonstrated clinical activity across multiple ROS1+ TKI-pretreated NSCLC cohorts, with confirmed ORRs of 30-39% in the TRIDENT-1 study. In ROS1+ TKI-pretreated NSCLC patients with G2032R solvent-front mutations, repotrectinib demonstrated a confirmed ORR of 53% (TRIDENT-1 Study Design and Preliminary Phase I/II Data as shown below). Turning Point also announced, in October 2021, the presentation of early clinical data from the ongoing Phase I/II CARE study in pediatric and young adult patients with advanced solid tumors harboring ALK, ROS1 or NTRK alterations.

**TRIDENT-1 Study Design Preliminary Phase I/II Data**




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

***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.

In December 2017, we entered into an exclusive license agreement with Five Prime Therapeutics, or Five Prime, to develop and commercialize bemarituzumab in Greater China for the treatment or prevention of any disease or condition in humans. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—Five Prime."

In March 2020, Five Prime announced the publication of results from its Phase I escalation and expansion study of bemarituzumab monotherapy in patients with advanced solid tumors and FGFR2b-selected gastroesophageal adenocarcinoma. No dose-limiting toxicities were reported.

We enrolled Chinese patients into Five Prime's Phase II FIGHT trial to evaluate bemarituzumab plus mFOLFOX6 chemotherapy in patients with fibroblast growth factor receptor 2b-positive (FGFR2b+), non HER2 positive (non HER2+) advanced gastric and GEJ cancer. In November 2020, Five Prime reported topline results from the FIGHT trial showing that bemarituzumab met all three efficacy endpoints and demonstrated statistically significant and clinically meaningful improvements in the primary endpoint of progression-free survival and secondary endpoints of overall survival and overall response rate. In January 2021, Five Prime announced its plan to launch a Phase III trial for gastric cancer.

In April 2021, Five Prime was acquired by Amgen.

In September 2021, the CDE of the NMPA 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).

In November 2021, Amgen announced that the registrational Phase III program for bemarituzumab in first-line advanced gastric and GEJ cancer had initiated. The program will explore bemarituzumab in combination with either backbone chemotherapy or chemotherapy plus a checkpoint inhibitor. We plan to initiate a registrational study of bemarituzumab in first-line advanced gastric and GEJ cancer in China in the fourth quarter of 2022.

***CLN-081***

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 Management, Inc., formerly Cullinan Oncology, LLC, for the treatment of patients with EGFR exon 20 insertion NSCLC.

In December 2020, we entered into an exclusive license agreement with Cullinan Pearl for the research, development, manufacturing and commercialization of CLN-081 in Greater China in all uses in humans and animals. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements – Cullinan."

Cullinan Pearl is currently 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. We anticipate that we will join the global Phase IIa potentially pivotal study and plan to enroll the first patient in Greater China into this study in 2022.

In January 2022, Cullinan announced that the FDA 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.

***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 "Overview of Our Material License and Strategic Collaboration Agreements—Turning Point."

In October 2021, Turning Point provided a clinical data update from the dose-finding portion of the Phase I SHIELD-1 study. Elzovantinib demonstrated a confirmed ORR of 36% and 33%, respectively, in MET TKI-naïve NSCLC and gastric/GEJ cancer patients harboring genetic alterations in MET in the SHIELD-1 study.

In December 2021, Turning Point announced that the FDA agreed with the company's plan to proceed to the potentially registrational Phase II MET-amplified gastric/GEJ cancer expansion cohorts of SHIELD-1 after recommended Phase II dose (RP2D) determination. Turning Point anticipates initiating the Phase II portion of SHIELD-1 in the second half of 2022, pending FDA feedback on data from the intermediate dose level.

In January 2022, Turning Point announced that clearance from the FDA was received for the IND application for the combination of elzovantinib and aumolertinib in EGFR-mutant MET-amplified advanced NSCLC.

***Retifanlimab***

Retifanlimab is an investigational humanized, hinge-stabilized, IgG4k monoclonal antibody that inhibits interactions between PD-1 and its ligands, PD-L1 and PD-L2.

In July 2019, we entered into an exclusive license agreement with Incyte Corporation, or Incyte, to develop and commercialize retifanlimab in Greater China in hematology and oncology. Incyte retains an option to assist in the promotion of retifanlimab. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—Incyte."

In 2017, Incyte entered into an exclusive collaboration and license agreement with MacroGenics for global rights to retifanlimab. The molecule is currently being evaluated both as monotherapy and in combination therapy across various tumor types. Potentially registration-enabling trials in microsatellite instability-high (MSI-H) endometrial cancer and Merkel cell carcinoma (MCC) are ongoing.

The Phase III POD1UM-303 trial of retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with squamous cell anal cancer (SCAC) is underway. In July 2021, Incyte announced that the FDA issued a complete response letter for the BLA of retifanlimab for the treatment of SCAC. In October 2021, Incyte announced the withdrawal of the Marketing Authorization Application seeking approval of retifanlimab in SCAC. We have not participated in the global study for SCAC.

We are participating in the global Phase III POD1UM-304 trial, evaluating retifanlimab in combination with platinum-based chemotherapy as a first-line treatment for patients with NSCLC. In October 2020, we enrolled the first patient in mainland China in the study.

We are also participating in the global study for endometrial cancer. In October 2020, the first patient in mainland China was dosed in the global POD1UM-101 trial evaluating retifanlimab in patients with MSI-H endometrial cancer that had progressed following platinum-based chemotherapy.

Retifanlimab has been granted Fast-Track designation for the treatment of certain patients with advanced or metastatic MSI-H or dMMR endometrial cancer, locally advanced or metastatic SCAC and MCC.

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

BLU-945 is a selective and potent investigational inhibitor of triple-mutant EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired T790M and C797S mutations, the most common on-target resistance to first-generation EGFR inhibitors and osimertinib, respectively. Updated preclinical data for BLU-945 demonstrated potent anti-tumor activity in triple-mutant osimertinib-resistant tumor models, as well as activity in a triple-mutant intracranial patient-derived xenograft model.

In November 2021, we entered into a license and collaboration agreement with Blueprint Medicines Corporation, or Blueprint, pursuant to which we obtained rights to develop and exclusively commercialize BLU-701 and BLU-945 and certain other forms thereof, including backup compounds, in mainland China. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—Blueprint."

The global Phase I/II SYMPHONY trial of BLU-945 in treatment-resistant EGFR-driven NSCLC was initiated in 2021 with initial data expected in the second quarter of 2022.

***ZL-2314 (BLU-701)***

BLU-701 is a selective and potent investigational inhibitor of double-mutant EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired C797S mutation, the most common on-target resistance mutation to osimertinib. Foundational preclinical data for BLU-701 showed strong and durable inhibition of tumor growth at doses that are EGFR wild-type sparing and the potential for BLU-701 to be used in both first and second-line settings.

The global Phase I/II HARMONY trial of BLU-701 in EGFR-driven NSCLC was initiated with initial data expected in the second half of 2022.

***ZL-2309 (Simurosertib)***

Simurosertib is an orally active, selective and ATP-competitive cell division cycle 7 (CDC7) kinase inhibitor. In December 2020, we entered into an exclusive worldwide license agreement (excluding Japan) with Takeda Pharmaceutical Company Limited to research, develop and commercialize simurosertib in all uses in humans or animals.

A Phase Ib dose escalation clinical trial of simurosertib was completed. Anti-cancer activity was observed in both pre-clinical and clinical data. Simurosertib is under investigation in clinical trial NCT03261947 (A Study to Evaluate the Safety, Tolerability and Activity of TAK-931 in Participants with Metastatic Pancreatic Cancer, Metastatic Colorectal Cancer and Other Advanced Solid Tumors).

We plan to initiate a Phase II biomarker-driven proof-of-concept study in the second quarter of 2022.

***ZL-1201 (CD47)***

ZL-1201 is a humanized, IgG4 monoclonal antibody engineered to reduce effector function that specifically targets CD47. We made modifications to the antibody that may reduce the incidence of hemolysis seen with other agents in the class based on pre-clinical data. CD47 has recently emerged as a novel target for macrophage immune checkpoint inhibition and a promising target for therapeutic intervention. Our pipeline includes several assets, including a novel bi-specific T cell engager and checkpoint inhibitors that lend themselves to potential combination with a CD47-targeted therapeutic. The therapeutic potential of these ZL-1201 combinations will be assessed in both solid tumors and hematological malignancies. In June 2020, we initiated dosing of a Phase I clinical trial for ZL-1201. Depending on the results of this trial, we may proceed with a Phase II clinical trial.

We anticipate determining a recommended Phase II dose in the ongoing Phase I trial in mid-2022.

***Tebotelimab***

Tebotelimab (previously known as MGD013) is an investigational, bispecific, tetravalent IgG4 monoclonal antibody designed to independently or coordinately block PD-1 and LAG-3 checkpoint molecules to sustain or restore the function of exhausted T cells for the treatment of cancer.

In November 2018, we entered into the MacroGenics Agreement pursuant to which we obtained an exclusive license to develop and commercialize tebotelimab in Greater China in all human fields of use except to the extent limited by any applicable third-party agreement of MacroGenics. For further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements – MacroGenics.”

Based on a review of the clinical data, we have decided to terminate the following studies of tebotelimab:

- A Phase I proof-of-concept China-only dose escalation and expansion trial of tebotelimab monotherapy and in combination with brivanib, a compound that we in-licensed from Bristol-Myers Squibb, in patients with advanced hepatocellular carcinoma (HCC). The study was initiated in April 2020.
- A Phase I China-only clinical trial of tebotelimab in patients with melanoma. In November 2020, we enrolled the first patient in the study.
- A Phase Ib dose escalation and multi-cohort expansion clinical study of tebotelimab in combination with ZEJULA in Greater China, including gastric cancer, triple negative breast cancer, biliary tract cancer, and endometrial carcinoma. We have initiated dosing in all cohorts.

**Our Autoimmune Disease Pipeline**

***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.

In January 2021, we entered into an exclusive license agreement with argenx BV, or argenx, to develop and commercialize efgartigimod in Greater China. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements – argenx."

In November 2021, we announced that the first patient had been dosed in the Greater China portion of the global registrational ADHERE study of efgartigimod in patients with chronic inflammatory demyelinating polyneuropathy (CIDP). The ADHERE trial is a registrational, prospective, multi-center study to investigate the safety and efficacy of weekly subcutaneous (SC) efgartigimod in adult patients with CIDP.

We also announced in November 2021 that the first patient had been treated in the Greater China portion of the global registrational Phase III ADDRESS study of efgartigimod in patients with pemphigus vulgaris (PV) or pemphigus foliaceus (PF). ADDRESS is a randomized, double-blind, placebo-controlled, multi-center trial evaluating the safety and efficacy of efgartigimod in patients with PV or PF.

Additionally, in November 2021, we announced that the first patient with primary immune thrombocytopenia (ITP) was treated with efgartigimod in Greater China as part of the global registrational ADVANCE-SC Phase III study. The ADVANCE-SC study is a randomized, double-blind, placebo-controlled, multi-center Phase III trial evaluating the efficacy and safety of subcutaneous (SC) efgartigimod in patients with primary ITP.

In December 2021, argenx announced that the FDA approved efgartigimod for the treatment of gMG in adult patients who are anti-acetylcholine receptor (anti-AChR) antibody positive. These patients represent approximately 85% of the total gMG population. With this regulatory milestone, efgartigimod is the first and only FDA-approved neonatal FcRn blocker.

In addition, we have conducted two pharmacokinetic studies in Greater China as part of the data package for the NDA submission to the NMPA for the treatment of gMG. We plan to submit an NDA to the NMPA for gMG in mid-2022.

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

ZL-1102 is a human Humabody® targeting interleukin-17A, or IL-17A, 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 subcutaneous injection. It is conventionally assumed that antibodies and other macromolecules do not penetrate skin.

In October 2021, we announced positive topline results from 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. We plan to initiate a global Phase II study for chronic plaque psoriasis in the second half of 2022.

**Our Infectious Disease Pipeline**

***Sulbactam/Durlobactam***

Sulbactam/durlobactam, or 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) 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 60-70% of such infections are the result of *Acinetobacter baumannii* MDR isolates and carbapenemase-producing isolates (carbapenem-resistant *Acinetobacter baumannii*, or CRAB).

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.

In April 2018, we entered into an exclusive license agreement with Entasis Therapeutics Holdings Inc., or 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 further details of the exclusive license, see “Overview of Our Material License and Strategic Collaboration Agreements—Entasis.”

We also completed a pharmacokinetic study in the fall of 2020 for SUL-DUR in mainland China in normal healthy volunteers.

In October 2021, we and Entasis announced topline results from the ATTACK trial, a global Phase III registrational trial evaluating the safety and efficacy of sulbactam and durlobactam (SUL-DUR) versus colistin in patients with infections caused by Acinetobacter baumannii. The study showed a reduced mortality rate with SUL-DUR versus colistin in the CRAB population. At Test of Cure, there was a statistically significant difference in clinical response favoring SUL-DUR over colistin. SUL-DUR also met the primary safety objective of the study achieving statistically significant reduction in nephrotoxicity.

Entasis plans to submit an NDA to the FDA in mid-2022, and we plan to submit an NDA to the NMPA in the fourth quarter of 2022.

**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.

In November 2021, we entered into a license agreement with Karuna Therapeutics, Inc., or Karuna, pursuant to which we and Karuna agreed to collaboratively develop KarXT in Greater China. Under the agreement, we obtained an exclusive license to develop, manufacture, and commercialize KarXT in Greater China. For further details of the exclusive license, see "Overview of Our Material License and Strategic Collaboration Agreements—Karuna." We plan to initiate a bridging study in 2022.

**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-2309/simurosertib, ZL-1201, ZL-1102), Zai has additional internally discovered and developed compounds in preclinical development: ZL-1211, a humanized monoclonal antibody targeting Claudin18.2, which is highly expressed in various cancer types; ZL-2201, a potent selective inhibitor of DNA-PK involved in DNA damage repair in tumor cells; ZL-1218, a CCR8 inhibitor to block the immune-suppressive activity of regulatory T cells in tumor cells; and multiple other undisclosed compounds.

## OVERVIEW OF OUR MATERIAL LICENSE AND STRATEGIC COLLABORATION AGREEMENTS

### GSK

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, in mainland China, Hong Kong, and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer). 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 paid GSK a $15.0 million upfront payment and a $1.0 million development milestone and we have accrued but not yet paid one development milestone payment of $3.5 million and one sales milestone payment of $8.0 million to GSK. We may be required to pay an additional aggregate amount of up to $28.0 million in regulatory, development and commercialization milestone payments; we are also required to pay GSK certain tiered royalties (from mid- to high-teens on a percentage basis and subject to certain reductions) based on annual net sales of ZEJULA in the licensed territory.

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.

**Turning Point (TPX-0022)**

In January 2021, we entered into a license agreement with Turning Point 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 paid Turning Point a $25.0 million upfront payment and accrued a milestone payment of $2.0 million. We may be required to pay an additional aggregate amount of up to $334.0 million in development, regulatory and sales-based milestone payments, along with certain tiered royalties (from mid-teen to low twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed 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 mergers with or acquires a third party engaged in activities with a competing product, which is not divested or discontinued within a specified period.

**Turning Point (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 in Greater China products containing repotrectinib as an active ingredient in all human therapeutic indications.

To date, we have paid Turning Point a $25.0 million upfront payment and three milestone payments totaling $5.0 million. We may be required to pay an additional aggregate amount of up to $146.0 million in development, regulatory and sales-based milestone payments, along with certain tiered royalties (from mid-to-high teen royalties on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in the 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 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.

**argenx**

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.

To date, we have paid argenx an upfront payment, valued at $75.0 million at the time of issuance in the form of 568,182 newly issued ordinary shares of Zai Lab Limited, and $75.0 million in cash as a guaranteed non-creditable, non-refundable development cost-sharing payment. To date, we have made $25.0 million in development milestone payments to argenx, and may be required to pay certain tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in licensed territory.

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.

**Cullinan**

In December 2020, we entered into a license agreement with Cullinan Pearl, a subsidiary of Cullinan Management, Inc., formerly Cullinan Oncology, LLC, or Cullinan, pursuant to which we obtained an exclusive license under certain patents and know-how of Cullinan to develop, manufacture, and commercialize products containing CLN-081 as an active ingredient in all uses in humans and animals in Greater China. To date, we paid Cullinan an upfront payment in the amount of $20.0 million. We may be required to pay an additional aggregate amount of up to $211.0 million in development, regulatory, and sales-based milestone payments, along with certain tiered royalties (from high-single-digit to low-teen on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in the licensed territory. Cullinan Pearl received worldwide rights for CLN-081, excluding Japan, from Taiho Pharmaceutical, Co., Ltd. in 2018.

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 Cullinan Pearl if we determine that we shall discontinue all development and commercialization activities with respect to the products. Furthermore, Cullinan Pearl 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 Cullinan Pearl 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 Cullinan Pearl's failure to supply sufficient quantities of clinical supply product, then we will be deemed to have abandoned development for the product and Cullinan Pearl 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.

**Regeneron**

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

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

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.

**Incyte**

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.

To date, we have paid Incyte an upfront license fee in the amount of $17.5 million and have not paid Incyte any milestone payments. We may be required to pay an additional aggregate amount of up to $60.0 million in

development, regulatory, and commercial milestone payments, along with certain tiered royalties (from low-to high-twenties on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in licensed territory.

We will purchase licensed products exclusively from Incyte. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of the applicable royalty term for such licensed product and such region as specified in the 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 the licensed patents rights that covers the composition of matter, formulations or a method of treatment or use of such licensed product in such region, (ii) the expiration of regulatory exclusivity for such licensed product in such region or (iii) twelve (12) years from the first commercial sale of such licensed product in such region. In addition, each 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 Incyte may terminate the agreement under specified circumstances if we or our affiliates or sublicensees challenge its patent rights, subject to a certain cure period, or due to our certain development or commercialization diligence failures (subject to the dispute resolution mechanisms if disputes arise with respect to such failures).

**Deciphera**

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 the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in Greater China. To date, we have paid Deciphera an upfront payment in the amount of $20.0 million and three milestone payments in an aggregate amount of $12.0 million. We may be required to pay an additional aggregate amount of up to $173.0 million in additional development, regulatory and commercial milestone payments, along with certain tiered royalties (from low-to high-teens on a percentage basis and subject to certain reductions) based 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 exploit 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.

**MacroGenics**

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 paid MacroGenics an upfront payment in the amount of $25.0 million and two milestone payments in an aggregate amount of $4.0 million, and accrued one milestone payment of $5.0 million. We may also be required to pay certain additional development and regulatory-based milestone payments of up to an aggregate of $131.0 million, along with certain tiered royalties (from mid-teens to twenty for margetuximab, mid-teens for tebotelimab, and low-teens for the TRIDENT molecule, on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in licensed territory.

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 a 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.

Pursuant to the terms of this agreement, for all four programs, we have paid MacroGenics an upfront payment of $25.0 million. 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.

In addition, MacroGenics is eligible to receive up to $1.4 billion in potential development, regulatory, and commercial milestone payments. If products from the collaboration are commercialized, MacroGenics would also receive tiered royalties 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.

**Novocure**

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 paid Novocure an upfront payment in the amount of $15.0 million and two milestone payments in an aggregate amount of $10.0 million. We may be required to pay an additional aggregate amount of $68.0 million in development, regulatory, and commercial milestone payments, along with certain tiered royalties (from low- to mid-teens on a percentage basis and subject to certain reductions) based on annual net sales of the licensed products in 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.

**Entasis**

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 in total of $7.0 million to Entasis. Additionally, we may be required to pay Entasis an additional aggregate amount of up to $91.6 million in development and commercial milestone payments, along with certain tiered royalty payments (from high single digits to low-teens on a percentage basis and subject to certain reductions) based on annual net sales of 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.

**Five Prime / Amgen**

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, or 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 to Five Prime. Additionally, we may be required to pay an additional aggregate amount of up to $37.0 million to Five Prime in development and regulatory milestone payments, along with certain tiered royalties (from high-teens or low twenties depending on the number of patients we enroll in the bemarituzumab FPA144-004 study, and subject to certain reductions) based on annual net sales of 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.

**Paratek**

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.

To date, we have made an upfront payment of $7.5 million and three milestone payments in an aggregate amount of $14.0 million to Paratek Bermuda Ltd. We may be required to pay an additional aggregate amount of up to $40.5 million in milestone payments, along with certain tiered royalties (from low-to mid-teens on a percentage basis and subject to certain reductions) based on annual net sales of licensed products in 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.

**Bristol-Myers Squibb (BMS)**

In March 2015, we entered into a license agreement with BMS, pursuant to which we obtained an exclusive license under certain patents and know-how of BMS to develop, manufacture, and commercialize products containing BMS's proprietary multi-targeted kinase inhibitor, brivanib in mainland China, Hong Kong, and Macau in the field of diagnosis, prevention, treatment or control of oncology indications with the exclusive right to expand our licensed territory to include Taiwan and Korea under certain conditions. BMS retains the non-exclusive right to use the licensed compound to conduct internal research and the exclusive right to use the licensed compound as an intermediate or starting material to manufacture compounds that are not the licensed compound. Under the agreement, we agreed not to develop and commercialize certain competing products for specified time periods.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. BMS has the option to elect to co-promote the licensed products in our licensed territory. If BMS exercises its co-promotion option, BMS will pay us an option exercise fee and we will share equally with BMS the operating profits and losses of the licensed products in our licensed territory. If BMS does not exercise its co-promotion option, we may be required to pay BMS milestone payments for the achievement of certain development and sales milestone events of up to an aggregate of $114.5 million, and also certain tiered royalties (from mid-to high-teens on a percentage basis and subject to certain reductions) based on annual net sales of the licensed products in our licensed territory.

We also have the right to opt-out of the commercialization of the licensed products in our licensed territory under certain conditions. If we elect to opt-out, BMS will have the right to commercialize the licensed products in our licensed territory and will pay us royalties on the net sales of the licensed products in our licensed territory.

We have the right to manufacture the licensed products for commercialization in the licensed territory. The agreement with BMS will remain in effect until such time when there are no outstanding payment obligations for a period of twelve (12) consecutive months, where the royalty term for a licensed product in a region continues until the later of the expiration of the last-to-expire licensed patent that contains a valid claim covering the licensed product, the expiration of any market or data exclusivity for the licensed product, or the twelfth (12th) anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. In addition, either party may terminate this agreement for the other party's uncured material breach, subject to a certain cure period, for safety reasons or failure of the development of the licensed products. We have the right to terminate the agreement for convenience upon a certain notice period. BMS may also terminate the agreement for our bankruptcy or insolvency.

**Mirati**

In May 2021, we entered into a collaboration and license agreement with Mirati Therapeutics, Inc., or 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.

Pursuant to the terms of the agreement, we paid Mirati an upfront fee of $65.0 million, and we will pay milestone payments of up to an aggregate of $273.0 million upon the achievement of specified clinical, regulatory and sales milestones. Mirati will also be eligible to receive certain royalties at tiered percentage rates ranging from the high-teens to low twenties percent on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

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.

**Blueprint**

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-701 and BLU-945 and certain other forms thereof, including backup compounds, in Greater China.

Pursuant to the terms of the agreement, we paid Blueprint an upfront fee of $25.0 million, and will pay milestone payments of up to an aggregate of $590.0 million upon the achievement of specified clinical, regulatory and sales milestones. Blueprint will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to mid-teens on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

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) 12$^{th}$ 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.

**Karuna**

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.

Pursuant to the terms of the agreement, we paid Karuna an upfront fee of $35.0 million and will pay milestone payments of up to an aggregate of $152.0 million upon the achievement of specified clinical, regulatory and sales milestones. Karuna will also be eligible to receive certain royalties at tiered percentage rates ranging from the low to high-teens on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

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.

## 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, please 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, 2021, we exclusively licensed two issued patents in mainland China directed to ZEJULA's free base compound, and salts thereof, and analog of ZEJULA. These issued patents are projected to expire in 2027 and 2028. We also exclusively licensed one pending patent application in mainland China directed to the 4-methylbenzenesulfonate monohydrate salt of the compound, the active pharmaceutical ingredient, or API, of ZEJULA. If this patent application issues as a patent, such patent will be projected to expire in 2029. 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 filed an application in each of mainland China, the United States, the European Union, Israel, Japan, Korea, and India that covers intermediate synthesis process. Patents have issued in mainland China, the United States, Israel, Japan, Korea, and India. We own this family of patents/applications.

***Tumor Treating Fields***

As of December 31, 2021, 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.

***Margetuximab***

As of December 31, 2021, 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.

***QINLOCK***

As of December 31, 2021, 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.

***Adagrasib***

As of December 31, 2021, 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 2039. Additional patents/applications licensed from Mirati also include those related to combination therapy, method of use, or solid forms, which are projected to expire 2040 or thereafter.

***Odronextamab***

As of December 31, 2021, Regeneron has three issued patents and two pending patent applications in mainland China, two issued patents and three 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, 2021, we exclusively licensed one issued patent and two pending patent applications in mainland China, one issued patent and two 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 one pending patent application in mainland China, three pending patent applications in Hong Kong, one issued patent and one pending application 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.

***Bemarituzumab***

As of December 31, 2021, we exclusively licensed one issued patent in mainland China and three issued patents in Hong Kong. These issued patents 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.

***CLN-081***

As of December 31, 2021, 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 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, 2038, or 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

***Elzovantinib***

As of December 31, 2021, we exclusively licensed one pending patent application in each of mainland China, Hong Kong, and Taiwan specifically covering the drug substance. These applications are directed to composition of matter and their uses. Any patents granted from these applications are projected to expire in 2038. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

***Retifanlimab***

As of December 31, 2021, we exclusively licensed patents and pending patent applications directed to the API of retifanlimab (INCMGA0012 (PD-1)) and uses of retifanlimab in mainland China, Hong Kong, and Taiwan. As of December 31, 2021, there are three pending patent applications in mainland China, one issued patent and two pending patent applications in Taiwan and two pending patent applications in Hong Kong. If these patent applications issue as patents, such patents are projected to expire in 2036 or 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of Greater China.

***BLU-945***

As of December 31, 2021, we exclusively licensed a patent portfolio related to BLU-945. The patents or applications (if issued as patents) are projected to expire 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.

***BLU-701***

As of December 31, 2021, we exclusively licensed a patent portfolio related to BLU-701. The patents or applications (if issued as patents) are projected to expire after 2040. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

***Simurosertib***

As of December 31, 2021, we have exclusively licensed a portfolio including seven families of issued patents or pending applications worldwide excluding Japan. These seven families are directed to composition of matter, polymorphs, uses, manufacturing process or formulations. Composition-of-matter patents have issued in a number of countries/regions including, for example, the United States, Greater China, Europe, South Korea, Canada, Israel, and Australia. The issued patents and any patents issued from the pending applications in the portfolio are projected to expire between 2031 and 2040.

***ZL-1201***

We have filed patent applications in mainland China, Europe, South Korea, Japan, Australia, Canada, Israel, Russia, and the United States that are directed to composition of matter and their use. These applications are currently pending and the claims in a U.S. application are allowed. Any patents issued from these applications are projected to expire in 2038. We own these patent applications.

***ZL-1211***

As of December 31, 2021**,** we have filed applications in fourteen countries, including the United States, 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.

***Tebotelimab***

As of December 31, 2021, we exclusively licensed issued patents in mainland China, Hong Kong, and Taiwan related to antibody sequences and therapeutic uses of tebotelimab. These patents that we exclusively licensed are projected to expire in 2035. Additional licensed patents/applications include those related to lag-3 antibodies or PD-1 antibodies, which are projected to expire in 2036. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than Greater China.

***Efgartigimod***

As of December 31, 2021, 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 three pending patent applications in mainland China, four 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, 2021, we have exclusively licensed one issued patent in each of the United States, Japan, and mainland China and one pending patent application in each of the United States, Europe, mainland China, 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 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.

***Omadacycline***

As of December 31, 2021, 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.

***Durlobactam***

As of December 31, 2021, we exclusively licensed one issued patent in mainland China, one issued patent in Japan and one corresponding 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 territory of the Entasis Agreement.

***KarXT***

As of December 31, 2021, 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.

***Brivanib***

As of December 31, 2021, we exclusively licensed two issued patents in mainland China and one issued patent in Hong Kong that relate to brivanib. They are composition-of-matter patents that cover the brivanib compound and its analog and are projected to expire in 2023. Our exclusively licensed patents also include a patent in mainland China that covers a manufacturing process for the synthesis of brivanib's API. This patent is projected to expire in 2027. In addition, one patent we exclusively licensed in mainland China that covers a crystal form of brivanib alaninate is projected to expire in 2026. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than mainland China, Hong Kong, and Macau.

***ZL-2103***

As of December 31, 2021, we have exclusively licensed one pending application in each of mainland China, the United States, Japan, Europe, Israel, South Korea, Australia, Canada, Russia, New Zealand, and Taiwan. These applications are directed to composition of matter and their uses. Any patent issued from these applications are projected to expire in 2039.

***ZL-2201***

As of December 31, 2021, we have licensed a world-wide patent portfolio related to ZL-2201. The patents or applications (if issued as patents) are projected to expire 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, please 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 large unmet medical need in the Greater China and global markets, including in the fields of oncology, infectious and autoimmune 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 from discovery, translational medicine to 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 diseases. 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 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 "Suppliers."

For the years ended December 31, 2020 and 2021, our research and development expenses were US$222.7 million and US$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.

## GOVERNMENT REGULATION

### Government Regulation of Pharmaceutical Product Development and Approval

***Chinese regulation of pharmaceutical product development and approval***

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

In October 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Communist Party of China Central Committee jointly issued the Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion, which is a mandatory plan to further reform the review and approval system and to encourage the innovation of drugs and medical devices. Under the Innovation Opinion and other recent reforms, the expedited programs and other advantages encourage drug manufacturers to seek marketing approval in mainland China first and to develop drugs in high priority disease areas, such as oncology or rare disease.

To implement the regulatory reform introduced by the Innovation Opinion, the Standing Committee of the National People's Congress, or the SCNPC, and the NMPA have recently revised the fundamental laws, regulations and rules governing pharmaceutical products and the pharmaceutical industry, including the amendment of the framework law known as the Drug Administration Law of the People's Republic of China, or the Drug Administration Law, which became effective on December 1, 2019. The SAMR, has promulgated two key implementing regulations for the Drug Administration Law: (i) the amended Administrative Measures for Drug Registration and (ii) the amended Measures on the Supervision and Administration of the Manufacture of Drugs. Both regulations took effect on July 1, 2020.

*Regulatory authorities*

In mainland China, the NMPA is the authority under the SAMR that monitors and supervises the administration of pharmaceutical products, medical appliances and equipment, and cosmetics. The NMPA was established in March 2018 as part of the institutional reform of the State Council. Predecessors of the NMPA include the former China Food and Drug Administration, or the CFDA, established in March 2013, the State Food and Drug Administration, or the SFDA, established in March 2003, and the State Drug Administration, established in August 1998. The primary responsibilities of the NMPA include:

- monitoring and supervising the administration of pharmaceutical products, medical devices and equipment as well as cosmetics in mainland China;

- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical device and cosmetics industry;
- evaluating, registering and approving chemical drugs, biological products and traditional Chinese medicine, or the TCM;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products; and
- examining and evaluating the safety of pharmaceutical products, medical devices and cosmetics and handling significant accidents involving these products.

According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs published in March 2017, which became effective in May 2017, approvals of clinical trial applications should be issued by the CDE in the name of the CFDA.

China's National Health and Family Planning Commission, or the NHFPC, was rebranded as the National Health Commission, or NHC in March 2018. The NHC is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The NHC combines the responsibilities of the former NHFPC, the Leading Group Overseeing Medical and Healthcare Reform under the State Council, the China National Working Commission on Aging, partial responsibilities of the Ministry of Industry and Information Technology in relation to tobacco control, and partial responsibilities from the former State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the Ministry of Health, or the MOH. Following the establishment of the former SFDA in 2003, the MOH was put in charge of the overall administration of the national health in mainland China, excluding the pharmaceutical industry. The NHC performs a variety of tasks in relation to the health industry such as establishing and overseeing the operation of medical institutions, some of which also serve as clinical trial sites, regulating the licensure of hospitals, and producing professional codes of ethics for public medical personnel. The NHC plays a significant role in drug reimbursement.

*Drug Administration Law*

The Drug Administration Law as promulgated by the SCNPC in 1984, and the Implementing Measures of the Drug Administration Law as promulgated by the State Council in August 2002, established the legal framework for the administration of pharmaceutical products, including the development and manufacturing of new drugs and the medicinal preparations by medical institutions. The Drug Administration Law also regulates the distribution, packaging, labels and advertisements of pharmaceutical products in mainland China.

Certain amendments to the Drug Administration Law took effect on December 1, 2001, and subsequent amendments were made on December 28, 2013, April 24, 2015, and August 26, 2019. These amendments were formulated to strengthen the supervision and administration of pharmaceutical products and to ensure the quality and safety of pharmaceutical products. The current Drug Administration Law applies to entities and individuals engaged in the development, production, distribution, application, supervision and administration of pharmaceutical products. The Drug Administration Law regulates and prescribes a framework for the administration of the law to pharmaceutical manufacturers, pharmaceutical distribution companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products.

According to the Drug Administration Law, no pharmaceutical products may be produced in mainland China without a Pharmaceutical Manufacturing Permit. A local manufacturer of pharmaceutical products must obtain a Pharmaceutical Manufacturing Permit from one of the provincial administrations of medical products in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards.

In August 2019, the SCNPC promulgated the latest Drug Administration Law, or the 2019 Amendment, which became effective in December 2019. The 2019 Amendment brought a series of changes to the drug supervision and administration system, including (i) the formalization of the drug marketing authorization holder system, or the MAH system; (ii) expedited approval pathway; and (iii) the cancelation of relevant certification in relation to Good Manufacturing Practice and Good Supply Practice. The 2019 Amendment requires the marketing authorization holder to assume responsibilities for the entire product life cycle, including non-clinical studies, clinical trials, manufacturing, marketing, post-marketing studies, monitoring, reporting and handling of adverse reactions of the drug. The 2019 Amendment also stipulates that the state supports the innovation of drugs with clinical value, encourages the development of drugs with new therapeutic mechanisms and multi-targeted, systematic adjustment and intervention of physiological function, and promotes the technological advancement of drugs.

The Implementing Measures of the Drug Administration Law promulgated by the State Council on August 4, 2002 were amended on February 6, 2016 and March 2, 2019, and serve to provide detailed implementation regulations for the Drug Administration Law. As of the date of this Annual Report on Form 10-K, the Implementing Measures of the Drug Administration Law have not been further amended to reflect the changes in the 2019 Amendment.

*Administrative Measures for Drug Registration*

In July 2007, the former SFDA released the Administrative Measures for Drug Registration which took effect on October 1, 2007, or the 2007 Drug Registration Regulation. The 2007 Drug Registration Regulation covers (i) definitions of drug marketing authorization applications and regulatory responsibilities of the former SFDA; (ii) general requirements for drug marketing authorization; (iii) drug clinical trials; (iv) application, examination and approval of drugs (such as new drugs, generic drugs, imported drugs and OTC drugs); (v) supplemental applications and marketing authorization renewals of drugs; (vi) re-registration of drugs; (vii) inspections; (viii) marketing authorization standards and specifications; (ix) time limits; (x) re-examination; and (xi) liabilities and other supplementary provisions.

In January 2020, the SAMR released the amended Administrative Measures for Drug Registration, which took effect in July 2020, or the 2020 Drug Registration Regulation. Compared to the 2007 Drug Registration Regulation, the 2020 Drug Registration Regulation provides detailed procedural and substantive requirements for the key regulatory concepts established by the 2019 Amendment and confirms a number of reform actions that have been taken in the past years, including but not limited to: (i) fully implementing the MAH system and implied approval for the commencement of clinical trials; (ii) implementing associated review of drugs, excipients and packaging materials; and (iii) introducing four expedited approval pathways, namely the breakthrough designation, conditional approvals, prioritized reviews and special reviews and approvals.

*Collecting and Using Patients' Human Genetic Resources and Derived Data*

In June 1998, the Ministry of Science and Technology, or MOST, and the former MOH jointly established the Interim Measures for the Administration of Human Genetic Resources in China. In July 2015, the MOST issued the Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which provides that foreign entities that collect and use patients' human genetic resources in clinical trials shall be required to file for an advance approval with the Human Genetic Resources Administration Office of China, or the HGRAC, through its online system.

In October 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval process for collecting and using human genetic resources for the purpose of seeking marketing authorization of drugs in mainland China.

In May 2019, the State Council of the People's Republic of China issued the Regulation on the Administration of Human Genetic Resources, or the HGR Regulation, which stipulates the approval requirements

pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using Chinese patients' biospecimens at clinical study sites without involving the export of such biospecimens outside of mainland China. A notification filing that specifies the type, quantity and usage of the biospecimens, among others, with the HGRAC is required before conducting such clinical trials. The collection, use, and outbound transfer of Chinese patients' biospecimens in international collaboration for basic scientific research involving export of such biospecimens are still subject to the advance approval of the HGRAC.

In October 2020, the SCNPC promulgated the Biosecurity Law of the People's Republic of China, or the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative fines significantly in cases in which foreign entities are alleged to have collected, preserved or exported Chinese human genetic resources.

*Regulations on the Clinical Trials and Marketing Authorization of Drugs*

**Four Phases of Clinical Trials**

According to the 2020 Drug Registration Regulation, a clinical development program consists of Phases I, II, III and IV clinical trials as well as bioequivalence trials. Based on the characteristics of study drugs and research objectives, the four phases of studies respectively focus on clinical pharmacology, exploratory, confirmatory and post-approval assessment of efficacy and safety.

**Approval Authority and Process for Clinical Trial Applications**

According to the 2019 Amendment and the 2020 Drug Registration Regulation, clinical studies on investigational drugs must be approved by the CDE before its commencement.

Upon the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to the CDE for the CTA, to conduct a drug clinical trial. The CDE will organize pharmaceutical, medical and other reviewers to review the application and to decide whether to approve the drug clinical trial within 60 business days of accepting the application. Once the decision is made, the applicant can locate such decision on the CDE's website. If no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. The 2020 Drug Registration Regulation further requires that the applicant shall, prior to conducting a drug clinical trial, register the information of the drug clinical trial protocol, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant shall update registration information continuously and, upon completion, register information about the outcome of the drug clinical trial. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform. Pursuant to the Notice on the Drug Clinical Trial Information Platform promulgated by former SFDA in September 2013, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the CTA in order to obtain the trial's unique registration number and complete registration of certain follow-up information and first-time submission for disclosure of the drug clinical trial information on the platform before the first subject's enrollment in the trial. If the first-time submission for disclosure is not completed within one year after the approval of the CTA, the applicant shall submit an explanation, and if the first-time submission for disclosure is not completed within three years, the approval of the CTA shall automatically expire.

**Qualification of Clinical Trial Institutions and Compliance with GCP**

According to the Innovation Opinion, certification of clinical trial institutions by the former CFDA and the former NHFPC was no longer required. Instead, a clinical trial institution can be engaged by a drug marketing authorization applicant (i.e., a sponsor) to conduct a drug clinical study after it has been duly registered with the

online platform designated by the NMPA. On November 29, 2019, pursuant to the 2019 Amendment, the NMPA and the NHC jointly released the Rules for Administration of the Drug Clinical Trial Institutions, which became effective on December 1, 2019. The rules specify requirements for clinical trial institutions and recordal procedures. Pursuant to the rules, a clinical trial institution should comply with the requirements of the Good Practices for Drug Clinical Trials, or GCP, and be capable of undertaking drug clinical trials. It should also evaluate, or engage a third party to evaluate, its clinical trial proficiency, facilities and expertise before the recordation. According to the Implementing Measures of the Drug Administration Law, a drug marketing authorization applicant should only engage a clinical trial institution that complies with relevant regulations to carry out a drug clinical trial.

The conduct of clinical trials must adhere to the GCP and the protocols approved by the ethics committee. Since 2015, the former CFDA has strengthened the enforcement against widespread data integrity issues associated with clinical trials in mainland China. To ensure authenticity and reliability of the clinical data, the former CFDA mandated drug marketing authorization applicants to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, the former CFDA also regularly launched onsite clinical trial audits over selected applications and rejected those found with data forgery. The GCP audit has been ongoing and has been able to curb the number of unreliable marketing authorization applications.

In April 2020, the NMPA and the NHC released the Amended GCP that took effect on July 1, 2020. The Amended GCP provides comprehensive and substantive requirements on the design and conduct of clinical trials in mainland China. In particular, the Amended GCP enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

**International Multi-Center Clinical Trials Regulations**

On January 30, 2015, the former CFDA promulgated the Tentative Guidelines for International Multi-Center Clinical Trial, or the Multi-Center Clinical Trial Guidelines, which took effect on March 1, 2015. The Multi-Center Clinical Trial Guidelines aimed to provide guidance for the regulation of application, implementation and administration of International Multi-Center Clinical Trials in China, or the IMCCT. IMCCT applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the marketing authorization applicant plans to make use of the data derived from the IMCCTs, such IMCCTs shall satisfy, in addition to the requirements set forth in the Drug Administration Law and its implementation regulations, the Administrative Measures for Drug Registration, the GCP and relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;
- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the study drug, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore IMCCT research centers shall be subject to on-site inspections by the Chinese regulatory authorities.

IMCCTs shall follow the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH-GCP) principles and ethics requirements. Marketing authorization applicants shall ensure the truthfulness, reliability and trustworthiness of clinical trials results. The investigators shall have the qualification and capability to perform relevant clinical trials. The ethics committee shall continuously supervise the trials and protect the subjects' interests, benefits and safety. Before the commencement of the IMCCT, applicants shall obtain clinical trial approvals or complete

filings pursuant to requirements under the local regulations where clinical trials are conducted, and applicants shall register and disclose the information of all major investigators and study sites on the NMPA's drug clinical trial information platform.

Data derived from IMCCTs can be used for the marketing authorization applications with the NMPA. When using international multi-center clinical trial data to support marketing authorization applications in mainland China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements. Also, subgroup research results summary and comparative analysis shall be conducted concurrently.

In October 2017, the former CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration to reform the regulatory framework for IMCCT in China, which includes the following key points:

- The IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for preventive biological products. Phase I IMCCT is permissible in mainland China.
- The application for drug marketing authorization can be submitted directly after the completion of the IMCCT.
- With respect to clinical trial and market authorization applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.

**Clinical Trial Waivers and Acceptance of Foreign Clinical Trial Data**

On July 6, 2018, the NMPA issued the Technical Guidance for Accepting Foreign Clinical Trial Data, or the Foreign Clinical Trial Data Guidance, as one of the implementing rules for the Innovation Opinion. According to the Foreign Clinical Trial Data Guidance, sponsors may use the data of foreign clinical trials to support drug marketing authorization in mainland China, provided that sponsors must ensure the authenticity, completeness, accuracy and traceability requirements, and that such data must be obtained in consistency with the relevant requirements under the ICH-GCP. Clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of mainland China to be approved in mainland China on a conditional basis without pre-approval clinical trials being conducted in mainland China. Specifically, in 2018, the NMPA and the NHC issued the Procedures for the Review and Approval of Urgently Needed Foreign New Drugs. The procedures are intended to accelerate approvals for drugs that have been approved within the last ten years in the United States, the European Union, or Japan and that treat orphan diseases or prevent or treat serious life-threatening illnesses for which there is either no effective therapy in mainland China or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete post-approval trials in mainland China.

**Marketing Authorization Holder System**

Under the authorization of the SCNPC in November 2015, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, which provides a detailed pilot plan for the MAH system for drugs in 10 provinces in mainland China. Under the MAH system, domestic drug research and development institutions and individuals in the piloted regions are eligible to be holders of drug marketing authorizations without having to become drug manufacturers. The Pilot Plan was originally set for a 3-year period by the SCNPC and would end in November 2018. Effective as of November 5, 2018, the SCNPC decided to extend the pilot program for another year.

The latest Drug Administration Law purports to roll out the MAH system nationwide. Companies and research and development institutions can be drug marketing authorization holders. The drug marketing authorization holder should be responsible for their products throughout the life cycle, including nonclinical studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the 2019 Amendment. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that (i) pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs, the marketing authorization holder must meet the specified requirements and obtain the Pharmaceutical Manufacturing Permit for MAH holder; and (ii) each of the contract manufacturers has obtained and maintained a valid Pharmaceutical Manufacturing Permit for the specific type of drugs. The marketing authorization holders can also engage pharmaceutical distribution enterprises with a valid Pharmaceutical Distribution Permit for the distribution activities. Upon receiving the marketing authorizations from the NMPA, a drug marketing authorization holder may transfer its drug marketing authorization to a company that has the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality of the drug, and to fulfill the obligations of the drug marketing authorization holder.

**Drug Marketing Authorization**

According to the 2020 Drug Registration Regulation, the applicant may submit an application for drug marketing authorization to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination of the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by the Center for Food and Drug Inspection, or CFDI. The NMPA then determines whether to approve the application according to the comprehensive technical review by the CDE. We must obtain approval of drug marketing authorizations before our drugs can be manufactured and sold in the mainland China market.

*Drug Registration Classification*

According to the 2020 Drug Registration Regulation, drug marketing authorization applications are divided into three different types, namely traditional Chinese medicine, chemical drugs and biological products. Drugs falling into one of three general types are further divided by their characteristic, level of innovation and status of review and administration according to auxiliary regulatory documents to the 2020 Drug Registration Regulation.

In March 2016, the former CFDA issued the Reform Plan for Registration Classification of Chemical Medicine, or the Reform Plan, which outlined the reclassifications of drug marketing authorization applications under the 2007 Drug Registration Regulation. Under the Reform Plan, Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs that have equivalent quality and efficacy to the originator's drugs that have been marketed abroad but not yet in mainland China fall into Category 3. Generic drugs that have equivalent quality and efficacy to the originator's drugs and have been marketed in mainland China fall into Category 4. Category 5 drugs are chemical drugs which have already been marketed abroad but are not yet approved in mainland China.

As a support policy and implementing rule of the 2020 Drug Registration Regulation, the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan and made minor adjustments to the subclasses of Category 5. According to such rule, Category 5.1 are originator drugs and improved drugs with clear clinical advantages while Category 5.2 are generic drugs, all of which shall have been already marketed abroad but not yet approved in mainland China.

*Priority review and accelerated review and approval channels*

The NMPA and its predecessors have issued a series of regulatory documents aiming to simplify or accelerate the review and approval process for innovative new drugs or drugs in great clinical demand.

According to the Special Examination and Approval of Registration of New Drugs promulgated by the former SFDA on January 7, 2009, the former SFDA conducts special examination and approval for new drug marketing authorization applications when:

- the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in mainland China, and the material medicines and the preparations thereof are newly discovered;
- the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad;
- the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinical treatment; or
- the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval of Registration of New Drugs provide that the applicant may file for special examination and approval at the CTA stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until the marketing authorization application stage.

The Circular Concerning Several Policies on Drug Registration Review and Approval issued by the former CFDA on November 11, 2015 further provides the following policies, potentially simplifying and accelerating the approval process of clinical trials: (x) a single approval for all phases of clinical trials for a new drug, replacing the phase-by-phase application and approval procedure; and (y) a fast-track approval pathway for the following applications: (1) marketing authorization of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (2) marketing authorization of pediatric drugs; (3) marketing authorization of drugs treating specific or prevalent diseases in elders; (4) marketing authorization of drugs listed in national major science and technology projects or national key research and development plans; (5) marketing authorization of drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits that are urgently needed clinically; (6) marketing authorization of foreign innovative drugs to be manufactured locally in mainland China; (7) concurrent applications for CTA which are already approved in the United States or the European Union or concurrent drug marketing authorization applications for drugs which have applied to the United States or European Union regulatory authorities and are manufactured in mainland China using the same production line that passed the onsite inspections by the United States or the European Union regulatory authorities; and (8) CTA for drugs with urgent clinical need and patent expiry within three years, and marketing authorization applications for drugs with urgent clinical need and patent expiry within one year.

The Opinions on Encouraging Priority Review and Approval for Drug Innovations promulgated by the former CFDA on December 21, 2017 provide that a fast-track CTA or marketing authorization pathway will be available to both innovative drugs with distinctive clinical benefits, which have not been sold within or outside mainland China, and drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

The 2020 Drug Registration Regulation has incorporated the previous reform with respect to the accelerated review and approval process for clinical trials and drug marketing authorizations. The 2020 Drug Registration Regulation and the auxiliary regulatory documents currently provide four procedures for fast-track review and approvals of drugs. The NMPA would prioritize the allocation of resources for communication, guidance, review, inspection, examination and approval of applications that are qualified for the application of the four procedures. The four procedures are (1) the review and approval procedures for break-through therapeutic drugs; (2) the review and approval procedures for drug conditional approval application; (3) the priority review procedures for drug marketing authorization approval; and (4) drug special review and approval procedures in case of public health emergency.

*Review and approval procedures for break-through therapeutic drugs*

In principle, during the drug clinical trials, an applicant may submit the application to the CDE for its drug to be designated as a break-through therapeutic drug if the following general conditions are met:

- The drug candidate must be an innovative new drug or improved new drug;
- The drug candidate must be used for the prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on the quality of life; and
- There is no other effective prevention or treatment method, or there is adequate evidence proving that the drug candidate has obvious clinical advantages over existing treatment methods.

*Review and approval procedures for drug conditional approval application*

At the clinical trial stage, an applicant may submit the application to the CDE for its drug to be qualified for conditional approval if the following general conditions are met:

- The drug candidate is for treatment of life-threatening illnesses with no effective treatment method or in dire need in case of a public health emergency; and clinical trial data on drug efficacy is available and the clinical value of the drug candidate can be predicated based on such data; or
- For vaccines urgently needed in major public health crisis or other vaccines that are deemed by the NHC to be urgently needed, they may receive conditional approvals if their assessed benefits outweigh the risks.

*Priority review procedures for drug marketing authorization approval*

Upon the submission of the marketing authorization application for a drug candidate that has obvious clinical value, an applicant may request that the marketing authorization application be qualified for priority review. Drugs that are qualified for priority review include:

- Drugs that are in short supply and urgently needed clinically, or innovative new drugs or improved new drugs for the prevention and treatment of major contagious diseases or rare diseases;
- Drugs for pediatric use with new product specification, dosage form and strength that comply with pediatric physiological characteristics;
- Vaccines and innovative vaccines urgently needed for the prevention and control of diseases;
- Drugs that received break-through therapeutic drug designation;
- Drugs that are qualified for conditional approval; and
- Others qualified for priority review as stipulated by the NMPA.

*Drug special review and approval procedures in case of public health emergency*

At the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for an urgently needed drug required for the prevention and treatment during the public health emergency. Drugs included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

*Administrative protection for new drugs*

Under the 2007 Drug Registration Regulation, the Implementing Measures of the Drug Administration Law (effective as of March 2, 2019) and the Reform Plan, the NMPA may provide for an administrative monitoring

period of not more than five years for Category 1 new drugs for the purpose of protecting public health. The new drug monitoring period commences from the date of approval, and the NMPA will continually monitor the safety of those new drugs. However, the 2020 Drug Registration Regulation omits the provisions relating to the administrative exclusivity created by the new drug monitoring period. The NMPA has not issued any written guidance regarding whether it will grant administrative exclusivity during the new drug monitoring period to new drugs approved after the 2020 Drug Registration Regulation took effect.

In July 2021, the NMPA and the China National Intellectual Property Administration, or the CNIPA, jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative), or the Measures on Patent Linkage. The Measures on Patent Linkage provide an operating mechanism for the NMPA and CNIPA to link generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. The most recent amendment to the Patent Law of the People's Republic of China, or the China Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, describes the general principles of Patent Linkage, but lacks operational details. The Measures on Patent Linkage are intended to answer these operational questions.

The Measures on Patent Linkage describe a framework for a patentee to defend their patent exclusivity. Upon discovery of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the CDE's publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. Moreover, for chemical drugs, the NMPA's approval stay is only nine months, and the technical review does not need to stay in this nine-month period. If the patentee or the interested person cannot secure 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. In mainland China no NMPA approval stay is available to biosimilar applications. The NMPA can proceed with the technical review and marketing authorization upon receiving biosimilar applications. To delay the entry of biosimilars, the originator/patentee will need to file an infringement claim with the court or CNIPA within 45 days after the CDE's publication of the biosimilar application, and secure a favorable decision before the NMPA's issuance of the marketing authorization. The NMPA will then convert the marketing authorizations into a conditional approval effective after the relevant patents expire.

The Measures on Patent Linkage further provides the conditions and procedures for the certification of non-infringement for generic companies and the marketing exclusivity period that may be granted to the first generic company receiving marketing authorization approval.

*Data Privacy and Data Protection*

The Chinese government continues to strengthen its regulation of network security, data protection, data privacy, and personal information (including personal health information). For example, the China Civil Code, which was promulgated by the National People's Congress of the People's Republic of China in May 2020 and became effective in January 2021, provides that the personal information of a natural person shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others.

In November 2016, the SCNPC promulgated the Cyber Security Law, which became effective in June 2017. The Cyber Security Law requires network operators to perform certain functions related to cybersecurity protection and strengthen their network information management and comply with certain requirements when collecting and using personal information. For instance, under the Cyber Security Law, network operators of critical information infrastructure generally are required to store personal information and important data

collected and produced during their operations in mainland China within the territory of mainland China. In addition, under the Cyber Security Law, when collecting and using personal information, network operators are required to abide by principles of lawfulness, justifiableness and necessity. Network operators that collect and use personal information are required to announce the rules for such collection and use, expressly disclose the purpose, methods and scope of such collection and use, and obtain the consent of the persons whose personal information are to be collected. Network operators are prohibited from collecting personal information that are unrelated to the services they provide, and from collecting or using personal information in violation of applicable laws and regulations and their agreements regarding their collection and use of such personal information. Network operators are also required to process the personal information they store in accordance with the provisions of laws and administrative regulations and their agreements reached with relevant persons. Network operators are prohibited from disclosing, tampering with or destroying personal information that they collect, and may not disclose personal information to others without the prior consent of the person whose personal information has been collected, unless such personal information has been anonymized by processing it in a manner that prevents the related persons from being identified and any information that can be used to re-identify the related persons from being restored. Under the Cyber Security Law, an individual has the right to require a network operator to delete his or her personal information if he or she finds that the collection and use of such information by such network operator violates applicable laws, administrative regulations or his or her agreement with such network operator, and to require a network operator to correct errors in his or her personal information collected and stored by such network operator. Also, under the Cyber Security Law, any individual or organization is prohibited from acquiring personal information by stealing it or through other illegal ways, and from illegally selling or providing personal information to others.

In July 2018, the National Health Commission promulgated the Measures on Health and Medical Big Data, which sets out guidelines and principles for standards management, security management and services management for the health and medical big data sector. Under the Measures, health and medical big data is defined as health and medical related data created in the course of preventing and treating illness and managing the health of individuals. The Measures require that all health and medical big data be stored in secure servers located in mainland China, and that relevant cross-border data transfer laws and regulations be followed and a security assessment be conducted when it is necessary to transfer such data outside of mainland China.

In June 2021, the SCNPC promulgated the Data Security Law, which became effective on September 1, 2021. The Data Security Law establishes a tiered system for data protection in terms of the data's importance, and requires that data identified as important data, which will be identified by governmental authorities through the use of catalogs, be treated with a higher level of protection. Specifically, the Data Security Law requires any processors of important data to appoint a data security officer and a management department to take charge of data security. In addition, any processors of important data are required to periodically evaluate the risk of its data processing activities and file risk assessment reports with relevant regulatory authorities. The Data Security Law, in addition to reiterating the Cyber Security Law requirements for cross-border transfers of important data collected and produced during operations within the territory of mainland China of critical information infrastructure operators, also references additional requirements that are yet-to-be formulated regulating the cross-border transfer of important data by all processors. Additionally, the Data Security Law prohibits any organization or individual located within the territory of mainland China from providing to a foreign judicial or law enforcement authority any data stored within the territory of mainland China without the approval of relevant regulatory authorities. Since the Data Security Law is relatively new, uncertainties still exist in relation to its interpretation and implementation.

On July 10, 2021, the Cyberspace Administration of China, or the CAC, published a draft revision to the existing Cybersecurity Review Measures for public comment, or the Revised Draft CAC Measures, and together with 12 other Chinese regulatory authorities, released the final version of the Revised Draft CAC Measures, or the Revised CAC Measures, on January 4, 2022, which came into effect on February 15, 2022. Pursuant to the Revised CAC 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.

On August 20, 2021, the National People's Congress promulgated the PIPL, which became effective on November 1, 2021. The PIPL is an omnibus regulation that provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information of individuals located within the territory of mainland China and the processing of personal information of individuals located in mainland China conducted outside of mainland China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, individuals located in mainland China. Under the PIPL, the processing of personal information is not permitted unless a legal basis exists. The legal bases for processing personal information under the PIPL include (i) where the consent of the relevant individual is obtained, (ii) where it is necessary to conclude or perform a contract to which the relevant individual is a party or for implementing human resources management in accordance with labor rules and regulations that are formulated in accordance with the law or collective contracts concluded in accordance with the law, (iii) where it is necessary to perform legal duties or obligations, (iv) where it is necessary to respond to a public health emergency or to protect the life and health of persons or their property, (v) where it is for news reporting and supervision of public opinion carried out for the public interest, and the processing is reasonable in scope, (vi) where it is necessary to process the personal information disclosed by the relevant individual or otherwise legally disclosed, and the processing is reasonable in scope, and (vii) under other circumstances prescribed by laws and regulations. The PIPL clarifies and prescribes new notice and consent requirements for personal information processors, including the requirement to obtain separate consent in five circumstances: (i) when disclosing personal information to another personal information processor, (ii) when processing sensitive personal information, (iii) when transferring personal information outside the territory of mainland China, (iv) when publicly disclosing the personal information of an individual, and (v) when using an individual's personal image or identification information collected by image capture or personal identification equipment installed in public places for purposes other than maintaining public security. 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. The PIPL enumerates a number of data subject rights, including the right of notice, access, correction, deletion, and portability. Additionally, the PIPL prohibits any personal information processor from providing to a foreign judicial or law enforcement authority any data stored within the territory of mainland China without the approval of relevant regulatory authorities. Lastly, the PIPL provides for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities.

On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment), or the Draft Management Regulations, under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Management Regulations reiterate that data processors shall be subject to cybersecurity review if they process personal information of more than one million persons and aiming to list on foreign stock markets, or the data processing activities influence or may influence national security. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by 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.

On January 13, 2022, the draft Guidelines for Identification of Important Data were released, which sets out six principals for identifying critical data: (i) data must be assessed based on its security impact from the perspectives of state security, economy, social stability, public health and safety, etc., data which is only important to organizations internally shall not be regarded as critical data; (ii) data classification is important in

identifying the area(s) of focus for protection, by classifying data and specifying security protection priorities, only critical data would be subject to additional requirements to the ensure free flow of non-critical data; (iii) existing local regulations and industry practice must be considered to ensure the additional measures work seamlessly with them, (iv) risks should be assessed in a holistic matter including the data's confidentiality, completeness, availability, authenticity, and accuracy, etc.; (v) both the quality and quantity of data must be considered; and (vi) the assessment must be conducted and reviewed on a regular basis because the uses of the data, the way that the data is shared and the importance of data may change over time.

Additional regulations, guidelines, and measures relating to data privacy and data protection are expected to be adopted, including the Measures for Data Security Management (Draft for Comment), published in 2019, the Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment), published in 2019, and the Measures on Security Assessment of Outbound Data Transfers (Draft for Comment), published in October 2021, each of which indicates a trend of more stringent compliance requirements, and, if and when adopted or effective, would require security assessment and review before transferring personal health information out of mainland China.

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

**Good Pharmacovigilance Practice**

The latest Drug Administration Law provides that the State shall establish a pharmacovigilance system for monitoring, identifying, assessing and controlling adverse drug reactions and other harmful reactions associated with the use of drugs. As a supporting document in this regard, the Good Pharmacovigilance Practice (GVP), which was promulgated by the NMPA and became effective as of December 1, 2021, outlines the key requirements for pharmacovigilance activities to be carried out by drug marketing authorization holders and/or drug clinical trial sponsors. The GVP clarifies that pharmacovigilance activities, including collection, identification, evaluation and control of adverse drug reactions, shall take place in the total life cycle of drugs, from the clinical development stage through the post-approval stage. The GVP calls for effective and differentiated pharmacovigilance activities for different types of drugs, such as innovative drugs, traditional Chinese medicines and ethnic medicines.

**Good Laboratories Practice certification for nonclinical research**

To improve the quality of nonclinical research, the former SFDA promulgated the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory in 2003, or the GLP 2003, and began to conduct the certification program of the GLP. The GLP 2003 was then abolished and replaced by the Administrative Measures for Good Laboratories Practice of Pre-clinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, providing that the former SFDA (now the NMPA) is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, the former SFDA (now the NMPA) decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution's organizational administration, personnel, laboratory equipment and facilities and its operation and management

of nonclinical pharmaceutical projects. If all requirements are met, a GLP certification will be issued by the former SFDA (now the NMPA) and published on the government website.

**Animal testing permits**

According to Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission in November 1988, as amended by the State Council in January 2011, July 2013 and March 2017, and Administrative Measures on the Certificate for Animal Experimentation (Tentative) promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experiments on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- the environment and facilities for the animals' living and propagating must meet state requirements;
- the animals' feed must meet state requirements;
- the animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- the management systems must be effective and efficient; and
- the applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

**Drug Technology Transfer and Marketing Authorization Transfer**

On August 19, 2009, the former SFDA promulgated the Administrative Regulations for Registration of Drug Technology Transfer to standardize the registration process of drug technology transfer, which includes application for, and evaluation, examination, approval and monitoring of, drug technology transfer. Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the provisions in the technology transfer regulations. Drug technology transfer includes new drug technology transfer and drug production technology transfer.

*Conditions for the application for new drug technology transfer*

Applications for new drug technology transfer may be submitted prior to the expiration date of the monitoring period of the new drugs with respect to:

- drugs with new drug certificates only; or
- drugs with new drug certificates and drug approval numbers.

For drug products with new drug certificates only and not yet in the monitoring period, or drug substances with new drug certificates, applications for new drug technology transfer should be submitted prior to the respective expiration date of the monitoring periods.

*Conditions for the application of drug production technology transfer*

Applications for drug production technology transfer may be submitted if:

- the transferor holds new drug certificates or both new drug certificates and drug approval numbers, and the monitoring period has expired or there is no monitoring period; or
- with respect to drugs without new drug certificates, both the transferor and the transferee are legally qualified drug manufacturing enterprises, one of which holds over 50% of the equity interests in the other, or both of which are majority-owned subsidiaries of the same drug manufacturing enterprise.

With respect to imported drugs with imported drug licenses, the original applicants for the imported drug licenses may transfer these drug production technologies to domestic drug manufacturing enterprises.

*Application for, and examination and approval of, drug technology transfer*

Applications for drug technology transfer should be submitted to the provincial administration of medical products where the transferee is located. If the transferor and the transferee are located in different provinces, the provincial administration of medical products where the transferor is located should provide examination opinions. The provincial administration of medical products where the transferee is located is responsible for examining application materials for technology transfer and organizing inspections on the production facilities of the transferee. Drug control institutes are responsible for testing three batches of drug samples.

The CDE should further review the application materials, provide technical evaluation opinions and form a comprehensive evaluation opinion based on the site inspection reports and the testing results of the samples. The NMPA should determine whether to approve the application according to the comprehensive technical review opinions of the CDE. An approval letter of supplemental application and a drug approval number will be issued to qualified applications. The CDE may require the conduct of clinical studies. For rejected applications, a notification letter of the examination opinions will be issued with the reasons for rejection.

*Conditions for the application for marketing authorization transfer*

As previously discussed under “Risk Factors—Risks related to our dependence on third parties,” the Drug Administration Law and the 2020 Drug Registration Regulation allow for the transfer of marketing authorization under the MAH system. If the manufacturing location of an imported drug is relocated to mainland China through drug manufacturing technology transfer, the transferee in mainland China can choose to file a supplemental application pursuant to the Administrative Regulations for Technology Transfer Registration of Drugs with the provincial medical product administration which contains technical data showing consistency of quality and manufacturing processes during the two-year grace period from January 13, 2021. Alternatively, the transferee in mainland China can file a marketing authorization application with the CDE referencing technical data in the original import drug approval application dossier pursuant to the NMPA’s Administrative Measures for Post-approval Changes to Drugs (Tentative).

**Permits and licenses for drug manufacturing operations**

*Pharmaceutical Manufacturing Permit and GMP requirements*

According to the Drug Administration Law and the Implementing Measures of the Drug Administration Law, to manufacture pharmaceutical products in mainland China, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the relevant provincial medical products administration where the enterprise is located. Among other things, such a permit must set forth the scope of production and effective period. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards.

According to the Implementing Measures of the Drug Administration Law and Measures on the Supervision and Administration of the Manufacture of Drugs, promulgated in August 2004 and amended in November 2017 and January 2020, each Pharmaceutical Manufacturing Permit issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Manufacturing Permit is subject to review by the relevant regulatory authorities on an annual basis. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal. The Good Manufacturing Practice was promulgated in March 1988 and was amended in June 1999 and January 2011. The Good Manufacturing Practice comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

*Pharmaceutical Distribution Permit and GSP Requirements*

To distribute pharmaceutical products in mainland China, including wholesale and retail distribution, a pharmaceutical distribution enterprise must first obtain a Pharmaceutical Distribution Permit.

Pursuant to the Administrative Measures of the Pharmaceutical Distribution Permit promulgated by the former CFDA in February 2004 and subsequently amended in November 2017, each Pharmaceutical Distribution Permit issued to a pharmaceutical distribution enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Distribution Permit is subject to periodic review and inspection by the relevant regulatory authorities. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

The Good Supply Practice for Drugs was promulgated in April 2000 and was amended in November 2012, May 2015 and June 2016. The Good Supply Practice for Drugs is the basic rules for drug operation and quality control, setting forth the requirements for pharmaceutical distribution enterprises throughout the process of procurement, storage, sales and transportation.

**U.S. Regulation of Pharmaceutical Product Development and Approval**

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and their implementing regulations. Drugs and biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions. These sanctions could include, among other actions, FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or DOJ, or other governmental entities. Our drug and biologic candidates must be approved by the FDA through the NDA and BLA processes, respectively, before they may be legally marketed in the United States. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's GLP regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board (IRB) representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices, or GCPs and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug or biological product for its proposed indication;
- preparation and submission to the FDA of an NDA or BLA;
- a determination by the FDA within sixty (60) days of its receipt of an NDA or BLA to accept the application for filing referral to the NDA or BLA to an FDA advisory committee, if FDA determines it to be appropriate;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug or biological product are produced to assess compliance with the FDA's current Good Manufacturing Practices, or cGMP;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA or BLA; and
- payment of user fees and FDA review and approval of the NDA or BLA prior to any commercial marketing or sale of the drug or biologic in the United States.

*Pre-clinical Studies*

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, or NCEs, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including GLPs and the U.S. Department of Agriculture's Animal Welfare Act. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective thirty (30) days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that thirty-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

*Clinical Studies*

The clinical stage of development involves the administration of the product candidate to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of clinical trials, and GCPs are intended to assure that the data and reported results are accurate, and that the rights, safety and well-being of study participants are protected. GCPs also include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. For example, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their www.clinicaltrials.gov website.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

- Phase I: The product candidate is initially introduced into a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase II: The product candidate is administered to a limited patient population to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.
- Phase III: The product candidate is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the product candidate for its intended use, its safety profile and to establish the overall benefit/risk profile of the product candidate and provide an adequate basis for approval and labeling. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments.
- Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase IV clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*NDA and BLA Review and Approval*

After the successful completion of clinical studies of a drug or biological product, FDA approval of an NDA or BLA respectively must be obtained before commercial marketing of the product. The results of non-clinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug or biologic and proposed labeling, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the drug or biologic for one or more specified indications. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be offered for sale in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a substantial application user fee in the range of several million dollars. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual prescription drug program fee for human drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an application for filing. The FDA conducts a preliminary review of an NDA or BLA within sixty days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of an NDA or BLA and respond to the applicant within ten months from the filing date for a standard NDA or BLA and, and within six months from the filing date for a priority NDA or BLA. The FDA does not always meet its PDUFA goal dates for standard and Priority Review NDAs and BLAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed drug or biologic is safe and effective for its intended use, and whether the drug or biologic is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality and purity. The FDA may refer applications for novel products or product candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may re-analyze the clinical trial data, which can result in extensive discussions between the FDA and us during the review process.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA or BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the product will be produced, it may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The CRL may require additional clinical data and/or an additional pivotal clinical trial(s) and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient populations or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA or BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other

conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs or biologics. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

*Pediatric Trials*

Under the Pediatric Research Equity Act of 2003, a NDA or BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With the enactment of FDASIA in 2012, a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials and/or other clinical development programs.

*Orphan Drug Designation and Exclusivity*

Under the Orphan Drug Act, FDA may grant orphan designate to a drug or biological product intended to treat a rare disease or condition (generally meaning that the disease or condition affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA or BLA. If the request is granted, FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but if the product ultimately receives FDA approval, the product will be entitled to orphan product exclusivity, meaning that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or biological product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

*Post-Marketing Requirements*

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements and complying with applicable promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the product’s approved labeling (known as “off-label use”), limitations on industry-sponsored

scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may legally prescribe products for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA and BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including, among other things, recall or withdrawal of the product from the market. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

*Other U.S. regulatory matters*

Even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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

For other countries outside of mainland China and the United States, such as 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.

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.

**Coverage and Reimbursement**

***Chinese Coverage and Reimbursement***

Historically, most Chinese healthcare costs had been borne by patients out-of-pocket, which had limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the National Healthcare Security Administration, or the NHSA, as of December 2020, approximately 1.36 billion residents in mainland China were enrolled in the Basic Medical Insurance scheme, representing a coverage rate of above 95% of the total population.

*Reimbursement under the National Medical Insurance Program*

The Basic Medical Insurance scheme was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Basic Medical Insurance scheme and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions for the Pilot of Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance.

Pursuant to the Chinese Social Insurance Law promulgated by the SCNPC in October 2010 and subsequently amended in December 2018, all employees are required to enroll in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees as required by the state.

The Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance was promulgated by NHSA in July 2020 and came into effect in September 2020. According to which, expenses of drugs listed in the Basic Medical Insurance Catalog, typically known in the industry as the National Reimbursable Drug List (NRDL), will be paid in full or part from the basic medical insurance fund in accordance with applicable provisions, and the drugs with the same generic names as those specified in the Basic Medical Insurance Catalog will be automatically regulated by the Basic Medical Insurance Catalog and shall also be eligible for the reimbursement by the basic medical insurance fund. These measures further clarify that the Basic Medical Insurance Catalog shall be promulgated by the NHSA and adjusted on an annual basis. Provinces shall have the right to add eligible ethnic drugs, preparations of medical institutions, and traditional Chinese medicine decoction pieces into the provincial medical insurance-based payment scope, which shall be implemented after being filed with the NHSA for record.

The Chinese Ministry of Human Resources and Social Security, together with other government authorities, have the power to determine the medicines included in the NRDL. In December 2021, the NHSA and the Chinese Ministry of Human Resources and Social Security released the National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, or the 2021 NRDL, and 74 new drugs were admitted to the 2021 NRDL. Previous updates to the NRDL occurred in 2020, 2019, 2017 and 2009. Admission to the NRDL depends on a number of factors, including on-market experience, scale of patient adoption, physician endorsement, cost effectiveness and budget impact. Since 2019, provincial governments were not allowed to create provincial reimbursable drug lists by adding or removing chemical and biological drugs from the NRDL.

Medicines included in the NRDL are divided into two classes, Class A and Class B. Patients purchasing medicines included in the NRDL are entitled to reimbursement of the entire amount or a certain percentage of the purchase price. The percentage of reimbursement for Class B medicines differs from region to region in mainland China.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the Basic Medical Insurance scheme in a calendar year is capped at the amount in

such participant's individual account under such program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

*National List of Essential Drugs*

On August 18, 2009, the former MOH and eight other ministries and commissions in mainland China issued the Provisional Measures on the Administration of the National List of Essential Drugs, or NEDL, and the Guidelines on the Implementation of the NEDL System. The provisional measures aimed to promote essential medicines sold to consumers at fair prices in mainland China and ensured that the general public in mainland China has equal access to the drugs contained in the NEDL. The Provisional Measures on the Administration of the National List of Essential Drugs was then amended in February 2015. The former MOH promulgated the NEDL (Catalog for the Basic Healthcare Institutions) on August 18, 2009, a revised NEDL on March 13, 2013, and another revised NEDL on September 30, 2018, which became effective on November 1, 2018. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The drugs listed in NEDL shall be purchased by centralized tender process and shall be subject to the price control by NDRC. Drugs listed in the NEDL will be given priority to being listed in the NRDL.

*Commercial Insurance*

On October 25, 2016, the State Council and the Central Committee of the Communist Party of China jointly issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around Basic Medical Insurance, with other forms of insurance supplementing the Basic Medical Insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

*Price Controls*

Instead of direct price controls which were historically used in mainland China but abolished in June 2015, the government regulates prices mainly by establishing price negotiations, consolidated procurement mechanism and revising medical insurance reimbursement standards as discussed below.

*Price Negotiations*

The Chinese government has initiated several rounds of price negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply and oncology drugs since 2016. The average percentage of price reduction has been around 50%. Once the government agreed with the drug manufacturers on the supply prices, the drugs would be automatically listed in the NRDL and qualified for public hospital purchase.

There were NRDL price negotiations in 2018, 2019, 2020 and 2021. In 2021, 74 new drugs were added to the 2021 NRDL, among which, the average price reduction of 67 drugs is 61.71%.

*Centralized Procurement and Tenders*

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aims to regulate the purchasing process of pharmaceutical products by medical institutions. The former MOH and other relevant government authorities have promulgated a series of regulations in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000, and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, non-for-profit medical institutions established by county or higher-level government are required to implement centralized tender procurement of drugs.

The former MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the former MOH, the former SFDA and other four national departments jointly promulgated the Notice of the Financial Planning Department of Ministry of Health on Issue of the Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions. According to the notice, non-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalog of drugs subject to centralized procurement. Except for drugs in the NEDL (the procurement of which shall comply with the relevant rules on NEDL), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and TCMs, in principle, all drugs used by non-for-profit medical institutions medical institutions shall be subject to centralized procurement. On July 7, 2010, the former MOH and six other ministries and commissions jointly promulgated the Notice on Printing and Distributing the Working Regulations of Medical Institutions for Centralized Procurement of Drugs to further regulate the centralized procurement of drugs and clarify the code of conduct of the parties in centralized drug procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs promulgated in January 2017 aim to deepen the reform of medical health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralized Procurement and Use of the Drug Organized by the State promulgated in January 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and model of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralized tender process is in principle conducted once every year in the relevant province or city in mainland China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

*"4+7" Volume-based Drug Procurement and Tenders*

In June 2018, the State Council decided to launch a new round of drug pricing and procurement reform. This reform is implemented mainly by the NHSA, a new government authority established in 2018 as part of the institutional restructuring with a mandate of pricing and procurement of drugs and medical disposables. The NHC supports the reform by introducing policy that encourages purchasing and prescribing of the selected drug and managing the supplier's behavior. The NMPA is responsible for the quality assurance of the drug.

On November 15, 2018, the Joint Procurement Office, the procurement alliance formed by representatives of procurement agencies in 11 pilot cities established to oversee the bidding and procurement process, published the Paper on Drug Centralized Procurement in "4+7" Regions, launching the national pilot scheme for centralized volume-based drug procurement and tenders. According to the papers, the initial procurement of 31 generic drugs was implemented in 4 municipalities, namely Beijing, Shanghai, Tianjin and Chongqing and 7 cities, namely

Shenyang, Guangzhou, Shenzhen, Xi'an, Dalian, Chengdu and Xiamen. This pilot program is thus also referred to as the "4+7" procurement scheme. On January 1, 2019, the General Office of the State Council published a circular on National Pilot Program for Centralized Procurement and Use of the Drug Organized by the State, which provides detailed implementing measures for the nation-wide centralized drug procurement and tender scheme.

The "4+7" pilot program puts special emphasis on procurement volume guarantee. Public hospitals in pilot regions are encouraged to form a group procurement organization to increase the negotiation leverage. The committed volume will be shared by all qualified bid-winners, and public hospitals should prioritize their use of drugs purchased through the volume-based procurement in order to realize the volume commitment. Under this program, a company is provided with a substantial volume guarantee. The selected drugs must pass the generic drug consistency evaluation on quality and effectiveness. The reform policy is aimed to lower drug costs for patients, reduce transaction costs for enterprises, regulate drug use of hospitals, and improve the centralized drug procurement and pricing system. The centralized volume-based procurement is open to all approved enterprises that manufacture drugs on the government-set procurement list in mainland China. Clinical effects, adverse reactions and batch stability of the drugs are considered, and their quality consistency with the originator drugs will be the main criteria for evaluation. Production capacity and stability of the supplier are also considered.

On December 17, 2018, the preliminary results of the "4+7" centralized volume-based procurement were announced: 25 out of 31 generic drugs were selected, of which there are 3 originator drugs and 22 generics. As of December 2019, many provinces have published regional implementation measures, expanding the pilot program. On January 21, 2020, the results of the second round of the national centralized volume-based procurement and tender program were published: the average price reduction reached more than 50%, and the highest reduction has reached 90%. The results of the third, the fourth, the fifth and the sixth (specially for insulin) round of the national centralized volume-based procurement and tender program were published on August 24, 2020, February 8, 2021, June 28, 2021, and November 30, 2021, respectively, show similar levels of reduction in average price reduction of about 50%, with the highest reduction reaching about 93%, 96%, 98%, and 74%, respectively.

*Two-invoice System*

In addition to the centralized tender process, the Chinese government also rolled out a "two-invoice system." Under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms issued by the General Office of the State Council in April 2016, the two-invoice system will be fully implemented in mainland China. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (Tentative), which came into effect in December 2016, the two-invoice system means, in principle, there cannot be more than two invoices issued for drug products supplied by manufacturers to public hospitals. To meet this requirement, many drug manufacturers have reduced the tiers of distributors, or converted drug distributors into contracted service organizations. This excludes the sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to its exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary (or between its wholly owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in mainland China. The reduction in distribution tiers resulted in a decrease in distribution mark-ups, hence the supply prices to public hospitals would also be reduced. Compliance with the two-invoice system is a prerequisite for pharmaceutical companies to participate in the tender and procurement processes of public hospitals, which currently provide most of Chinese healthcare services. Manufacturers and distributors that fail to implement the two-invoice system may lose their qualifications to participate in the tender and procurement process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals. The two-invoice system has been implemented in all provinces, each with its own regional implementation rules.

*Medical Insurance Reimbursement Standards*

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents, issued by the State Council on January 3, 2016, call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified Basic Medical Insurance system. This unified Basic Medical Insurance system will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangement who participate in the Basic Medical Insurance for urban employees.

The General Office of the State Council further announced a master plan for the medical insurance reimbursement reform in June 2017. The main objectives are to implement a diversified reimbursement mechanism including Diagnosis Related Groups, or DRGs, per-capita caps, and per-bed-day caps. Local administration of healthcare security will introduce a total budget control for their jurisdictions and decide the amount of reimbursement to public hospitals based on hospitals' performance and the spending targets of individual Basic Medical Insurance funds. In June 2019, the NHSA, the Ministry of Finance, the NHC and the National Administration of Traditional Chinese Medicine jointly issued the Notice on the National List of Pilot Cities for the DRG Payment Mechanism, identifying 30 cities as pilot cities for the DRG payment pilot program, proposing to further the medical insurance reimbursement reform.

To further standardize payment in the Basic Medical Insurance schemes, in October 2019, the NHSA issued two key technical documents for a pilot project that introduces DRGs, the Technical Guideline of the Classification and Payment for China Healthcare Security Diagnosis Related Groups (CHS-DRG) and the CHS-DRG Classification Plan. According to the classification plan, patients will be sorted into 26 major diagnostic categories and 376 adjacent diagnosis-related groups. DRG-based settlement is currently only applicable to expenses of inpatient care incurred by the insureds at designated hospitals participating in the DRG payment pilot programs and payable by regional medical insurance fund under the Basic Medical Insurance schemes. DRG-based payments are made directly to the participating medical institutions, while the covered benefits enjoyed by the insureds, under the current public insurance schemes, are not affected by such settlement. In June 2020, the NHSA issued a more detailed CHS-DRG Classification Plan, further diving the 376 diagnosis-related groups into 618 basic reimbursement unit. The 30 municipalities participating in the DRG pilot project were required to submit technical assessment report to the local branch of NHSA before August 31, 2020. Upon receiving NHSA's approval, the participating municipalities may commence conducting simulation runs of the pilot project. After the simulation runs, the DRG-based settlement system is expected to be launched gradually from 2022 to 2024. In February 2020, the Central Committee of the Communist Party of China and the State Council jointly promulgated the Opinions on Deepening the Reform of the Healthcare Security System, which suggests that a multi-compound medical insurance payment method based on payment by disease shall be implemented. In October 2020, the NHSA issued the Notice on Issuance of the Pilot Work Plan for Total Budget by Regional Points Method and Diagnosis-Intervention Packet Payment to introduced and further implement the Diagnosis-Intervention Packet (DIP) payment. DIP and DRG are the same in essence and principle, and therefore DIP can be considered as a variant of DRG. In November 2020, the NHSA issued two key technical documents for the DIP payment pilot project, the China Healthcare Security Technical Specification of Diagnosis-Intervention Packet (DIP) and the DIP Classification Catalogue (Version 1.0). In May 2021, the NHSA issued the Medical Insurance Handling Management Regulations (Trial) for Diagnosis-Intervention Packet (DIP) Payment to provide detailed guidance for implementing medical insurance payment based on DIP. In the List of Pilot Cities for DRG/DIP Payment published by NHSA on December 17, 2021, 18 cities were identified as pilot cities for the DRG payment pilot program, 12 cities were identified as pilot cities for the DIP payment pilot program, and 2 cities were identified as pilot cities for both the DRG payment pilot program and the DIP payment pilot program. In order to accelerate the reform of DRG / Dip payment, the NHSA has formulated and made public a Three-Year Action Plan for DRG / DIP payment reform on November 19, 2021, which makes it clear that by the end of 2024, DRG / DIP payment reform will be carried out in all overall planning areas across the country. By the end of 2025, DRG / DIP payment will cover all qualified medical institutions providing inpatient services.

***Healthcare System reform***

In the past decade, the Chinese government promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the Central Committee of the Communist Party of China and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. The State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System on December 27, 2016. The General Office of the State Council issued a Notice on the Main Tasks of Strengthening the Reform of Healthcare System for each year of 2017, 2018, 2019, and 2021. The General Office of the State Council issued a Notice on the Issuance of the 14th Five-year Medical-Security Plan on September 29, 2021.

Highlights of these healthcare reform policies and regulations include the following:

One of the main objectives of the reform was to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. During the 14$^{th}$ five-year period (2021-2025), Basic Medical Insurance coverage will remain above 95% of the country's population every year.

Another main objective of reform was to improve the healthcare system, through the reform and development of a graded diagnosis and treatment system, modern hospital management, Basic Medical Insurance, drug supply support and comprehensive supervision.

The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education were to be provided to urban and rural residents. In the meantime, the reforms also encouraged innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to prove definite efficacy and positive risk-benefit ratio.

The key tasks of the reform in the 13th five-year period were as follows: (1) to deepen the reform of public hospitals, (2) to accelerate the development of a graded diagnosis and treatment system, (3) to consolidate and improve the universal medical insurance system, (4) to guarantee drug supply, (5) to establish and improve a comprehensive supervision system, (6) to cultivate talented health-care practitioners, (7) to stabilize and perfect the basic public health service equalization system, (8) to advance the construction of health information technology, (9) to accelerate the development of the health services industry generally, and (10) to strengthen organization and implementation.

On December 28, 2019, the SCNPC promulgated the Law of the People's Republic of China on Promotion of Basic Medical and Health Care, which came into effect in June 2020. Such law established the legal framework for the administration of basic medical and health services for citizens in mainland China, including the administration of basic medical care services, medical care institutions, medical staff, guarantee of drug supply, health promotion and guarantee of medical funds.

On February 25, 2020, the Central Committee of the Communist Party of China and the State Council jointly promulgated the Opinions on Deepening the Reform of the Healthcare Security System, which envisages that a higher-level healthcare system should be established by 2030, which centers on basic medical insurance, is underpinned by medical aid and pursues the joint development of supplementary medical insurance, commercial health insurance, charitable donations and medial mutual assistance. To this end, such opinions map out tasks in several respects, including making the mechanism of medical insurance benefits more impartial and appropriate, improving the robust and sustainable operating mechanism for funds raised, establishing more effective and efficient healthcare payment mechanism, and enhancing the supervision and administration on medical security fund and etc.

According to the 14th Five-year Medical-Security Plan, China should enhance the medical insurance system through collaborative governance, optimizing medical insurance payments and the drug pricing mechanism, while strengthening the medical fund supervision system. Efforts should also be made to build up a strong supporting system with a solid legal basis and better digital services. More efforts are needed too to enhance the basic medical security system, improve the mechanism that provides insurance and aid for the treatment of major and serious diseases, and boost the synergy between health insurance and medical assistance.

***U.S. Coverage and Reimbursement***

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs are covered and adequately reimbursed by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. These third-party payors are increasingly limiting coverage of medical drugs, reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. Federal and state governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. If our drug candidates are approved, limitations on coverage or reimbursement as well as price controls and cost-containment measures could have a material adverse effect on our sales, results of operations and financial condition.

Health care reform initiatives have resulted in significant changes to the coverage, reimbursement and delivery of health care, including drugs. Health care reform efforts are likely to continue and such efforts have included, and may include in the future, attempts to repeal or modify prior healthcare reform.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2030 (except May 1, 2020 to March 31, 2021) unless additional Congressional action is taken. If we obtain approval to market a drug candidate in the United States, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

**Other Healthcare Laws**

***Other Chinese Healthcare Laws***

*Advertising of Pharmaceutical Products*

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes promulgated by the SAMR in December 2019 and effective in March 2020, an enterprise seeking to advertise its pharmaceutical products must apply for an advertisement approval number. The advertisement approval number is issued by the relevant local administrative authority. The validity term of the advertisement approval number for drugs shall be consistent with the shortest validity term of the pharmaceutical product marketing authorization, filing certificate or Pharmaceutical Manufacturing Permit. If no valid term is prescribed in the pharmaceutical product marketing authorization, filing certificate or Pharmaceutical Manufacturing Permit, the valid term of the advertisement approval number shall be two years. The content of an approved advertisement may not be altered without prior approval.

*Insert Sheet and Labels of Pharmaceutical Products*

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the former SFDA (now the NMPA). A drug insert sheet should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindication, precautions, storage, production date, batch number, expiry date and drug manufacturer.

*Packaging of Pharmaceutical Products*

According to the Measures for the Administration of Pharmaceutical Packaging effective on September 1, 1988, pharmaceutical packaging must comply with national and industry standards. If no national or industry standards are available, the enterprise can formulate its own standards and implement after obtaining the approval of administration of medical products and bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its own packaging standards. Drugs that have not developed and received approval for packing standards must not be sold or traded in mainland China (except for drugs for the military).

***Other U.S. Healthcare and Regulatory Laws***

Within the United States, manufacturing, sales, promotion and other activities that may follow drug approval are also subject to regulation by numerous federal, state and local regulatory authorities, including, the FDA, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, and the Environmental Protection Agency.

We may therefore be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following:

- the U.S. Foreign Corrupt Practices Act (FCPA), which prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls;
- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, which prohibits executing a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public; and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, state laws regulating or requiring the reporting of prices, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, the distribution of pharmaceutical drugs is subject to specific regulatory requirements, including licensure, extensive record-keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

If and when we become subject to these various healthcare and regulatory laws, efforts to ensure that our activities comply with applicable healthcare laws may involve substantial costs. Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we could be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, or contracting with government authorities and the curtailment or restructuring of our operations, which could significantly harm our business.

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

***Chinese Regulation of Foreign Investment***

The establishment, operation and management of corporate entities in mainland China are governed by the Company Law of the People's Republic of China, or the China Company Law, which was adopted by the SCNPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the China Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The China Company Law also applies to foreign-invested limited liability companies and foreign-invested companies limited by shares. Pursuant to the China Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail. In December 2021, the SCNPC issued the draft amendment to the China Company Law for comment. The draft amended China Company Law has made roughly 70 substantive changes on the basis of the 13 chapters and 218 articles of the current Company Law (rev. 2018). It would (i) refine special provisions on state-funded companies; (ii) improve the company establishment and exit system; (iii) optimize corporate structure and corporate governance; (iv) optimize the capital structure; (v) tighten the responsibilities of controlling shareholders and management personnel; and (vi) strengthen corporate social responsibility.

Investment activities in mainland China by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002, and came into effect on April 1, 2002, and the latest Special Administrative Measures (Negative List) for Foreign Investment Access (2021), or the Negative List, which was promulgated by the Ministry of Commerce, or the MOFCOM, and the NDRC on December 27, 2021, and took effect on January 1, 2022. The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

The Foreign Investment Law of the People's Republic of China, or the Foreign Investment Law was promulgated by the NPC in March 2019 and become effective in January 2020. After the Foreign Investment Law came into force, the Law of the People's Republic of China on Wholly Foreign-Owned Enterprises, the Law of the People's Republic of China on Sino-foreign Equity Joint Ventures and the Law of the People's Republic of China on Sino-foreign Contractual Joint Ventures have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of mainland China shall comply with and be governed by the Foreign Investment Law, including: 1) establishing by foreign investors of foreign-invested enterprises in mainland China alone or jointly with other investors; 2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in mainland China alone or jointly with other investors; and 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law, which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law came into effect, the Regulation on Implementing the Law on Sino-foreign Equity Joint Ventures, Provisional Regulations on the Duration of Sino-Foreign Equity Joint Ventures, the Regulations on Implementing the Law on Wholly Foreign-Owned Enterprises and the Regulations on Implementing the Law on Sino-Foreign Cooperative Joint Ventures have been repealed simultaneously.

In December 2019, the MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information, which came into effect in January 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Invested Enterprises has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in mainland China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities pursuant to these measures.

*Chinese Regulation of Commercial Bribery*

Pursuant to specific provisions in the China Anti-Unfair Competition Law, commercial bribery is prohibited. Both the bribe giver and the bribe recipient are subject to civil and criminal liability. Further, pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for the establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant Chinese government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the

distributors or third-party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third-party promoters, and it will not be subject to penalties or sanctions by relevant Chinese government authorities as a result of failure to monitor their operating activities.

*Chinese Regulation of Product Liability*

In addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in mainland China. Under current Chinese law, manufacturers and vendors of defective products in mainland China may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the People's Republic of China, or the China Civil Law, promulgated on April 12, 1986, and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the People's Republic of China, or the China Civil Code, which was promulgated in May 2020 and became effective on January 1, 2021, amalgamates and replaces a series of specialized laws in civil law area, including the China Civil Law. The rules on product liability in the China Civil Code remain consistent with the rules in the China Civil Law.

On February 22, 1993, the Product Quality Law of the People's Republic of China, or the Product Quality Law was promulgated to supplement the China Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised on July 8, 2000, August 27, 2009, and December 29, 2018 respectively. Pursuant to the revised Product Quality Law, manufacturers who produce defective products and distributors who sell defective products may be subject to civil or criminal liability and revocation of their business licenses.

The Law of the People's Republic of China on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993, and was amended on August 27, 2009 and October 25, 2013, to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

*Chinese Tort Law*

Under the Tort Law of the People's Republic of China, or the Tort Law, which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as the issuance of a warning, the recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages. The China Civil Code amalgamated and replaced the Tort Law effective January 1, 2021. The rules on tort in the China Civil Code are generally consistent with the Tort Law.

*Chinese Regulation of Intellectual Property Rights*

Mainland China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

**Patents**

Pursuant to the China Patent Law, most recently amended in December 2008 and October 2020, and its implementation rules, most recently amended in January 2010, patents in mainland China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the China Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten and fifteen years, respectively, from the date of application. The China Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity and deficiencies in patent application. In mainland China, a patent must have novelty, creativity and practical applicability. Under the China Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in mainland China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of mainland China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in mainland China are filed with the CNIPA. Normally, the CNIPA publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date of application.

Article 19 of the China Patent Law provides that, for an invention or utility model completed in mainland China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of mainland China, must first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in mainland China or outsource research and development activities to service providers in mainland China. The China Patent Law also sets up the framework and adds the provisions for patent linkage and patent term extension.

**Patent Term Extension and Adjustment**

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 certain patents. 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 examination was requested. It remains to be seen how the patent term extensions and adjustments under the China Patent Law will be implemented. The Chinese government published draft amendments to the Implementing Regulations of the Patent Law on November 27, 2020, which provides further details on what is an unreasonably delay in respect of patent term adjustments and proposes certain limitations on the types of patents

eligible for patent term extensions, details of how amount of the extension would be determined and applicability to drug products covered by the relevant patent. For example, there is a risk that the patent term extension will only apply where approval in mainland China by the NMPA is the first approval anywhere in the world.

**Patent Linkage**

The China Patent Law describes the general principles of linking generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. In July 2021, the NMPA and the China National Intellectual Property Administration, or CNIPA, jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative), or Measures on Patent Linkage, providing an operating mechanism for Patent Linkage. Upon notification of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the CDE's publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. For chemical drugs, the NMPA would initiate a nine-month approval stay period upon notification. If the patentee or the interested person cannot secure 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.

**Patent Enforcement**

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

**Medical Patent Compulsory License**

According to the China Patent Law, for the purpose of public health, the CNIPA may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which mainland China has acceded.

**Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented Products**

The China Patent Law provides five exceptions permitting the unauthorized manufacture, use, sale or import of patented products. None of following circumstances is deemed an infringement of the patent rights, and any

person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of mainland China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between mainland China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;
- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in China Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

**Trade Secrets**

According to the China Anti-Unfair Competition Law promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the China Anti-Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder’s requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of abovementioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others’ trade secrets, the third party may be deemed to have committed a misappropriation of the others’ trade secrets.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

**Trademarks and Domain Names**

*Trademarks.* According to the Trademark Law of the People’s Republic of China, promulgated by the SCNPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its

implementation rules (collectively, the "Trademark Law"), the Trademark Office of China National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout mainland China. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration.

*Domain Names.* Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective from November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of Chinese internet domain names.

*Chinese Regulation of Labor Protection*

Under the Labor Law of the People's Republic of China, effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the Employment Contract Law of the People's Republic of China, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the People's Republic of China.

Pursuant to the Work Safety Law of the People's Republic of China effective on November 1, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Good Manufacturing Practice effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable Chinese laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011 and was amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds which became effective on January 22, 1999 and was amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees which became effective on January 1, 1995, and the Regulations on Work-related Injury Insurance which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

***Regulations Relating to Foreign Exchange Registration of Offshore Investment by Chinese Residents***

In July 2014, SAFE issued SAFE Circular 37 and its implementation guidelines. Pursuant to SAFE Circular 37 and its implementation guidelines, residents of mainland China (including Chinese institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or SPV, directly established or indirectly controlled by Chinese residents for the purposes of offshore investment and financing with their legally owned assets or

interests in domestic enterprises, or their legally owned offshore assets or interests. Such Chinese residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a Chinese resident individual shareholder, the name or operating period of the SPV or when there is a significant change to the SPV, such as changes of the Chinese individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or Chinese residents to penalties under Chinese foreign exchange administration regulations.

*Regulations Relating to Employee Stock Incentive Plan*

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules. In accordance with the Stock Option Rules and 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. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in mainland China who exercise share options, or whose restricted shares vest, will be subject to Chinese individual income tax, or the IIT. The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities.

*Regulations Relating to Dividend Distribution*

Pursuant to the China Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law, foreign investors may freely remit into or out of mainland China, in RMB or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of mainland China.

In January 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote the Reform of Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

*Regulations Relating to Foreign Exchange*

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange

Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of mainland China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, or SAFE Circular 142, regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular 142 provides that the RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within mainland China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE's approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued the Circular of the State Administration of Foreign Exchange on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or the SAFE Circular 19, which took effective and replaced SAFE Circular 142 on June 1, 2015. Although SAFE Circular 19 allows for the use of RMB converted from the foreign currency-denominated capital for equity investments in mainland China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to unassociated enterprises. Violations of SAFE Circular 19 or SAFE Circular 16 could result in administrative penalties.

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment was promulgated by SAFE in November 2012 and amended in May 2015, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in mainland China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in mainland China shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in mainland China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment, or SAFE Circular 13, which took effect on June 1, 2015 and was amended in December 2019. SAFE Circular 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

*Regulations on Securities Offering and Listing outside of China*

On December 24, 2021, the CSRC, promulgated the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments), or the Draft Administration Provisions, and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments), or the Draft Filing Measures, to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form.

The Draft Administration Provisions 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 Draft Filing 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 China, and its main places of business operation are located in China or main business activities are conducted in China.

Under the Draft Administration Provisions and the Draft Filing Measures, 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 this 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, issue a filing notice thereof 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, after the issuer completes the overseas initial public offering and listing, it shall file the status of overseas offering and listing as required by the CSRC.

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 constitute a threat to or 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, major assets, and core technologies, etc. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the CSRC and the competent authorities under the State Council shall impose a postponement or termination of the intended overseas offering and listing. The CSRC may cancel the corresponding filing if the intended overseas offering and listing application documents has been filed.

If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they would be warned and fined up to RMB10 million and even ordered to suspend relevant business or halt operation for rectification, revoke relevant business permits or business license in severe cases. The controlling shareholders, actual controllers, directors, supervisors, and senior management of such domestic companies would be warned and fined up to RMB5 million separately or aggregately.

*Other Chinese National- and Provincial-Level Laws and Regulations*

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control in all material aspects. We believe that we are currently in compliance with these laws and regulations in material aspects; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

## 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, 2022, our commercialization team consisted of approximately 945 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 into a contract sales agreement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd., or Hanhui, a direct wholly owned subsidiary of Hanhui Pharmaceutical Co., Ltd., 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. For the years ended December 31, 2021 and 2020, the aggregate amount of product revenue generated from our five largest customers accounted for approximately 39.9% and 48.6% of our product revenue, 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.

## 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. We do not manufacture Optune; instead, we source Optune from our licensor, Novocure. Since the construction of a cGMP-compliant small molecule facility in Suzhou with manufacturing facility of producing 50 million units per year for oral solid dosage form. In 2021, the small molecule facility in Suzhou added a new capability of early clinical manufacturing workshop for oral solids with capacity of approximately 30,000 units/batch. Additional R&D capability for small molecule CMC was enabled in Suzhou that supported technology transfer, process development, and method validation. Supplies of multiple projects including Simurosertib for global clinical trials, have been successfully manufactured. In 2021, we received market authorization for both Omdacycline for Injection and Omdacycline Tablets and successfully launched the Omdacycline for Injection in 2021. The Omdacycline for Injection is manufactured by Zhejiang Hisun Pharmaceutical Co., Ltd., and the Omdacycline Tablet is manufactured by Haimen Pharm. QINLOCK is manufactured in the United States and imported to China by us.

In 2018, we completed construction of a large molecule facility in Suzhou using Cytiva FlexFactory platform technology 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 1000L clinical batches, respectively. We are investing in the expansion of our large molecule manufacturing facility in anticipation of the increased activities of our internally developed pipeline. 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 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. See “Risk Factors —We have limited experience manufacturing our products and product candidates on a large clinical or commercial scale.”

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 facilities cover the entire production process from mixing, roller compression, tableting to bottling. 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, our first commercialized product. Additionally, we obtained the Marketing Authorization Holder (MAH) manufacturing license for ZEJULA and NUZYRA. 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 any of these third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed. As of January 31, 2022, our manufacturing team consisted of approximately 81 employees.

**Contract Manufacturing Organizations**

We outsource to a limited number of external CMOs the production of some product 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. 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 ensure that the production qualifications, facilities and processes of our third-party CMOs comply with the relevant regulatory requirements and our internal guidelines. We select our CMOs by taking into account a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules and terms offered by such CMOs. 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, a risk exists that an interruption to supplies would materially harm our business. 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.

## 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 “Part I—Item 1A—Risk Factors” included in this Annual Report on Form 10-K.

## INSURANCE

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

## HUMAN CAPITAL RESOURCES

As of January 31, 2022, we had approximately 1,951 full-time employees, of which 1,862 were located in Greater China and 89 were not. The number of full-time employees by function as of such date was as follows:

| By Function | Number of employees |
|---|---|
| Research and Development | 788 |
| Commercial | 945 |
| Manufacturing | 81 |
| General and Administrative* | 137 |
| Total | 1,951 |

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

Our management executive team is comprised of our CEO and her direct reports who, collectively, have management responsibility for our business. Our management team places significant focus and attention on

matters concerning our human capital assets-particularly our diversity, capability development and succession planning. Accordingly, we regularly review employee development for each of our functions to identify and develop our pipeline of talent. Across our broader population, approximately 58% of full-time employees are women. We have programs in place to attract and retain talent, including stock-based compensation and cash performance awards as well as tuition support for technical and other training. We also have a performance management and talent development process in which managers provide regular feedback and coaching to develop employees.

Our worldwide teams are united by a common mission. 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.

We provide formal and comprehensive company-level and department-level training to our new employees followed by on-the-job training. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures. Given our emphasis on operating a fully integrated platform for our product candidate development processes, some of the training is conducted jointly by different groups and departments serving different functions but working with or supporting each other in our day-to-day operations.

As required under Chinese regulations, we participate in 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.

None of our employees is represented by a labor union or covered by a collective bargaining agreement, and we have not experienced any work stoppages. We believe that we maintain a good working relationship with our employees. We have not experienced any material labor disputes or any difficulty in recruiting staff for our operations.

Further, to help achieve the Company’s mission, we have begun integrating environmental protection, social responsibility, and governance practices, or ESG, into the Company’s daily operations. The Company’s executive management team is responsible for the development and delivery of the Company’s ESG priorities, strategies, and plans. In 2021, the Company hired Mr. Jim Massey as its Chief Sustainability Officer, who is responsible for the day-to-day management of the enterprise ESG program, and the Nominating and Governance Committee of the Board of Directors assumed oversight for all ESG matters. In September 2021, the Company issued its first ESG report, aligned to industry appropriate standards set by the Sustainable Accountability Standards Board, with influence from other sources, including the United Nations Sustainable Development Goals and guidelines of Institutional Shareholders Services. In 2022, the Company will conduct its first materiality process review focused on ESG-related issues. The Company will engage with key stakeholders including patients, employees, partners, and investors to inform its long-term ESG strategy with prioritized material topics, goals, and timelines.

## 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 ensuring that we are in compliance with all 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 AND INTERNAL CONTROL RISK MANAGEMENT

We have adopted a consolidated risk management methodology and program which sets out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. The Audit Committee of our Board of Directors, and ultimately our Directors, supervise the implementation of our risk management programs. Risks identified by management will be analyzed on the basis of likelihood and impact and will be properly followed up and mitigated and rectified by management and reported to our Directors.

The following key principles outline our approach to risk management and internal control:

- Our Board is responsible for establishing our risk management and internal control system and reviewing its effectiveness.
- Our Audit Committee oversees and manages the overall risks associated with our business operations, including (i) developing, reviewing, and approving our risk management programs and procedures to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iii) reviewing our corporate risk matrix in the light of our corporate risk tolerance; (iv) reviewing the significant residual risks and the need to set up mitigating controls; and (v) monitoring and ensuring the appropriate application of our risk management framework across the company.
- Our Chief Legal Officer, Mr. F. Ty Edmondson, is responsible for (i) formulating and updating our risk management program and target; (ii) reviewing and approving major risk management issues of the Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in the Company; (v) reviewing the relevant departments' reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across the Company; (viii) developing and operating an enterprise risk management program for the Company, the results of which are reported to the Audit Committee throughout the year; (ix) developing and managing the Company's government affairs efforts; (x) reporting to our Audit Committee on our material risks; and (xi) coordinating and providing updates to the Board of Directors as necessary.
- The relevant departments in the Company are responsible for implementing our risk management program under the oversight of our Legal and Compliance Departments.
- Our Finance Department is responsible for developing and implementing our internal controls systems.

As of December 31, 2021, there were no material outstanding issues relating to our risk management and internal controls.

### Investment Risk Management

We have an investment policy that is approved by the Audit Committee of the Board of Directors. In accordance with that policy, we engage in short-term investments with surplus cash on hand. Our investment portfolio primarily consists of time deposits. Our primary objective of short-term investment is to preserve principal and increase liquidity without significantly increasing risks. Under the supervision of our Chief Financial Officer, our finance department is responsible for managing our short-term investment activities.

Before making any investment proposal, our finance department will assess our cash flow levels, operational needs and capital expenditures. We operate under our investment policy, which provides the guidelines and specific instructions on 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 thoroughly considering a number of factors, including, but not limited to, the macro-economic environment, general market conditions and the expected profit or potential loss of the investment. Our portfolio to date has been required to hold only instruments with an effective final maturity of twelve months or less, with effective final maturity being defined as the obligation of the issuer to repay principal and interest. Under our investment policy, we are prohibited from investing in high-risk products and the proposed investment must not interfere with our business operations or capital expenditures. We may invest in time deposits, consistent with our investment policy, when we believe it is prudent to do so.

We believe that our internal investment policy and the related risk management mechanisms are adequate. As of December 31, 2021, our investment decisions did not deviate from our investment policy.

**Corporate Information**

We are an exempted company incorporated in the Cayman Islands with limited liability on March 28, 2013. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The principal executive office of our research and development operations is located at 4560 Jinke Road, Bldg. 1, Fourth Floor, Pudong, Shanghai, China 201210. Our telephone number at this address is +86 21 6163 2588. Our current registered office in the Cayman Islands is located at the offices of International Corporation Services Ltd., Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KYI-1106, Cayman Islands. Our website address is www.zailaboratory.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report on Form 10-K.

We own various registered trademarks, trademark applications and unregistered trademarks and service marks, including various forms of the "ZAI LAB" and "再鼎医药" brands, as well as domain names incorporating some or all of these trademarks and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 10-K are the property of their respective holders. Solely for convenience, some of the trademarks and trade names in this document are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of, any other company.

**Available Information**

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC, in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our annual reports on Form 20-F and 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 6-K and 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act. Additionally, we make available on our website our securities filings with the Stock Exchange of Hong Kong. We make this information available on or through 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 Stock Exchange of Hong Kong. We use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD.

## Item 1A. Risk Factors

### Risk Factors

*The following section includes the most significant factors that we believe may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K, including our financial statements and the related notes and "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our ADSs or ordinary shares. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our ADSs and ordinary shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business 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.

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities markets and promote the high-quality development of 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.

***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.

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

In response to the SEC's July 30, 2021 statement, the CSRC announced on August 1, 2021, that "[i]t is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of Chinese companies listed in the United States so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," it emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

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.

***The audit report included in this Annual Report on Form 10-K was prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection, we may be subject to additional Nasdaq listing criteria or other penalties and our ADSs may be delisted from the U.S. stock market.***

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

Inspections of auditors conducted by the PCAOB outside mainland China and Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in mainland China and Hong Kong prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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

On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act, or the HFCA Act, which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction and to prohibit the securities of such issuers that have has three consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020. Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and departments with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. On November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks.

On September 22, 2021, the PCAOB adopted PCAOB Rule 6100, *Board Determinations Under the Holding Foreign Companies Accountable Act*, implementing the HFCA Act, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCA Act, whether the Board is unable to inspect or

investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction. PCAOB Rule 6100 establishes the manner of the PCAOB's determinations; the factors the PCAOB will evaluate and the documents and information it will consider when assessing whether a determination is warranted; the form, public availability, effective date, and duration of such determinations; and the process by which the PCAOB will reaffirm, modify or vacate any such determinations. On November 5, 2021, the SEC announced that it has approved Rule 6100. On December 2, 2021, the SEC adopted an amendment to finalize the rules implementing the submission and disclosure requirements in the HFCA Act and those rules became effective on January 10, 2022. We will be required to comply with these rules if the SEC identifies us as a Commission-Identified Issuer (as defined in the final rules), and the SEC could prohibit the trading of our securities on national securities exchanges if we are identified as a Commission-Identified Issuer. Under the HFCA Act, our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years, and this ultimately could result in our ADSs being delisted.

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

Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, or AHFCA Act, which, if enacted, would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. On January 25, 2022, a similar bill, H.R. 4521, The America COMPETES Act of 2022, was introduced in the House of Representatives which, if enacted, like the AHFCA would prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years.

While we understand that there has been dialogue among the CSRC, the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in mainland China and Hong Kong, there can be no assurance that we or our auditor will be able to comply with the requirements imposed by U.S. regulators or Nasdaq. We are evaluating, designing, and implementing additional business processes and control changes to meet the requirements of the HFCA Act, which we believe will enable us to engage an independent public accounting firm that satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements, subject to compliance with SEC and other requirements prior to the three-year (or two-year under the AHFCA Act) deadline of the HFCA Act. However, any business processes and control changes that we may implement may not be sufficient or may take time for us to implement and they ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act (or, if enacted into law, the AHFCA Act or the America COMPETES Act of 2022). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong or may incur increased costs or suffer losses in order to do so. The market price of our ADSs could be materially adversely affected as a result of anticipated negative impacts of these rules and executive, regulatory or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in mainland China and Hong Kong that are listed in the United States, regardless of whether these rules and executive, regulatory or legislative actions are implemented and regardless of our actual operating performance.

Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs and ordinary shares.

***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.***

In December 2012, the SEC instituted administrative proceedings under Rule 102(e)(1)(iii) of the SEC's Rules of Practice against China-based accounting firms alleging that these firms had violated U.S. securities laws and the SEC's rules and regulations thereunder by failing to provide to the SEC the firms' audit work papers with respect to certain Chinese companies under the SEC's investigation. On January 22, 2014, the administrative law judge, or ALJ, presiding over the matter rendered an initial decision that each of the firms had violated the SEC's rules of practice by failing to produce audit workpapers to the SEC. The initial decision censured each of the firms and barred them from practicing before the SEC for a period of six months. On February 12, 2014, certain of these China-based accounting firms appealed the ALJ's initial decision to the SEC. On February 6, 2015, the four China-based accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC, in response to future document requests by the SEC made through the CSRC. If the China-based accounting firms fail to comply with the documentation production procedures in the settlement agreement or if there is a failure of the process between the SEC and the CSRC, the SEC could restart the proceedings against the firms.

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major Chinese operations may find it difficult or impossible to retain auditors in respect of their operations in mainland China, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based, United States-listed companies and the market price of our ADSs may be adversely affected.

If the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements would substantially reduce or effectively terminate the trading of our ADSs in the United States.

***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.

We maintain personally identifiable health information of patients in mainland China in limited situations. We also collect and maintain de-identified or anonymized health data for clinical trials in compliance with local regulations. 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 data derived from mainland China, the

outbound transmission of de-identified health data for clinical trials may be subject to the new national security legal regime, including the Data Security Law, the Cyber Security Law of the People's Republic of China, or the Cyber Security Law, the PIPL, the Regulation on the Administration of Human Genetic Resource, and various implementing regulations and standards.

China's Data Security Law took effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in mainland China from transferring data stored in mainland China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or the legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the PIPL, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

Additionally, 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, or MLPS, under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, 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 the entity's 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. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems as fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not adequately protect us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we face.

Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying with reporting obligations to applicable regulators. We may also be required to disclose to regulators business-sensitive or network security-sensitive details regarding our processing of important data and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in mainland China with judicial and law enforcement authorities outside of mainland China. 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."

On July 10, 2021, the CAC published a revised draft revision to the existing Cybersecurity Review Measures for public comment, or the Revised Draft CAC Measures, and together with 12 other Chinese regulatory authorities, released the final version of the Revised Draft CAC Measures, or the Revised CAC Measures, on January 4, 2022, which came into effect on February 15, 2022. Pursuant to the Revised CAC 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.

On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment), or the Draft Management Regulations, under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Management Regulations reiterate that data processors shall be subject to cybersecurity review if they process personal information of more than one million persons and aiming to list on foreign stock markets, or the data processing activities influence or may influence national security. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by 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.

As of the date of this Annual Report on Form 10-K, 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 the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. Based on our understanding of the Revised CAC 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, given that: (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 for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC 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 Revised CAC Measures and the 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 Revised CAC Measures, the Draft Management Regulations or other laws and regulations related to privacy, data protection and information security.

On October 29, 2021, the CAC published the Measures on Security Assessment of Outbound Data Transfers (Draft for Comment), or the Draft Measures. The Draft Measures are enacted in accordance with the Cyber Security Law, the Data Security Law and the PIPL. Under the Draft Measures, a data processor would be subject to mandatory security assessment for transfers of data out of mainland China under any of the following

circumstances: (i) where the outbound data is personal information and important data collected and generated by critical information infrastructure operators; (ii) where the outbound data contains important data; (iii) where a personal information processor that has processed personal information of more than one million people transfers personal information overseas; (iv) where the personal information of more than 100,000 people or sensitive personal information of more than 10,000 people is transferred overseas accumulatively; or (v) other circumstances under which a security assessment of outbound data transfers is required as prescribed by the CAC. It is 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 or 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.

The National People's Congress released the PIPL, which became effective on November 1, 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 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 RMB 50 million or 5% of annual revenues from the prior year and violators may also be ordered to suspend any related activity by competent authorities. We do not believe that, based on our understanding of the PIPL and its current and draft supplementing rules released by the authorities, and subject to further interpretation that may be released and enacted in the future, that we are either a critical information infrastructure operator or process a sufficient amount of personal information to be a personal information processor subject to the above storage and security assessment requirements.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in mainland China. For example, the Regulation on the Administration of Human Genetic Resources, or the HGR Regulation, promulgated by the State Council of the People's Republic of China, or the State Council, which became effective on July 1, 2019, applies to activities that involve collection, biobanking, use of human genetic resources (HGR), which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substances (the China Biospecimens) and derived data in China (together with the China Biospecimens, the China-Sourced HGR), and the provision of such items to foreign parties or entities established or actually controlled by them. The HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced HGR in China, as well as providing such China-Sourced HGR 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, or 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 on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR and the illegal transfer of China-sourced

biospecimens outside of 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 of the People's Republic of China, or the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law will establish 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 Ministry of Science and Technology, or MOST, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in 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 HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAC to take rectification measures and was also banned by the HGRAC from submitting any clinical trial applications until the HGRAC was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in 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 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 and/or related implementing 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 confidential information and be subject to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or delays in the initiation of new trials, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in 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 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, obtain government approval or certification, 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, conduct 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 continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss of use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of 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.

As of the date of this Annual Report on Form 10-K, we are not required to obtain 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. However, the CSRC recently released the Draft Rules for public comment. If the Draft Rules are adopted in its current form, we would likely be required to submit filings to the CSRC in connection with the future issuance of our equity securities to foreign investors. For more details, see “Governmental 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, or 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, on July 6, 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 Draft Rules, if declared into effect, will implement a new regulatory framework requiring China-based companies such as us to submit filings to CSRC in connection with the issuance of equity securities to foreign investors. The instructions on the Draft Rules released by the CSRC suggest that companies already listed on overseas exchanges will be grandfathered, such that prior offerings will not need to be filed with the CSRC. However, if the Draft Rules are declared into effect, we may be required to submit filings to the CSRC in connection with any 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.

As of the date of this Annual Report on Form 10-K, we have not received any inquiry, notice, warning or sanction regarding obtaining approval, completing filing or other procedures in connection with issuing securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. Based on the above and our understanding of the Chinese laws and regulations currently in effect, we were not required to submit an application to the CSRC or any other Chinese regulatory authorities for issuing securities to foreign investors. However, there remains significant uncertainty as to the enactment, 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 it is determined in the future that the approval of, filing or other procedure with the CSRC or any other regulatory authority is required for issuing our securities to foreign investors, it is uncertain whether we will be able and how long it will take for us to obtain the approval or complete the filing or other procedure, despite our best efforts. If we, for any reason, are unable to obtain or complete, or experience significant delays in obtaining or completing, the requisite relevant approval(s), filing or other procedure(s), we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in mainland China, limit our ability to pay dividends outside of mainland China, limit our operations in mainland China, delay or restrict the repatriation of the proceeds from our public offerings into mainland China or take 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. In addition, if the CSRC or other regulatory authorities later promulgate new rules requiring that we obtain their approvals or complete filing or other procedures for any future public offerings, we may be unable to obtain a waiver of such requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such an requirement 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 U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.***

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 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 date of this Annual Report on Form 10-K, 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 $366.5 million in capital contributions via twenty-four separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2021, 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 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.

***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 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 on August 30, 2007 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 we actually receive any financial incentive.

We generally do not have the ability to influence local governments in making these decisions. 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 for the years ended December 31, 2021 and 2020 were $4.1 million and $7.3 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 Chinese Securities Law, or Article 177, 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 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.***

China Enterprise Income Tax Law, or 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, or the SAT, on April 22, 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 its 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. 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, other than imposing penalties such as late payment interest on the transferors, the tax authority may also 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, or 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, or CFIUS, which may delay or block a transaction from closing.***

The Committee on Foreign Investment in the United States (CFIUS) has jurisdiction over investments in which a foreign person acquirers 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.

***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 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.***

On July 14, 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, or 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. On January 18, 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, or 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.

***We may be subject to fines due to the lack of registration of our leases.***

Pursuant to the Measures for Administration of Lease of Commodity Properties, which was promulgated by the Ministry of Housing and Urban-Rural Development of China on December 1, 2010, and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we leased certain properties primarily as office space in mainland China and did not register all of our lease agreements as tenant. We may be required by relevant governmental authorities to file these lease agreements for registration within a time limit and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each lease agreement. As of the Latest Practicable Date, we were not aware of any action, claim or investigation being conducted or threatened by the competent governmental authorities with respect to such defects in our leased properties.

***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 on Nasdaq in September 2017, multiple follow-on offerings and a secondary listing on the Stock Exchange of Hong Kong in September 2020. For the years ended December 31, 2021 and 2020, we generated net revenue of $144.3 million and $49.0 million mainly from product sales, 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 the years ended December 31, 2021 and 2020, we reported a net loss of $704.5 million and $268.9 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;
- 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.***

For the years ended December 31, 2021 and 2020, we generated net revenue of $144.3 million and $49.0 million mainly from product sales, 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 on Nasdaq in September 2017, multiple follow-on offerings and a secondary listing on the Stock Exchange of Hong

Kong in September 2020. As of February 28, 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, our secondary listing and our follow-on offerings. For the years ended December 31, 2021 and December 31, 2020, the net cash used in our operating activities was $549.2 million and $216.1 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 develop 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, 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. Accordingly, 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 any future commercialization efforts.

We believe our cash and cash equivalents and short-term investments as of December 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and 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, collaboration, licensing or other arrangement 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;
- 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 ensure 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. In the event of adverse market conditions, we may be unable to obtain capital or credit market financing on favorable terms.

**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;
- 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.

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 Turning Point to manufacture and supply TPX-0022 and repotrectinib (TPX-0005), argenx to manufacture and supply efgartigimod, MacroGenics to manufacture and supply margetuximab, tebotelimab and a pre-clinical multi-specific TRIDENT molecule, Entasis to manufacture and supply SUL-DUR, Novocure to manufacture and supply Optune, Deciphera to manufacture and supply QINLOCK, Incyte to manufacture and supply retifanlimab (INCMGA0012 (PD-1)), Regeneron to manufacture and supply odronextamab, Mirati to manufacture and supply adagrasib, and Blueprint to manufacture and supply BLU-701 and BLU-945.

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.

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 especially challenging given 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;
- 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 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 New Drug Application, or 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 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 Item 1—Business—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 March 2020, Medical Products Administration of Hainan Province promulgated the Interim Measures for the Administration of Taking Away the Imported Urgently Needed Drug from the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province. These Interim Measures permit a patient to take away, following his therapeutic schedules, a small amount of the legally imported drugs that is not yet registered domestically but is on urgent medical need from the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province, subject to the approval of Hainan Health Commission and Medical Products Administration of Hainan Province. This program is also known as the special Named Patient Program, or NPP. However, as NPP is newly adopted, 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 ensure that our activities 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 temozolomide 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 and infectious diseases 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.

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 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;
- 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.

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, particularly 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.

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 contra-indication;
- 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 clinical trial applications, or 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.

***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, Chairwoman and Chief Executive Officer. 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 months' 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.

***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, 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;
- 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, or 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 National Reimbursable

Drug List, or 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%. NHSA, together with other government authorities, review the inclusion or removal of drugs from the NRDL, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. In December 2020, ZEJULA was included in the updated NRDL. As a result, the prices for ZEJULA have significantly decreased and our potential revenue from the sales of ZEJULA 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.

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 "Regulation—Government Regulation of Pharmaceutical Product Development and Approval," "Regulation—Coverage and Reimbursement" and "Regulation—Other Healthcare Laws."

***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, tebotelimab 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, tebotelimab 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 Incyte for retifanlimab is terminated for certain reasons, we are required to assign to Incyte certain trademarks and certain other business premises, data and regulatory materials that relate to retifanlimab. 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 Turning Point for TPX-0022 and Repotrectinib or with Cullinan 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.

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 D&O 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.

***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 security 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 damage from computer viruses and unauthorized access. 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 regime 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, damage to our reputation or a loss of revenues, and invite regulator’s scrutiny. 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. 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 is costly and 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 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, or CCPA, which became effective on January 1, 2020, and has been enforced by the California Attorney General since July 1, 2020. The CCPA 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. These protections will be expanded by the California Privacy Rights Act (CPRA), which was approved by California voters in November 2020 and will be operational in most key respects on January 1, 2023. Colorado 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, or 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 goods and services to individuals located in the EEA or monitoring the behavior of individuals located in the EEA. GDPR imposes 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 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 Euros 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. GDPR additionally places 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 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.

**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, or 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 Our Material 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 Turning Point for TPX-0022 and repotrectinib, Cullinan for CLN-081, Novocure for TTFields, argenx for Efgartigimod, Karuna for KarXT, and Blueprint for BLU-701 and 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 the years ended December 31, 2021 and 2020, the aggregate amount of product revenue generated from our five largest customers accounted for approximately 39.9% and 48.6% of our product revenue, respectively. Product revenue generated from our largest customer for the same periods accounted for approximately 21.5% and 27.5% 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 cost 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. We had cash and cash equivalents (in millions of dollars) of $964.1 and $442.1, restricted cash of $0.8 and $0.7 and short-term investments of $445.0 and $744.7 at December 31, 2021 and 2020, 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, 2021 and 2020, our short-term investments consisted of time deposits with original maturities more than three months.

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

**Risks Related to Intellectual Property**

***If we are unable to obtain and maintain 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, tebotelimab 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. In the case of our agreement with Takeda for simurosertib (TAK-931), our license is worldwide except for Japan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications relating to bemarituzumab (FPA144), Tumor Treating Fields, margetuximab, tebotelimab, 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, or USPTO, or 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 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 extend 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, cancelation 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.

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, or 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 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.

***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 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 cancelation 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. Since the cases would usually take several months, the Company will follow those administrative rulings / court decisions to have a deeper understanding on the protection 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 ba sed 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;

- 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 for our ADSs and/or our ordinary shares may be volatile which could result in substantial loss to you.***

The market price for our ADSs and/or ordinary shares has been volatile. From September 20, 2017 to February 28, 2022, 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 28, 2022, the closing price of our ordinary shares on the Stock Exchange of Hong Kong ranged from a high of HKD1,504.0 to a low of HKD327.8 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.

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 the year ended December 31, 2021, 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 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 fifth 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.

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

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

***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 depositary 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 depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act of 1933, as amended, or the Securities Act, but are not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of our ADSs.

***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 depositary 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 depositary 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.

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 United States person 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.

On December 22, 2017, the Tax Cut and Jobs Act, or the Tax Act, was signed into law which significantly revised the Internal Revenue Code of 1986, as amended, or the Code. In addition, the Biden Administration has proposed a significant number of changes to U.S. tax laws, including an increase in the maximum tax rate applicable to U.S. corporations and certain individuals. The likelihood of any such legislation being enacted is uncertain but could adversely impact us. We urge holders of our ADS to consult with their legal and tax advisors with respect to such proposed 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 persons 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 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 China Civil Procedures Law. Chinese courts may recognize and enforce foreign judgments in accordance with the requirements of China 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 China 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 depositary. However, the depositary 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 depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

***Substantial future sales or perceived potential sales of our ordinary shares, ADSs or other equity or equity-linked securities 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 U.S. Securities Act. The shares held by our affiliates are also available for sale, subject to volume and other restrictions as applicable under Rule 144 of the U.S. Securities Act, under trading plans adopted pursuant to Rule 10b5-1 or otherwise.

Divestiture in the future of our 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 concurrently. The Stock Exchange of Hong Kong 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 Stock Exchange of Hong Kong 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 the 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, cancelation 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 Stock Exchange of Hong Kong. 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 Stock Exchange of Hong Kong and our ADSs on Nasdaq may be adversely affected.

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

There is no direct trading or settlement between Nasdaq and the Stock Exchange of Hong Kong 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 depositary for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancelation 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, or the Hong Kong IPO, we established a branch register of members in Hong Kong, or the Hong Kong share register. Our ordinary shares that are traded on the Stock Exchange of Hong Kong are registered on the Hong Kong share register, and the trading of these ordinary shares on the Stock Exchange of Hong Kong will be subject to the Hong Kong stamp duty. To facilitate ADS ordinary share conversion and trading between Nasdaq and the Stock Exchange of Hong Kong, 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 United States 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.

***Our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ordinary shares and/or our ADSs, may be adversely affected by the geopolitical factors arising in connection with Russia's invasion of Ukraine, including particularly how countries like the United States and China choose to respond to this war. As a result, the value of our ADSs and ordinary share may significantly decline.***

Our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ordinary shares and/or our ADSs, may be adversely affected by the geopolitical factors arising in connection with Russia's invasion of Ukraine. We do not conduct business in either Russia or Ukraine. However, our global operations expose us to geopolitical risks, including particularly here, how the United States and China choose to respond to the war between Ukraine and Russia. If this war continues, increases, or expands, or leads to continued political or economic instability, terrorist activity, or gives rise to further government actions such as sanctions or increased economic or political tensions between the United States and China, our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our ordinary shares and/or our ADSs, may be adversely impacted and the value of our ADSs and ordinary shares may significantly decline.

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

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

In December 2019, a respiratory illness caused by a novel strain of coronavirus, SARS-CoV2, causing the Coronavirus Disease 2019, also known as COVID-19 or coronavirus emerged. Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment and the pandemic has significantly increased economic volatility and uncertainty. The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders and business shutdowns. The continued COVID-19 pandemic could adversely impact our

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

For example, due to business interruptions to hospitals and treatment centers in mainland China arising in connection with the outbreak of COVID-19, some patients have experienced difficulties in accessing hospital care and, as a result, our commercialization team has had fewer opportunities to reach patients who could benefit from ZEJULA, Optune, QINLOCK, or NUZYRA. In addition, we have experienced delays in the enrollment of patients in our clinical trials due to the outbreak of COVID-19. Our commercial partners and licensors also have similarly experienced delays in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. However, none of our NDA submission and acceptance nor CTA approvals have been materially delayed.

However, as the outbreak of COVID-19 has largely been contained in mainland China, we believe we have experienced only minimal disruption to our overall commercialization efforts for our products and our planned clinical trials since the outbreak. Nevertheless, outbreaks may occur again and may result in similar business interruptions in the future. Additionally, although we have not experienced material supply disruptions due to the outbreak of COVID-19, we cannot guarantee that we will not experience supply disruptions in the future due to COVID-19 or any other pandemic, epidemic or other public health crises, natural catastrophe or other disasters.

There are no comparable recent events that provide guidance as to the effect the COVID-19 outbreak as a global pandemic may have and, as a result, the ultimate impact of the pandemic is highly uncertain and subject to change, and the actual effects will depend on many factors beyond our control. To the extent the outbreak of COVID-19 results in delays and interruptions to our or our commercial partners' and licensors' clinical trials in the future, such delays may result in increased development costs for our products and product candidates, which could cause the value of the Company to decline and limit our ability to obtain additional financing.

***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.

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 2021 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.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

We lease all of our facilities. We are headquartered in Shanghai where we have our main administrative and laboratory offices, which is 3,632 square meters in size. The lease for this facility expires in 2023. We also have a 2,475 square meter commercial office for in Shanghai, the lease for which expires in 2022, and a 723 square meter office in Beijing, the lease for which expires in 2022. We have a 445 square meter commercial office in Hong Kong, the leases for which expire in 2022. We lease an administrative office in Guangzhou from a third party. We also have a 2,892 square foot administrative office and an 18,707 square foot laboratory office in the San Francisco Bay area, the leases for which expire in 2022 and 2026, respectively. We also lease corporate offices in Cambridge, Massachusetts. In early 2017, we built a small molecule drug product facility in Suzhou, China, capable of supporting clinical and commercialized production, which is 4,223 square meters. The lease for this facility expires in 2023. In 2018, we built a large molecule facility in Suzhou, China, using Cytiva FlexFactory platform technology capable of supporting clinical production of our drug candidates, which is 4,223 square meters. The lease for this facility expires in 2024. The cost to complete the small molecule facility was approximately US$6.7 million and was paid with cash on hand. The construction of the large molecule facility was completed in 2018, which cost approximately US$12.9 million and was financed with cash. We believe our current facilities are sufficient to meet our near-term needs. In 2019, we acquired land use rights of 50,851 square meters in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou. The terms of the land use rights are 30 years.

Please refer to “Note 20: Commitments and Contingencies” in the notes to our consolidated financial statements in this Annual Report on Form 10-K for further information on our real property leases.

**Item 3. Legal Proceedings**

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

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

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

**Market Information**

Our ADSs have been listed on the Nasdaq Global Market since September 20, 2017 under the symbol "ZLAB." Our ordinary shares have been publicly traded on the Stock Exchange of Hong Kong since September 28, 2020 under the stock code "9688."

**Shareholders**

As of February 28, 2022, we had approximately 23 holders of record of our ordinary shares and one holder of record of our ADSs. This number does not include beneficial owners whose ordinary shares or ADSs are held by nominees in street name. Because many ordinary shares and ADSs are held by broker nominees, we are unable to estimate the total number of beneficial holders represented by these record holders.

**Dividend Policy**

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 of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

**Equity Compensation Plan Information**

Our equity compensation plan information required by this item is incorporated by reference in the information in "Part III—Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report on Form 10-K.

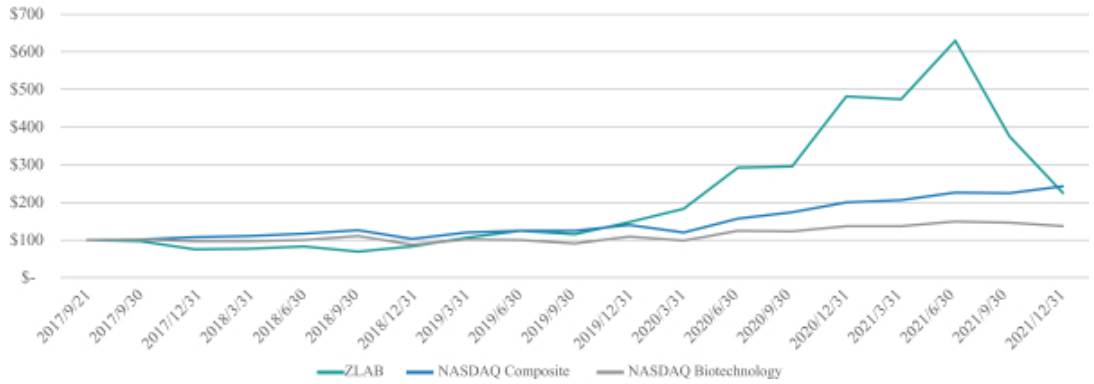
**Performance Comparison Graph**

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

The following graph shows the total shareholder return of an investment of $100 in cash at market close on September 19, 2017 (the first day of trading of our ADSs) through December 31, 2021 for our ADSs, the NASDAQ Composite Index (U.S.), and the NASDAQ Biotechnology Index.

Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of any dividends, although no dividends have been declared to date. The shareholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future shareholder returns.

Quarterly Performance of $100 of ZLAB ADSs, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index, 9/21/17-12/31/21




- Note: Reflects opening prices for 9/21/17, the date of initial trading of ZLAB ADSs, and closing prices for all other quarterly dates.

| | 9/21/17 | 9/30/17 | 12/31/17 | 3/31/18 | 6/30/18 | 9/30/18 | 12/31/18 | 3/31/19 | 6/30/19 | 9/30/19 |
|---|---|---|---|---|---|---|---|---|---|---|
| Zai Lab Limited | $ 100.00 | $ 95.81 | $ 75.34 | $ 75.76 | $ 82.51 | $ 69.13 | $ 82.40 | $ 104.72 | $ 123.74 | $ 114.80 |
| NASDAQ Composite | $ 100.00 | $ 100.73 | $ 107.05 | $ 109.54 | $ 116.46 | $ 124.78 | $ 102.90 | $ 119.86 | $ 124.16 | $ 124.05 |
| NASDAQ Biotechnology | $ 100.00 | $ 100.45 | $ 96.52 | $ 96.46 | $ 99.31 | $ 110.29 | $ 87.52 | $ 101.00 | $ 98.58 | $ 89.94 |

| | 12/31/19 | 3/31/20 | 6/30/20 | 9/30/20 | 12/31/20 | 3/31/21 | 6/30/21 | 9/30/21 | 12/31/21 |
|---|---|---|---|---|---|---|---|---|---|
| Zai Lab Limited | $ 147.59 | $ 182.68 | $ 291.45 | $ 295.14 | $ 480.27 | $ 473.49 | $ 628.07 | $ 373.99 | $ 223.03 |
| NASDAQ Composite | $ 139.14 | $ 119.41 | $ 155.98 | $ 173.18 | $ 199.86 | $ 205.42 | $ 224.92 | $ 224.06 | $ 242.61 |
| NASDAQ Biotechnology | $ 108.89 | $ 97.55 | $ 123.58 | $ 122.41 | $ 136.85 | $ 135.87 | $ 148.03 | $ 146.23 | $ 135.99 |

**Recent Sales of Unregistered Securities**

None.

**Issuer Purchases of Equity Securities**

During the year ended December 31, 2021, we acquired 38,293 ADSs, at an average price of $111.76 per share to satisfy tax withholding obligations related to share-based compensation.

**Taxation**

The following is a discussion of the material Cayman Islands, People's Republic of China and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our ADSs or ordinary shares. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decisions to acquire ADSs or ordinary shares.

Material Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us or our shareholders or ADS holders levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by the Company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Material People's Republic of China Taxation

Zai Lab Limited is a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of mainland China with a "de facto management body" within mainland China is considered a "resident enterprise," and will be subject to the EIT on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation issued SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a Chinese-controlled enterprise that is incorporated offshore is located in mainland China. Although this circular only applies to offshore enterprises controlled by Chinese enterprises or Chinese enterprise groups, not those controlled by Chinese individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, all offshore enterprises controlled by a Chinese enterprise or a Chinese enterprise will be regarded as a Chinese tax resident by virtue of having its "de facto management body" in mainland China only if all of the following conditions are met:

(i) the primary location of the day-to-day operational management is in mainland China;

(ii) decisions relating to the enterprise's financial and human resource matters are made or are 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 shareholder resolutions, are located or maintained in mainland China; and

(iv) at least 50% of voting board members or senior executives habitually reside in mainland China.

We believe that none of Zai Lab Limited and its subsidiaries outside of mainland China is a Chinese resident enterprise for Chinese tax purposes. Zai Lab Limited is not controlled by a Chinese enterprise or Chinese enterprise group, and we do not believe that Zai Lab Limited meets all of the conditions above. Zai Lab Limited is a company incorporated outside mainland China. As a holding company, some of its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside mainland China. For the same reasons, we believe our other subsidiaries outside of mainland China are also non-Chinese resident enterprises for Chinese tax purpose. 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 Chinese tax authorities determine that Zai Lab Limited is a Chinese resident enterprise for EIT purposes, we may be required to withhold tax at a rate of 10% on dividends we pay to our shareholders, including 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 ADS 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-Chinese 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 dividends realized by non-Chinese individuals, it will generally apply at a rate of 20%. The Chinese tax liability may be reduced under applicable tax treaties. However, it is unclear whether non-Chinese shareholders of Zai Lab Limited would be able to claim the benefits of any tax treaty between their country of tax residence and mainland China in the event that Zai Lab Limited is treated as a Chinese resident enterprise.

See “Part I—Item 1A—Risk Factors—Risks Related to Doing Business in 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.”

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in mainland China or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its Chinese-sourced income at a rate of 10%. Pursuant to the Arrangement between mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a Chinese enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise is deemed the beneficial owner of any dividend paid by a Chinese enterprise by Chinese tax authorities and directly holds at least 25% of the Chinese enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the Chinese resident enterprise; and (ii) it must have directly owned such percentage in the Chinese resident enterprise throughout the 12 months prior to receiving the dividends. Additionally, mainland China has started an anti-tax treaty shopping practice since the issuance of Circular 601 in 2009. On February 3, 2018, the State Administration of Taxation released the Announcement on Issues concerning the “Beneficial Owner” in Tax Treaties, or PN9, which provides guidelines in determining a beneficial owner qualification under dividends, interest, and royalty articles of tax treaties. Chinese tax authorities in general often scrutinize fact patterns case-by-case in determining foreign shareholders’ qualifications for a reduced treaty withholding tax rate, especially against foreign companies that are perceived as being conduits or lacking commercial substance. Furthermore, according to the Administrative Measures for Non-Resident Enterprises to Enjoy Treatments under Tax Treaties, which became effective in January 2020, where non-resident enterprises judge by themselves that they meet the conditions for entitlement to reduced tax rate according to tax treaties, they may enjoy such entitlement after reporting required information to competent tax authorities provided that they shall collect and retain relevant documents for future reference and inspections. Accordingly, our subsidiary Zai Lab (Hong Kong) Limited may be able to enjoy the 5% tax rate for the dividends it receives from its subsidiaries incorporated in mainland China if they satisfy the conditions prescribed under SAT Circular 81, PN9 and other relevant tax rules and regulations and complete the necessary government formalities. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, Zai Lab Limited, is not deemed to be a Chinese resident enterprise, holders of our ADSs and ordinary shares who are non-Chinese residents will not be subject to Chinese income tax on dividends distributed by us or gains realized from the sale or other disposition of our ADSs or ordinary shares.

Material United States Federal Income Tax Consideration

The following discussion, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of ADSs or ordinary shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person’s decision to acquire our ADSs or ordinary shares. This discussion is limited to U.S. Holders who hold such ADSs or ordinary shares as capital assets (generally, property held for investment). This discussion is based on Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between mainland China and the United States, or the U.S.-

China Tax Treaty, each as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect, which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

For purposes of this summary, a "U.S. Holder" is a beneficial owner of an ADS or ordinary share that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- real estate investment trusts;
- regulated investment companies;
- grantor trusts;
- tax-exempt organizations (including private foundations);
- persons holding ADSs or ordinary shares through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies (including those who use a mark-to-market method of tax accounting);
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons who acquired our ADSs or ordinary shares pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding ADSs or ordinary shares as part of a position in a straddle or as part of a hedging, wash sale, constructive sale, conversion or integrated transaction for U.S. federal income tax purposes; or
- direct, indirect or constructive owners of 10% or more of our total combined voting power or value.

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, the U.S. federal estate and gift tax or the alternative minimum tax consequences of the acquisition, ownership, and disposition of ADSs or ordinary shares. We have not received nor do we expect to seek a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Further, the Biden Administration has proposed a significant number of changes to U.S. tax laws, including an increase in the maximum tax rate applicable to U.S. corporations and certain individuals. The likelihood of any such legislation being enacted is uncertain but could adversely impact us. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of ADSs or ordinary shares.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs or ordinary shares, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of ADSs or ordinary shares.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

***ADSs***

A U.S. Holder of ADSs will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depositary or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

***Taxation of Dividends***

We do not currently anticipate paying any distributions on our ADSs or ordinary shares in the foreseeable future. However, subject to the discussion below in "—Passive Foreign Investment Company Considerations," to the extent there are any distributions made with respect to our ADSs or ordinary shares, the gross amount of any distribution on the ADSs or ordinary shares (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to the ADSs or ordinary shares as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions on the ADSs or ordinary shares, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a "qualified foreign corporation" may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than one that is a PFIC in the taxable year or the preceding taxable year in which such dividends are paid) if (i) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (ii) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes.

Our ADSs are listed on the Nasdaq Global Market, which is an established securities market in the United States. IRS guidance indicates that the ADSs will be readily tradable for these purposes.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a Chinese resident enterprise under the EIT Law (see "—Material People's Republic of China Taxation" above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-China Tax Treaty, and if we were eligible for such benefits, dividends paid on the ADSs or ordinary shares, regardless of whether the ADSs or ordinary shares are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of U.S. federal income taxation, subject to applicable limitations. U.S. Holders should consult their own tax advisors regarding the availability of the reduced tax rates on dividends in light of their particular circumstances.

Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

In the event that we were deemed to be a Chinese resident enterprise under the EIT Law (see "—Material People's Republic of China Taxation" above), holders of ADSs or ordinary shares might be subject to Chinese withholding taxes on dividends paid with respect to ADSs or ordinary shares. In that case, subject to certain conditions and limitations, such Chinese withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder's U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on the ADSs or ordinary shares will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-China Tax Treaty benefits, any China taxes on dividends will not be creditable against such U.S. Holder's U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-China Tax Treaty rate. An eligible U.S. Holder who does not elect to claim a foreign tax credit for Chinese tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit or deduction rules in light of their particular circumstances.

***Taxation of Capital Gains***

Subject to the discussion below in "—Passive Foreign Investment Company Considerations" below, upon the sale, exchange, or other taxable disposition of ADSs or ordinary shares, a U.S. Holder generally will recognize gain or loss on the taxable sale or exchange in an amount equal to the difference between the amount realized on such sale or exchange and the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares. The initial tax basis of ADSs or ordinary shares to a U.S. Holder will generally be the U.S. Holder's U.S. dollar purchase price for the ADS or ordinary shares.

Subject to the discussion below in "—Passive Foreign Investment Company Considerations" below, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses may be subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a Chinese resident enterprise for EIT Law purposes and Chinese tax were imposed on any gain (see "—Material People's Republic of China Taxation" above), and if a U.S. Holder is eligible for the benefits of the U.S.-China Tax Treaty, the U.S. Holder may be able to treat such gain as Chinese source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-China Tax Treaty benefits if (for purposes of the treaty) such U.S. Holder is a resident of the United States and satisfies the other requirements specified in the U.S.-China Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a U.S. Holder's particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-China Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their

own tax advisors regarding the tax consequences in the event Chinese tax were to be imposed on a disposition of ADSs or ordinary shares, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as Chinese source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances. On the other hand, if we are not deemed to be a Chinese resident enterprise for EIT law purposes and we directly or indirectly hold Chinese subsidiaries, with respect to gains realized from the sale or other disposal of our ordinary shares or ADSs, there is a possibility that a Chinese tax authority may impose an income tax under the indirect transfer rules set out under SAT Circular 7, except that such transaction could fall under the safe harbor thereunder. Please refer to "Risk Factors—Risks Related to Doing Business in China—We and our shareholders face uncertainties in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises."

***Passive Foreign Investment Company Considerations***

*Status as a PFIC*

The rules governing PFICs can have adverse tax effects on U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (i) 75% or more of our gross income consists of certain types of passive income (the Income Test), or (ii) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income (including cash) is 50% or more of the value of all of our assets (the Asset Test).

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year applying principles, methodologies and legal rules that in some circumstances are unclear and subject to varying interpretation and which depends on the composition and nature of our income and the composition, nature and value of our assets for the relevant taxable year. The fair market value of our assets for purposes of the PFIC rules (including goodwill) may be determined in large part by reference to the quarterly market price of our ADSs, which is likely to fluctuate significantly. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash in our business, including any cash that is raised in a financing transaction.

We do not expect that Zai Lab Limited and its subsidiaries will be treated as PFICs for the current taxable year. However, because we hold a substantial amount of passive assets, including cash, and because the value of our assets (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early-stage of our drug candidates, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year.

If we are a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and (i) the U.S. Holder makes the "deemed sale election" described below, (ii) the U.S. Holder has a valid mark-to-market election in effect as described below, or (iii) the U.S. Holder makes a QEF election with respect to all taxable years in which we are a PFIC during such U.S. Holder's holding period or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election (as discussed below). If a U.S. Holder makes a deemed sale election, such U.S. Holder will be deemed to have sold the shares held by such U.S. Holder at their fair market value, and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, a U.S.

Holder's ADSs or ordinary shares subject to such election will not be treated as shares in a PFIC, and the rules described below with respect to any "excess distributions" or any gain from an actual sale or other disposition of the ADSs or ordinary shares will not apply. Prospective investors should consult their own tax advisors regarding our PFIC status for the current or any future taxable years.

*U.S. Federal Income Tax Treatment of a Shareholder of a PFIC*

If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs or ordinary shares, the U.S. Holder, absent the elections listed above, generally will be subject to adverse rules (regardless of whether we continue to be a PFIC) with respect to (i) any "excess distributions" (generally, any distributions received by the U.S. Holder on its ADSs or ordinary shares in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for its ADSs or ordinary shares) and (ii) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs or ordinary shares.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder's holding period in which we were a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year. Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we were a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs, or Lower-tier PFICs, and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

If we are classified as a PFIC and then cease to be so classified, a U.S. Holder may make an election, or a deemed sale election, to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's ADSs or ordinary shares on the last day of our taxable year during which we were a PFIC. A U.S. Holder that makes a deemed sale election would then cease to be treated as owning stock in a PFIC by reason of ownership of our ADSs or ordinary shares. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

*PFIC "Mark-to-Market" Election*

In certain circumstances if we are a PFIC for any taxable year, a U.S. Holder of our ADSs or ordinary shares can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs or ordinary shares, provided that the ADSs or ordinary shares are "marketable." ADSs or ordinary shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury Regulations. ADSs or ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs or ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. A "qualified exchange" includes a national securities exchange that is registered with the SEC.

Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on the Nasdaq Global Market (which constitutes a qualified exchange) and such ADSs are "regularly traded" for purposes of the mark-to-market election (for which no assurance can be given).

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S.

Holder's ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in its ADSs. Accordingly, such mark-to-market election may accelerate the recognition of income without a corresponding receipt of cash. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in its ADSs over the fair market value of its ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. The adjusted tax basis of a U.S. Holder's ADSs will be adjusted to reflect amounts included in gross income or allowed as a deduction because of such mark-to-market election. If a U.S. Holder makes an effective mark-to-market election, gains from an actual sale or other disposition of our ADSs in a year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of our ADSs will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are a PFIC for any taxable year in which a U.S. Holder owns our ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs (unless the shares of such subsidiaries are themselves marketable). Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

*PFIC "QEF" Election*

Alternatively, if we provide the necessary information, a U.S. Holder can be subject to rules different from those described above by electing to treat us (and each Lower-tier PFIC, if any) as a "qualified electing fund" or QEF under Section 1295 of the Code in the first taxable year that we (and each Lower-tier PFIC) are treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder's timely filed U.S. federal income tax return.

In any year in which we determine that we are a PFIC, we will provide the information necessary for a U.S. Holder to make a QEF election with respect to us upon the request of a U.S. Holder and will endeavor to cause each Lower-tier PFIC that we control to provide such information with respect to such Lower-tier PFIC. However, there can be no assurance that we will be able to cause any Lower-tier PFIC we do not control to provide such information. We may elect to provide the information necessary to make such QEF elections on our website.

If you make a QEF election with respect to a PFIC, you will be taxed currently on your pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC, even if no distributions were received. If a U.S. Holder makes a QEF election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs or ordinary shares by an amount equal to any income included under the QEF election and will decrease its tax basis by any amount distributed on the ADSs or ordinary shares that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ADSs or ordinary shares in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares, as determined in U.S. dollars. Once made, a QEF election remains in effect unless invalidated or terminated by the IRS or revoked by the U.S. Holder. A QEF election can be revoked only with the consent of the IRS. A U.S. Holder will not be currently taxed on the ordinary income and net capital gain of a PFIC with respect to which a QEF election was made for any taxable year of the non-U.S. corporation for which such corporation does not satisfy the PFIC Income Test or Asset Test.

U.S. Holders should note that if they make QEF elections with respect to us and any Lower-tier PFIC, they may be required to pay U.S. federal income tax with respect to their ADSs or ordinary shares for any taxable year significantly in excess of any cash distributions received on the ADSs or ordinary shares for such taxable year. Furthermore, recently proposed Treasury Regulations related to PFICs (which will not be effective until finalized) may affect the taxation and reporting obligations of partners of certain U.S. partnerships that invest in PFICs. U.S. Holders should consult their tax advisers regarding the advisability of, and procedure for, making QEF elections in their particular circumstances.

*PFIC Information Reporting Requirements*

If we are a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ADSs or ordinary shares, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership of our ADSs or ordinary shares.

THE U.S. FEDERAL INCOME TAX RULES RELATING TO PFICS ARE COMPLEX. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

***U.S. Backup Withholding and Information Reporting***

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, our ADSs or ordinary shares that are held by U.S. Holders. The payor may be required to withhold U.S. backup withholding tax on payments made with respect to the ADSs or ordinary shares to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of our ADSs or ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax return for each year in which they hold our ADSs or ordinary shares. U.S. Holders should consult their own tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of our ADSs or ordinary shares.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ADSs OR ORDINARY SHARES.

**Item 6. [Reserved]**

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe*

*could cause or contribute to these differences below and elsewhere in this Annual Report on Form 10-K, including those set forth under "Part I—Item 1A—Risk Factors" and under "Forward-Looking Statements and Market Data" in this Annual Report on Form 10-K.*

## A. Operating Results.

### Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are discovering, developing and commercializing innovative products that target medical conditions with unmet needs affecting patients in Greater China and worldwide, particularly in the areas of oncology, autoimmune disorders, infectious diseases, and neuroscience. As described in "Part I—Item 1—Business," we currently have four commercialized products that have received marketing approval in one or more territories in Greater China and twelve programs in late-stage product development. Refer to "Part I—Item 1—Business" for a summary of our clinical programs.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high-quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and to generate positive cash flow from operations over the next several years depends upon our ability to successfully market our four commercial products—ZEJULA, Optune, QINLOCK and NUZYRA—and our other product candidates that we are able to successfully commercialize. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements and totaled $58.7 million, $108.2 million and $384.1 million for the years ended December 31, 2019, 2020 and 2021, respectively. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

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

### Recent Developments

On November 19, 2021, our Board of Directors, or the Board, appointed Richard Gaynor as an independent director, effective immediately. The Board also approved the formation of a new committee of the Board named the Research & Development Committee, or the R&D Committee, to assist the Board in its oversight of the Company's research and development activities. Mr. Gaynor, Samantha Du, William Lis, and Kai-Xian Chen were appointed to serve as the initial members of the R&D Committee, with Mr. Gaynor serving as the Chairperson of the R&D Committee.

On December 3, 2021, we issued a press release announcing that the National Reimbursement Drug List released by China's National Healthcare Security Administration has been updated to include ZEJULA

(niraparib) as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status.

On December 16, 2021, we issued a press release announcing that the NMPA has approved its New Drug Application for NUZYRA® (omadacycline) for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. NUZYRA® was approved as a Category 1 innovative drug by the NMPA and is locally manufactured in mainland China. It is the Company's fourth product approved over the last 24 months.

On December 22, 2021, we announced the promotion of Harald Reinhart, M.D., from his current role as Chief Medical Officer to President and Head of Global Development for Neuroscience, Autoimmune and Infectious Diseases. Dr. Reinhart, age 70, has been with the Company since inception, first as an advisor and since 2017, as Chief Medical Officer responsible for the autoimmune and infectious diseases portfolio.

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

**Basis of Presentation**

Our consolidated statement of operations data for the years ended December 31, 2019, 2020 and 2021 and our consolidated statement of financial position data as of December 31, 2020 and 2021 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K have been prepared in accordance with U.S. GAAP.

**Factors Affecting our Results of Operations**

**Research and Development Expenses**

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of product candidates has been steadily advancing and expanding, with thirteen late-stage clinical product candidates being investigated as of December 31, 2021. For more information on the nature of the efforts and steps necessary to develop our product candidates, see "Business" and "Regulation."

To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, a secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through December 31, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, our secondary listing and our follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $191.0 million, $216.1 million and $549.2 million, for the years ended December 31, 2019, 2020 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 and continue research and development of our clinical and pre-clinical-stage product candidates and

initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. These expenditures include:

- expenses incurred for payments to 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
- costs associated with operating as a public company.

For more information on the research and development expenses incurred for the development of our product candidates, 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 commercialize, develop, and manufacture our products and assets. These increases will likely include increased headcount, increased share compensation charges, increased product distribution and promotion costs, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

**Our Ability to Commercialize Our Product Candidates**

As of December 31, 2021, twelve of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may never occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

**Our License Arrangements**

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant products under these agreements as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements and totaled $58.7 million, $108.2 million and $384.1 million for the years ended December 31, 2019, 2020 and 2021, respectively.

## Key Components of Results of Operations

### Taxation

***Cayman Islands***

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see "Taxation—Material Cayman Islands Taxation."

***People's Republic of China***

Our subsidiaries incorporated in mainland China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see "Taxation—Material People's Republic of China Taxation."

***Hong Kong***

Our subsidiaries incorporated in Hong Kong are subject to two-tiered tax rates for the years ended December 31, 2021, 2020 and 2019 on assessable profits earned in Hong Kong where the profits tax rate for the first HK$2 million of assessable profits is subject to profits tax rate of 8.25% and the assessable profits above HK$2 million is subject to profits tax rate of 16.5%. Our subsidiaries incorporated in Hong Kong did not have assessable profit for the years ended December 31, 2021, 2020 and 2019.

### Results of Operations

***Year Ended December 31, 2021 Compared to Year Ended December 31, 2020***

***Revenues***

Total revenues consist of the following:

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Revenues:** | | | | |
| Product revenue, net | $144,105 | 99.9 | $48,958 | 100.0 |
| Collaboration revenue | 207 | 0.1 | — | 0.0 |
| **Total** | $144,312 | 100.0 | $48,958 | 100.0 |

***Product Revenue, net***

Our product revenue is primarily derived from the sale of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The following table disaggregates net product revenue by product for the years ended December 31, 2021 and December 31, 2020:

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Product revenue, net:** | | | | |
| ZEJULA | $ 93,579 | 64.9 | $32,138 | 65.7 |
| Optune | 38,903 | 27.0 | 16,418 | 33.5 |
| QINLOCK | 11,620 | 8.1 | 402 | 0.8 |
| NUZYRA | 3 | 0.0 | — | — |
| **Total** | $144,105 | 100.0 | $48,958 | 100.0 |

Our collaboration revenue is revenue from our collaborative arrangement.

***Cost of Sales***

Cost of sales increased by $35.5 million to $52.2 million for the year ended December 31, 2021 from $16.7 million for the year ended December 31, 2020. The increase was primary due to the increasing product cost, higher royalties and $8.0 million sales milestone payment of ZEJULA during the year ended December 31, 2021.

***Research and Development Expenses***

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

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Research and development expenses:** | | | | |
| Personnel compensation and related costs | $ 77,227 | 13.5 | $ 40,257 | 18.1 |
| Licensing fees | 384,104 | 67.0 | 108,169 | 48.6 |
| Payment to CROs/CMOs/Investigators | 82,571 | 14.4 | 53,275 | 23.9 |
| Other costs | 29,404 | 5.1 | 21,010 | 9.4 |
| **Total** | $ 573,306 | 100.0 | $ 222,711 | 100.0 |

Research and development expenses increased by $350.6 million to $573.3 million for the year ended December 31, 2021 from $222.7 million for the year ended December 31, 2020. The increase in research and development expenses included the following:

- $37.0 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $275.9 million for increased licensing fees in connection with the upfront and milestone fee paid for licensing agreements;
- $29.3 million for increased payment to CROs/CMOs/Investigators during the year ended December 31, 2021 as we advanced our drug candidate pipeline; and
- $8.4 million for increased lab consumables and other cost during the year ended December 31, 2021.

The following table summarizes our research and development expenses by program for the years ended December 31, 2021 and 2020, respectively:

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2021 | % | 2020 | % |
| **Research and development expenses:** | | | | |
| Clinical programs | $ 433,021 | 75.5 | $ 160,674 | 72.1 |
| Pre-clinical programs | 47,768 | 8.3 | 10,598 | 4.8 |
| Unallocated research and development expenses | 92,517 | 16.2 | 51,439 | 23.1 |
| **Total** | $ 573,306 | 100.0 | $ 222,711 | 100.0 |

During the year ended December 31, 2021, 75.5% and 8.3% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the year ended December 31, 2020, 72.1% and 4.8% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. Though 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 time.

***Selling, General and Administrative Expenses***

The following table sets forth the components of our selling, general and administrative expenses for the years indicated.

| (in thousands) | Year ended December 31, 2021 | % | 2020 | % |
|---|---|---|---|---|
| **Selling, General and Administrative Expenses:** | | | | |
| Personnel compensation and related costs | $ 124,675 | 57.0 | $ 63,010 | 56.6 |
| Professional service fees | 22,901 | 10.5 | 12,751 | 11.5 |
| Other costs | 71,255 | 32.5 | 35,551 | 31.9 |
| **Total** | $ 218,831 | 100.0 | $ 111,312 | 100.0 |

Selling, general and administrative expenses increased by $107.5 million to $218.8 million for the year ended December 31, 2021 from $111.3 million for the year ended December 31, 2020. The increase in general and administrative expenses included the following:

- $61.7 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during year ended December 31, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $10.1 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK and NUZYRA in mainland China after our commercial launch of these four commercialized products; and
- $35.7 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong, Taiwan and mainland China.

***Interest Income***

Interest income decreased by $2.9 million for the year ended December 31, 2021, primary due to the decreased interest rate and balance for short-term investments in 2021.

***Interest Expenses***

Interest expenses were nil for the year ended December 31, 2021, compared to $0.2 million for the same period of last year, as all the short-term borrowings were repaid in December 2020.

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

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We recorded the gain on deemed disposal in this investee of $0.5 million and share of loss of $1.5 million for the year ended December 31, 2021, and recorded our share of loss in this investee of $1.1 million for the year ended December 31, 2020.

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

Other expenses were $5.5 million for the year ended December 31, 2021, as compared to other income of $29.1 million for the year ended December 31, 2020, primarily as a result of the foreign exchange gain decreased and the fair value loss of $14.6 million for the equity investment in MacroGenics.

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

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $704.5 million for the year ended December 31, 2021 compared to net loss attributable to ordinary shareholders of $268.9 million for the year ended December 31, 2020.

***Year Ended December 31, 2020 Compared to Year Ended December 31, 2019***

***Revenue, net***

Our revenue is primarily derived from the sale of ZEJULA and Optune in mainland China and Hong Kong. The following table disaggregates net product revenue by product for the years ended December 31, 2020 and December 31, 2019:

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2020 | % | 2019 | % |
| **Product revenue, net:** | | | | |
| ZEJULA | $32,138 | 65.7 | $ 6,625 | 51.0 |
| Optune | 16,418 | 33.5 | 6,360 | 49.0 |
| QINLOCK | 402 | 0.8 | — | 0.0 |
| **Total** | $48,958 | 100.0 | $12,985 | 100.0 |

***Research and Development Expenses***

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

| | Year ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2020 | % | 2019 | % |
| **Research and development expenses:** | | | | |
| Personnel compensation and related costs | $ 40,257 | 18.1 | $ 30,820 | 21.6 |
| Licensing fees | 108,169 | 48.6 | 58,682 | 41.3 |
| Payment to CROs/CMOs/Investigators | 53,275 | 23.9 | 36,814 | 25.9 |
| Other costs | 21,010 | 9.4 | 15,905 | 11.2 |
| **Total** | $ 222,711 | 100.0 | $ 142,221 | 100.0 |

Research and development expenses increased by $80.5 million to $222.7 million for the year ended December 31, 2020 from $142.2 million for the year ended December 31, 2019. The increase in research and development expenses included the following:

- $9.4 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2020, and the grants of new share options and vesting of restricted shares to certain employees;
- $49.5 million for increased licensing fees in connection with the upfront and milestone fee paid for licensing agreement;
- $16.5 million for increased payment to CROs/CMOs/Investigators in fiscal year 2020 as we advanced our drug candidate pipeline; and
- $5.1 million for increased lab consumables and professional service expenses.

The following table summarizes our research and development expenses by program for the years ended December 31, 2020 and 2019, respectively:

| (in thousands) | Year ended December 31, 2020 | % | 2019 | % |
|---|---|---|---|---|
| **Research and development expenses:** | | | | |
| Clinical programs | $ 160,674 | 72.1 | $ 96,442 | 67.8 |
| Pre-clinical programs | 10,598 | 4.8 | 8,268 | 5.8 |
| Unallocated research and development expenses | 51,439 | 23.1 | 37,511 | 26.4 |
| **Total** | $ 222,711 | 100.0 | $ 142,221 | 100.0 |

During the year ended December 31, 2020, 72.1% and 4.8% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the year ended December 31, 2019, 67.8% and 5.8% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. Though 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 time.

***Selling, General and Administrative Expenses***

The following table sets forth the components of our selling, general and administrative expenses for the years indicated.

| (in thousands) | Year ended December 31, 2020 | % | 2019 | % |
|---|---|---|---|---|
| **Selling, General and Administrative Expenses:** | | | | |
| Personnel compensation and related costs | $ 63,010 | 56.6 | $43,572 | 62.1 |
| Professional service fees | 12,751 | 11.5 | 2,887 | 4.1 |
| Other costs | 35,551 | 31.9 | 23,752 | 33.8 |
| **Total** | $111,312 | 100.0 | $70,211 | 100.0 |

Selling, general and administrative expenses increased by $41.1 million to $111.3 million for the year ended December 31, 2020 from $70.2 million for the year ended December 31, 2019. The increase in general and administrative expenses included the following:

- $19.4 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during year ended December 31, 2020, and the grants of new share options and vesting of restricted shares to certain employees;
- $9.9 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA and Optune in mainland China after our commercial launch of these two commercialized products; and
- $11.8 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and mainland China.

***Interest Income***

Interest income decreased by $3.1 million for the year ended December 31, 2020, primary due to the decreased interest rate for short-term investments in 2020.

***Interest Expenses***

Interest expenses decreased by $0.1 million for the year ended December 31, 2020, primary attributable to less short-term borrowings balance in 2020.

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

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. An investment loss of $1.1 million and $0.8 million related to this investment was recorded for the year ended December 31, 2020 and 2019, respectively.

***Other Income, net***

Other income, net increased by $28.1 million for the year ended December 31, 2020, primarily as a result of an increase in governmental subsidies and foreign exchange gain.

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

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $268.9 million for the year ended December 31, 2020 compared to net loss attributable to ordinary shareholders of $195.1 million for the year ended December 31, 2019.

**Critical Accounting Policies and Significant Judgments and Estimates**

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

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

***Revenue recognition***

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

***Research and Development Expenses***

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

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

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

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

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

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

***Income Taxes***

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

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

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the

recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of December 31, 2020 and 2021, we did not have any significant unrecognized uncertain tax positions.

**B. Liquidity and Capital Resources.**

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering on the Nasdaq stock exchange, various follow-on offerings, and our September 2020 secondary listing on the Stock Exchange of Hong Kong. Through December 31, 2021, we have raised approximately $164.6 million in private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, subsequent follow-on offerings, and our secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $191.0 million. $216.1 million and $549.2 million, for the years ended December 31, 2019, 2020 and 2021, respectively. We have commitment for capital expenditure of $20.4 million as of December 31, 2021, 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 costs and revenues.

As of December 31, 2021, we had cash and cash equivalents, restricted cash and short-term investments of $1,409.9 million. Our expenditures as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of March 1, 2022, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this Annual Report are issued. However, in order to bring to fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

The following table provides information regarding our cash flows for the years ended December 31, 2021, 2020 and 2019:

| | Year ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2019 | 2020 | 2021 |
| Net cash used in operating activities | $ (191,011) | $ (216,055) | $ (549,231) |
| Net cash provided by (used in) investing activities | (14,892) | (554,830) | 249,957 |
| Net cash provided by financing activities | 219,302 | 1,132,440 | 820,202 |
| Effect of foreign exchange rate changes | 91 | 4,862 | 1,116 |
| Net increases in cash, cash equivalents and restricted cash | $ 13,490 | $ 366,417 | $ 522,044 |

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

During the year ended December 31, 2021, our operating activities used $549.2 million of cash, which resulted principally from our net loss of $704.5 million, adjusted for non-cash charges of $132.1 million, and by cash provided by our operating assets and liabilities of $23.1 million. Our net non-cash charges during the year ended December 31, 2021 primarily consisted of a $62.3 million non-cash research and development expenses, a $6.5 million depreciation expense, a $40.7 million share-based compensation expense, a $14.6 million share of loss from fair value changes of equity investment with readily determinable fair value and a $6.1 million of non-cash lease expense.

During the year ended December 31, 2020, our operating activities used $216.1 million of cash, which resulted principally from our net loss of $268.9 million, adjusted for non-cash charges of $34.6 million, and by cash provided in our operating assets and liabilities of $18.2 million. Our net non-cash charges during the year ended December 31, 2020 primarily consisted of $4.6 million depreciation expense, $24.8 million share-based compensation expense and $4.3 million noncash lease expense.

During the year ended December 31, 2019, our operating activities used $191.0 million of cash, which resulted principally from our net loss of $195.1 million, adjusted for non-cash charges of $27.3 million, and by cash used in our operating assets and liabilities of $23.2 million. Our net non-cash charges during the year ended December 31, 2019 primarily consisted of $3.8 million depreciation expense, $20.3 million share-based compensation expense and $2.8 million noncash lease expense.

***Net cash used in investing activities***

Net cash provided by investing activities was $250.0 million for the year ended December 31, 2021 compared to net cash used in investing activities of $554.8 million for the year ended December 31, 2020. The increase in cash provided by investing activities was due to proceeds from maturity of short-term investments, net off by purchases of short-term investments, purchase of property and equipment and equity method investment.

Net cash used in investing activities was $554.8 million for the year ended December 31, 2020 compared to $14.9 million for the year ended December 31, 2019. The increase in cash used in investing activities was primary due to the purchases of short-term investments, purchase of property and equipment and net of the proceeds from maturity of short-term investments.

Net cash used in investing activities was $14.9 million for the year ended December 31, 2019 compared to $212.6 million for the year ended December 31, 2018. The decrease in cash used in investing activities was primary due to the purchases of short-term investments, purchase of property and equipment, and net of proceeds from maturity of short-term investments.

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

Net cash provided by financing activities was $820.2 million for the year ended December 31, 2021 compared to $1,132.4 million for the year ended December 31, 2020. The decrease in cash provided by financing activities was primarily due to the less proceeds from the issuance of ADSs in our follow-on offering during the year ended December 31, 2021, compared with the proceeds from our follow-on offering in the year ended December 31, 2020 and our secondary listing in September 2020.

Net cash provided by financing activities was $1,132.4 million for the year ended December 31, 2020 compared to $219.3 million for the year ended December 31, 2019. The cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in 2020 as well as and a secondary listing on the Stock Exchange of Hong Kong in September 2020.

Net cash provided by financing activities was $219.3 million for the year ended December 31, 2019 compared to $144.1 million for the year ended December 31, 2018. The cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in 2019.

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

Full details of our research and development activities and expenditures are given in the “Business” and “Operating and Financial Review and Prospects” sections of this Annual Report above.

**D. Trend Information.**

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

***Recently Issued Accounting Standards***

For more information regarding recently issued accounting standards, please see “Part II—Item 8—Financial Statements and Supplementary Data—Recent accounting pronouncements” in this Annual Report.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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

***Foreign Exchange Risk***

RMB is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China (PBOC), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts of RMB 151.7 million and RMB155.9 million, which were denominated in RMB, as of December 31, 2021 and 2020, respectively, representing 2% and 5% of the cash and cash equivalents as of December 31, 2021 and 2020, respectively.

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

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

***Credit Risk***

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

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $964.1 million and $442.1 million and short-term investments of $445.0 million and $744.7 million, as of December 31, 2021 and 2020, respectively. As of December 31, 2020 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 believes are of high credit quality and continually monitors the credit worthiness of these financial institutions.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangement. We manage credit risk of accounts receivable through ongoing monitoring of the outstanding balances and limits the amount of credit extended based upon payment history and the debtor's current credit worthiness. Historically, we collected the receivables from customers within the credit terms with no significant credit losses incurred. As of December 31, 2021, two largest debtors accounted collectively approximately 44.8% of our total accounts receivable.

During the year ended December 31, 2021, certain accounts receivable balances are settled in the form of notes receivable. As of December 31, 2021, notes receivable represents 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 cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

**Inflation**

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

**Item 8. Financial Statements and Supplementary Data**

The financial statements required to be filed pursuant to this item are appended to this Annual Report on Form 10-K. An index of those financial statements is in Part IV—Item 15—Exhibits, Financial Statement Schedules.

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

None.

**Item 9A. Controls and Procedures**

**(a) Disclosure Controls and Procedures**

Our management, including our Chief Executive Officer and Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K, as required by Rule 13a-15(b) under the Exchange Act. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

Based upon that evaluation, our management has concluded that, as of December 31, 2021, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file and furnish under the Exchange Act was recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP in and includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the consolidated financial statements.

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

As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules as promulgated by the Securities and Exchange Commission, our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of internal control over financial reporting as of December 31, 2021 using the criteria set forth in the report "Internal Control-Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

**(c) Report of Registered Accounting Firm**

The effectiveness of internal control over financial reporting as of December 31, 2021 has been audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent registered public accounting firm, who has also audited our consolidated financial statements for the year ended December 31, 2021, as stated in their report which is included in "Part II-Item 8-Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

**(d) Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fiscal quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Item 9B. Other Information**

Not applicable.

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

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

### Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

### Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2021.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

The financial statements listed in the Index to Consolidated Financial Statements beginning on page F-1 are filed as part of this Annual Report on Form 10-K.

We have included Additional financial information of parent-company-Financial statement schedule I for the years ended December 31, 2019, 2020, and 2021 on page F-47. No other financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

### Item 16. Form 10-K Summary

Not applicable.

| Exhibit Number | Exhibit Title |
|---|---|
| **3.1** | Fifth Amended and Restated Memorandum Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| **3.2** | Fifth Amended and Restated Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 24, 2021) |
| **4.1** | Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| **4.2** | Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| **4.3** | Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| **4.4** | Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| **4.5** | Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act (incorporated by reference to Exhibit 4.5 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| **10.1**[#] | Zai Lab Limited 2015 Omnibus Equity Incentive Plan as amended on February 3, 2016 and April 10, 2016 (incorporated by reference to Exhibit 10.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| **10.2**[#] | Zai Lab Limited 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |

| Exhibit Number | Exhibit Title |
|---|---|
| 10.3# | Form Restricted Share Unit Award Agreement (incorporated by reference to Exhibit 10.23 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.4# | Form Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.5# | Form of Non-Statutory Stock Option Award Agreement (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.6* | Non-Employee Director Compensation Policy |
| 10.7# | Zai Lab Limited 2017 Cash Bonus Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.8+ | Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 28, 2016 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 10.9 | Amendment to Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd., dated February 26, 2018 (incorporated by reference to Exhibit 4.3 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018) |
| 10.10+ | License Agreement by and between Bristol-Myers Squibb Company and Zai Lab (Hong Kong) Limited dated March 9, 2015 (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 10.11+ | License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 10.12+ | License Agreement by and between Sanofi and Zai Lab (Hong Kong) Limited dated July 22, 2015 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 10.13+ | License Agreement by and between Five Prime Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated December 19, 2017 (incorporated by reference to Exhibit 4.11 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018) |
| 10.14+ | License and Collaboration Agreement by and between Entasis Therapeutics Holdings Inc. and Zai Lab (Shanghai) Co., Ltd. dated as of April 25, 2018 (incorporated by reference to Exhibit 10.12 to our Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-227159) filed with the SEC on September 5, 2018) |
| 10.15+ | License and Collaboration Agreement by and between Novocure Limited and Zai Lab (Shanghai) Co., Ltd. dated September 10, 2018 (incorporated by reference to Exhibit 10.15 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019) |
| 10.16+ | Collaboration Agreement by and between MacroGenics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated November 29, 2018 (incorporated by reference to Exhibit 10.16 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019) |

| Exhibit Number | Exhibit Title |
|---|---|
| 10.17^ | License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated June 10, 2019 (incorporated by reference to Exhibit 10.17 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 29, 2020) |
| 10.18^ | Amendment to License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated January 17, 2020 (incorporated by reference to Exhibit 10.18 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 29, 2020) |
| 10.19^ | Collaboration and License Agreement between Incyte Corporation and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2019 (incorporated by reference to Exhibit 10.19 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 29, 2020) |
| 10.20^ | Collaboration Agreement between Regeneron Ireland Designated Activity Company and Zai Lab (Shanghai) Co., Ltd. dated April 6, 2020 (incorporated by reference to Exhibit 10.20 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.21^ | License Agreement between Turning Point Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated July 6, 2020 (incorporated by reference to Exhibit 10.21 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.22^ | License Agreement between Cullinan Pearl Corp. and Zai Lab (Shanghai) Co., Ltd. dated December 24, 2020 (incorporated by reference to Exhibit 10.22 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.23*^ | License and Collaboration Agreement by and between Zai Lab (Shanghai) Co., Ltd. and Blueprint Medicines Corporation, dated November 8, 2021 |
| 10.24*^ | License Agreement by and between Zai Lab (Shanghai) Co., Ltd. and Karuna Therapeutics, Inc., dated November 8, 2021 |
| 10.25 | Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017) |
| 10.26# | Employment Agreement between Samantha (Ying) Du and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.18 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.27# | Letter Agreement between Samantha (Ying) Du and Zai Lab (US) LLC dated December 11, 2017 (incorporated by reference to Exhibit 4.16 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018) |
| 10.28# | Fourth Amended and Restated Founder Employment Agreement between Samantha (Ying) Du and Zai Lab Limited dated December 1, 2018 (incorporated by reference to Exhibit 10.18 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019) |
| 10.29# | Amended and Restated Employment Agreement between Tao Fu and Zai Lab (US) LLC dated December 3, 2018 (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019) |
| 10.30# | Amended and Restated Employment Agreement between William Ki Chul Cho and Zai Lab (Hong Kong) Limited dated March 22, 2019 (incorporated by reference to Exhibit 10.19 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019) |
| 10.31# | Employment Agreement between F. Ty Edmondson and Zai Lab (US) LLC dated August 15, 2020 (incorporated by reference to Exhibit 10.29 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |

| Exhibit Number | Exhibit Title |
|---|---|
| 10.32# | Employment Agreement between Alan Bart Sandler and Zai Lab (US) LLC dated December 1, 2020 (incorporated by reference to Exhibit 10.30 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.33 | Jinchuang Building House Leasing Contract by and between Zai Lab (Shanghai) Co., Ltd. and Shanghai Jinchuang Property Co., Ltd. dated September 1, 2016 (English translation) (incorporated by reference to Exhibit 10.26 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017) |
| 10.34 | Lease by and between Menlo Prepi I, LLC, TPI Investors 9, LLC and Zai Lab (US) LLC dated August 14, 2019 (incorporated by reference to Exhibit 10.32 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 10.35 | Indenture of Lease by and between MIT 314 Main Street Leasehold LLC and Zai Lab (US) LLC dated December 22, 2020 (incorporated by reference to Exhibit 10.33 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021) |
| 21.1* | Subsidiaries of the Registrant |
| 23.1* | Consent of Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited |
| 31.1* | Certification of Chief Executive Officer Required by Rule 13a-14(a) |
| 31.2* | Certification of Chief Financial Officer Required by Rule 13a-14(a) |
| 32.1** | Certification of Chief Executive Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code |
| 32.2** | Certification of Chief Financial Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code |
| 101.INS* | Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF* | Inline XBRL Taxonomy Extension Definitions Linkbase Document |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Filed herewith
** Furnished herewith
# Management contract or compensatory plan
+ Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.
^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

## POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Samantha (Ying) Du, Billy Cho and F. Ty Edmondson, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities indicated below and on the dates indicated:

| Signature | Title | Date |
|---|---|---|
| /s/ Samantha (Ying) Du<br>Samantha (Ying) Du | Chief Executive Officer and Chairwoman<br>*(Principal Executive Officer)* | March 1, 2022 |
| /s/ Billy Cho<br>Billy Cho | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | March 1, 2022 |
| /s/ John Diekman<br>John Diekman | Director | March 1, 2022 |
| /s/ Kai-Xian Chen<br>Kai-Xian Chen | Director | March 1, 2022 |
| /s/ Nisa Leung<br>Nisa Leung | Director | March 1, 2022 |
| /s/ William Lis<br>William Lis | Director | March 1, 2022 |
| /s/ Leon O. Moulder, Jr.<br>Leon O. Moulder, Jr. | Director | March 1, 2022 |
| /s/ Peter Wirth<br>Peter Wirth | Director | March 1, 2022 |
| /s/ Richard Gaynor<br>Richard Gaynor | Director | March 1, 2022 |
| /s/ Scott Morrison<br>Scott Morrison | Director | March 1, 2022 |

**SIGNATURES**

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

**ZAI LAB LIMITED**

Date: March 1, 2022

By: /s/ Samantha (Ying) Du
Name: Samantha (Ying) Du
Title: Chief Executive Officer

**Zai Lab Limited**

**Index to Consolidated Financial Statements**

**Report of independent registered public accounting firm**

To the Shareholders and Board of Directors of Zai Lab Limited

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows, for each of the three years in the period ended December 31, 2021, the related notes and schedule listed in the Schedule I (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

**Basis for Opinion**

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

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

**Critical Audit Matter**

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

***Research and development expenses — Cut-off — Refer to Note 2(v) to the financial statements***

*Critical Audit Matter Description*

As disclosed in the consolidated statements of operations, for the year ended December 31, 2021, the Company incurred significant research and development ("R&D") expenses of approximately USD 573 million. A large portion of the Company's R&D expenses are comprised of service fees paid to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") (collectively referred as "Outsourced Service Providers").

The R&D activities contracted with these Outsourced Service Providers are documented in detailed agreements and are generally performed over an extended period. There are also typically several milestones pertaining to the services in one agreement, therefore allocation of the service expenses to the appropriate financial reporting period based on the progress of the R&D projects involved judgement and estimation.

We identified cut-off of R&D activities as a critical audit matter due to the potential significance of misstatements to the financial statements that could arise from not accruing R&D expenses incurred for services provided by the Outsourced Service Providers in the appropriate reporting period.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to the cut-off of research and development expenses included the following, among others:

- We tested the effectiveness of key controls over the accrual of the R&D expenses payable to the Outsourced Service Providers.
- We obtained and read the key terms set out in the research agreements with Outsourced Service Providers and evaluated the completion status with reference to the progress reported by the representatives of the Outsourced Service Providers, on a sample basis, to determine whether the service fees were recorded based on respective contract sums, progress and/or milestones achieved.
- We sent audit confirmations to Outsourced Service Providers, on a sample basis, to confirm the amount of the R&D service fees incurred for the year ended December 31, 2021 and the amounts payable under the contracts as of December 31, 2021.
- We selected projects from the open contract list as of December 31, 2021 on a sample basis, made inquiries of responsible personnel regarding the project status and inspected invoices and other communications from the Outsourced Service Providers to identify potential additional Outsourced Service Providers and related unrecorded R&D expenditures.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, the People's Republic of China

March 1, 2022

We have served as the Company's auditor since 2017.

**Report of independent registered public accounting firm**

To the Shareholders and Board of Directors of Zai Lab Limited

**Opinion on Internal Control over Financial Reporting**

We have audited the internal control over financial reporting of Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated March 1, 2022, expressed an unqualified opinion on those financial statements and financial statement schedule.

**Basis for Opinion**

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

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

**Definition and Limitations of Internal Control over Financial Reporting**

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

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

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, the People's Republic of China

March 1, 2022

**Zai Lab Limited**

**Consolidated balance sheets**

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

| | Notes | As of December 31, 2020 $ | As of December 31, 2021 $ |
|---|---|---|---|
| **Assets** | | | |
| **Current assets:** | | | |
| Cash and cash equivalents | 3 | 442,116 | 964,100 |
| Short-term investments | 5 | 744,676 | 445,000 |
| Accounts receivable (net of allowance for credit loss of $1 and $11 as of December 31, 2020 and 2021, respectively) | 6 | 5,165 | 47,474 |
| Notes receivable | | — | 7,335 |
| Inventories | 7 | 13,144 | 18,951 |
| Prepayments and other current assets | | 10,935 | 18,021 |
| Total current assets | | 1,216,036 | 1,500,881 |
| Restricted cash, non-current | 4 | 743 | 803 |
| Long-term investments (including the fair value measured investment of nil and $15,383 as of December 31, 2020 and 2021, respectively) | 8 | 1,279 | 15,605 |
| Prepayments for equipment | | 274 | 989 |
| Property and equipment, net | 9 | 29,162 | 43,102 |
| Operating lease right-of-use assets | 10 | 17,701 | 14,189 |
| Land use rights, net | | 7,908 | 7,811 |
| Intangible assets, net | | 1,532 | 1,848 |
| Long-term deposits | | 862 | 870 |
| Value added tax recoverable | | 22,141 | 23,858 |
| **Total assets** | | **1,297,638** | **1,609,956** |
| **Liabilities and shareholders' equity** | | | |
| **Current liabilities:** | | | |
| Accounts payable | | 62,641 | 126,163 |
| Current operating lease liabilities | 10 | 5,206 | 5,927 |
| Other current liabilities | 13 | 30,196 | 60,811 |
| Total current liabilities | | 98,043 | 192,901 |
| Deferred income | | 16,858 | 27,486 |
| Non-current operating lease liabilities | 10 | 13,392 | 9,613 |
| **Total liabilities** | | **128,293** | **230,000** |
| **Commitments and contingencies (Note 20)** | | | |
| **Shareholders' equity** | | | |
| Ordinary shares (par value of $0.00006 per share; 500,000,000 shares authorized, 87,811,026 and 95,536,398 shares issued and outstanding as of December 31, 2020 and 2021, respectively) | | 5 | 6 |
| Additional paid-in capital | | 1,897,467 | 2,825,948 |
| Accumulated deficit | | (713,603) | (1,418,074) |
| Accumulated other comprehensive loss | | (14,524) | (23,645) |
| Treasury stock (at cost, nil and 38,293 shares as of December 31, 2020 and 2021, respectively) | | — | (4,279) |
| **Total shareholders' equity** | | **1,169,345** | **1,379,956** |
| **Total liabilities and shareholders' equity** | | **1,297,638** | **1,609,956** |

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

**Zai Lab Limited**

**Consolidated statements of operations**

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

| | Notes | Year ended December 31, 2019 $ | 2020 $ | 2021 $ |
|---|---|---|---|---|
| Revenues: | | | | |
| Product revenue, net | 11 | 12,985 | 48,958 | 144,105 |
| Collaboration revenue | | — | — | 207 |
| Total revenues | | 12,985 | 48,958 | 144,312 |
| Expenses: | | | | |
| Cost of sales | | (3,749) | (16,736) | (52,239) |
| Research and development | | (142,221) | (222,711) | (573,306) |
| Selling, general and administrative | | (70,211) | (111,312) | (218,831) |
| Loss from operations | | (203,196) | (301,801) | (700,064) |
| Interest income | | 8,232 | 5,120 | 2,190 |
| Interest expenses | | (293) | (181) | — |
| Other income (expenses), net | | 938 | 29,076 | (5,540) |
| Loss before income tax and share of loss from equity method investment | | (194,319) | (267,786) | (703,414) |
| Income tax expense | 12 | — | — | — |
| Share of loss from equity method investment | | (752) | (1,119) | (1,057) |
| Net loss | | (195,071) | (268,905) | (704,471) |
| Net loss attributable to ordinary shareholders | | (195,071) | (268,905) | (704,471) |
| Loss per share — basic and diluted | 14 | (3.03) | (3.46) | (7.58) |
| Weighted-average shares used in calculating net loss per ordinary share — basic and diluted | | 64,369,490 | 77,667,743 | 92,992,112 |

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

**Zai Lab Limited**

**Consolidated statements of comprehensive loss**

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Net loss | (195,071) | (268,905) | (704,471) |
| Other comprehensive income (loss), net of tax of nil: | | | |
| Foreign currency translation adjustments | 1,958 | (19,144) | (9,121) |
| Comprehensive loss | **(193,113)** | **(288,049)** | **(713,592)** |

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

**Zai Lab Limited**

**Consolidated statements of shareholders' equity**

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

| | Ordinary shares | | Additional paid in capital | Accumulated deficit | Accumulated other comprehensive income (loss) | Treasury Stock | | Total |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | | | | Number of Shares | Amount | |
| | | $ | $ | $ | $ | | $ | $ |
| Balance at January 1, 2019 | 58,006,967 | 3 | 498,043 | (249,627) | 2,662 | — | — | 251,081 |
| Issuance of ordinary shares upon vesting of restricted shares | 539,733 | 0 | 0 | — | — | — | — | — |
| Exercise of shares option | 670,939 | 0 | 1,055 | — | — | — | — | 1,055 |
| Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $854 | 9,019,608 | 1 | 215,345 | — | — | — | — | 215,346 |
| Share-based compensation | — | — | 20,291 | — | — | — | — | 20,291 |
| Net loss | — | — | — | (195,071) | — | — | — | (195,071) |
| Foreign currency translation | — | — | — | — | 1,958 | — | — | 1,958 |
| Balance at December 31, 2019 | 68,237,247 | 4 | 734,734 | (444,698) | 4,620 | — | — | 294,660 |
| Issuance of ordinary shares upon vesting of restricted shares | 225,768 | 0 | 0 | — | — | — | — | — |
| Exercise of shares option | 899,361 | 0 | 6,664 | — | — | — | — | 6,664 |
| Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $746 | 6,300,000 | 0 | 280,549 | — | — | — | — | 280,549 |
| Issuance of ordinary shares upon secondary listing, net of issuance cost of $5,698 | 12,148,650 | 1 | 850,690 | — | — | — | — | 850,691 |
| Share-based compensation | — | — | 24,830 | — | — | — | — | 24,830 |
| Net loss | — | — | — | (268,905) | — | — | — | (268,905) |
| Foreign currency translation | — | — | — | — | (19,144) | — | — | (19,144) |
| Balance at December 31, 2020 | 87,811,026 | 5 | 1,897,467 | (713,603) | (14,524) | — | — | 1,169,345 |
| Issuance of ordinary shares upon vesting of restricted shares | 205,450 | 0 | 0 | — | — | — | — | — |
| Exercise of shares option | 1,235,340 | 0 | 7,417 | — | — | — | — | 7,417 |
| Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $839 | 5,716,400 | 1 | 818,035 | — | — | — | — | 818,036 |
| Issuance of ordinary shares in connection with collaboration and license arrangement (Note 17) | 568,182 | 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 | — | — | — | — | — | (38,293) | (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 | 95,536,398 | 6 | 2,825,948 | (1,418,074) | (23,645) | (38,293) | (4,279) | 1,379,956 |

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

**Zai Lab Limited**

**Consolidated statements of cash flows**

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| **Operating activities** | | | |
| Net loss | (195,071) | (268,905) | (704,471) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Allowance for credit loss | — | 1 | 10 |
| Inventory write-down | — | 29 | 1,368 |
| Depreciation and amortization expenses | 3,766 | 4,640 | 6,487 |
| Amortization of deferred income | (312) | (312) | (521) |
| Share-based compensation | 20,291 | 24,830 | 40,714 |
| Noncash research and development expenses | — | — | 62,250 |
| Share of loss from equity method investment | 752 | 1,119 | 1,057 |
| Loss from fair value changes of equity investment with readily determinable fair value | — | — | 14,617 |
| Loss (gain) on disposal of property and equipment | 15 | (21) | 29 |
| Noncash lease expenses | 2,831 | 4,318 | 6,119 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (3,701) | (1,375) | (42,319) |
| Notes receivable | — | — | (7,335) |
| Inventories | (6,001) | (7,168) | (7,174) |
| Prepayments and other current assets | (1,125) | (4,199) | (7,086) |
| Long-term deposits | 180 | (485) | (8) |
| Value added tax recoverable | (5,693) | (8,404) | (1,717) |
| Accounts payable | (14,772) | 39,981 | 63,522 |
| Other current liabilities | 9,136 | (10,977) | 19,463 |
| Operating lease liabilities | (2,436) | (3,416) | (5,385) |
| Deferred income | 1,129 | 14,289 | 11,149 |
| Net cash used in operating activities | (191,011) | (216,055) | (549,231) |
| **Cash flows from investing activities:** | | | |
| Purchases of short-term investments | (277,640) | (949,161) | (445,000) |
| Proceeds from maturity of short-term investments | 277,990 | 405,000 | 743,902 |
| Purchase of investment in equity investee | — | — | (30,000) |
| Purchase of property and equipment | (6,035) | (10,130) | (18,295) |
| Disposal of property and equipment | — | — | 3 |
| Purchase of land use rights | (7,836) | — | — |
| Purchase of intangible assets | (1,371) | (539) | (653) |
| Net cash provided by (used in) investing activities | (14,892) | (554,830) | 249,957 |
| **Cash flows from financing activities:** | | | |
| Proceeds from short-term borrowings | 7,252 | — | — |
| Repayment of short-term borrowings | (4,351) | (6,527) | — |
| Proceeds from exercises of stock options | 1,055 | 6,664 | 7,417 |
| Proceeds from issuance of ordinary shares upon public offerings | 216,200 | 1,137,683 | 818,875 |
| Payment of public offering costs | (854) | (5,380) | (1,837) |
| Employee taxes paid related to settlement of equity awards | — | — | (4,253) |
| Net cash provided by financing activities | 219,302 | 1,132,440 | 820,202 |

**Zai Lab Limited**

**Consolidated statements of cash flows**

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

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash | 91 | 4,862 | 1,116 |
| Net increase in cash, cash equivalents and restricted cash | 13,490 | 366,417 | 522,044 |
| Cash, cash equivalents and restricted cash — beginning of the year | 62,952 | 76,442 | 442,859 |
| Cash, cash equivalents and restricted cash — end of the year | 76,442 | 442,859 | 964,903 |
| **Supplemental disclosure on non-cash investing and financing activities:** | | | |
| Payables for purchase of property and equipment | 416 | 788 | 2,568 |
| Payables for intangible assets | — | 70 | 191 |
| Payables for public offering costs | — | 1,063 | — |
| Payables for treasury stock | — | — | 26 |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash and cash equivalents | 75,932 | 442,116 | 964,100 |
| Restricted cash, non-current | 510 | 743 | 803 |
| Total cash and cash equivalents and restricted cash | 76,442 | 442,859 | 964,903 |
| Interest paid | 288 | 189 | — |

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

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

## 1. Organization and principal activities

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

The Company has a substantial presence in mainland China, Hong Kong, Macau and Taiwan (collectively referred to as the "Greater China") and the United States. The accompanying consolidated financial statements include the financial statements of Zai Lab Limited and its subsidiaries.

As of December 31, 2021, the Company's significant operating subsidiaries are as follows:

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

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

## 2. Summary of significant accounting policies

### *(a) Basis of presentation*

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

### *(b) Principles of consolidation*

The consolidated financial statements include the financial statements of Zai Lab Limited and its subsidiaries. All intercompany transactions and balances among Zai Lab Limited and its subsidiaries 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 and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, accrual of rebate, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets and a lack of marketability discount of the ordinary shares issued in connection with collaboration and license arrangement (Note 17). Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

### *(d) 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 United States dollar (“$”). The Company’s Chinese subsidiaries determined their functional currency to be Chinese Renminbi (“RMB”). The Company’s Australia subsidiary determined its functional currency to be Australian dollar (“A$”). The Company’s Taiwan subsidiary determined their functional currency to be Taiwan dollar (“TWD”). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification (“ASC”) 830, *Foreign Currency Matters*. The Company uses the United States 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, and expenses, gains and losses are translated using the average rate for the year. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of other comprehensive loss in the consolidated statements of changes in shareholders’ equity and comprehensive loss.

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

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

***(e) Cash, cash equivalents and restricted cash***

*Cash and cash equivalents*

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

*Restricted cash*

Restricted cash mainly consists of the bank deposits held as collateral for issuance of letters of credit.

***(f) Short-term investments***

Short-term investments are time deposits with original maturities more than three months. 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 include receivable arise from product sales and represent amounts due from its customers. In addition, the Company records accounts receivable arising from its collaborative agreement. 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 the customers to the Company. The Company considers the notes receivable to be fully collectible. Accordingly, no allowance for credit loss has been established for the year ended December 31, 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 in order 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) Long-term investments***

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

The Company uses the equity method to account for an equity investment over which it has significant influence but does not own a majority equity interest or otherwise control. The Company records equity method adjustments in share of earnings and losses. Equity method adjustments include the Company’s proportionate share of investee income or loss, adjustments to recognize certain differences between the Company’s carrying value and its equity in net assets of the investee at the date of investment, impairments, and other adjustments required by the equity method. Dividends received are recorded as a reduction of carrying amount of the investment. Cumulative distributions that do not exceed the Company’s cumulative equity in earnings of the investee are considered as a return on investment and classified as cash inflows from operating activities. Cumulative distributions in excess of the Company’s cumulative equity in the investee’s earnings are considered as a return of investment and classified as cash inflows from investing activities.

The Company is required to perform an impairment assessment of its investments whenever events or changes in business circumstances indicate that the carrying value of the investment may not be fully recoverable. An impairment loss is recorded when there has been a loss in value of the investment that is other than temporary. No impairment was recorded for the years ended December 31, 2019, 2020 and 2021.

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

***(k) Prepayments for equipment***

The prepayments for equipment purchase are recorded in long-term prepayments considering the prepayments are all related to property and equipment.

***(l) 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 |
| Vehicle | 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.

***(m) Lease***

From January 1, 2019, the Company adopted the ASC Topic 842, *Leases* (“ASC 842”). The Company adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The Company determines if an arrangement is a lease at inception. The Company classifies the lease as a finance lease if it meets certain criteria or as an operating lease when it does not. The Company has lease agreements with lease and non-lease components, which the Company has elected to account for the components as a single lease component. The Company leases facilities for office, research and development center, and manufacturing facilities in mainland China, Hong Kong, and the United States, which 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.

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 it’s reasonably certain that the renewal options will be exercised and periods for which it’s reasonably certain that the termination options will not be exercised. The future fixed lease payments are discounted using the rate implicit in the lease, if available, or the incremental borrowing rate (“IBR”). Upon adoption of ASU 2016-02, the Company elected to use the remaining lease term as of January 1, 2019 in the Company’s estimation of the applicable discount rate for leases that were in place at adoption. For the initial measurement of the lease liability for leases commencing after January 1, 2019, the Company uses the discount rate as of the commencement date of the lease, incorporating the entire lease term. Additionally, the Company elected not to recognize leases with lease terms of 12 months or less at the commencement date in the consolidated balance sheets.

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 will evaluate the carrying value of ROU assets if there are indicators of impairment and review the recoverability of the related asset group. If the carrying value of the asset group is determined to not be recoverable and is in excess of the estimated fair value, the Company will record an impairment loss in other expenses in the consolidated statements of operations. ROU assets for operating leases are included in operating lease right-of-use assets in the consolidated balance sheets.

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.

Lease expense is recognized on a straight-line basis over the lease term.

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

***(n) Land use rights***

All land in mainland China is owned by the Chinese government. The Chinese government may sell land use rights for a specified period of time. The purchase price of land use rights represents the operating lease prepayments for the rights to use the land in mainland China 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 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. The land use rights are being amortized over the respective lease terms, which are 30 years.

***(o) Long-term deposits***

Long-term deposits represent amounts paid in connection with the Company’s long-term lease agreements.

***(p) Value added tax recoverable***

Value added tax recoverable represent amounts paid by the Company for purchases. The amounts were recorded as long-term assets considering they are expected to be deducted from future value added tax payables arising on the Company’s future revenues.

***(q) Intangible assets***

Intangible assets mainly consist of externally purchased software which are amortized over one to five years on a straight-line basis. Amortization expenses for the years ended December 31, 2019, 2020 and 2021 were $305, $307 and $493, respectively. Amortization expenses of the Company’s intangible assets are expected to be approximately $570, $556, $436, $212, $74 and nil for the years ended December 31, 2022, 2023, 2024, 2025, 2026 and thereafter, respectively.

***(r) Impairment of long-lived assets***

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2019, 2020 and 2021, there was no impairment of the value of the Company’s long-lived assets.

***(s) Fair value measurements***

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

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

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

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

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.

The Company did not have any assets or liabilities that were measured at fair value on a recurring basis prior to 2021. As of December 31, 2021, information about inputs into the fair value measurement of the Company’s assets that are measured at a fair value on a recurring basis in periods subsequent to their initial recognition is as follows:

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

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, 2020 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 approximates its fair value based on the nature and the assessment of the ability to recover these amounts.

***(t) Revenue recognition***

In 2018, the Company adopted of ASC Topic 606 (“ASC 606”), *Revenue from Contracts with Customers*, in recognition of revenue. 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 receive 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 fee and sales milestone payment.

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.

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 products delivery 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, sales volumes and 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 arrangement, 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, 2020 and 2021.

***(u) 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 ASC606. For elements of collaboration arrangements that are accounted pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606.

***(v) 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 when these expenditures relate to the Company’s research and development services 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.

***(w) Deferred income***

Deferred income mainly consists of deferred income from government grants, American Depositary Receipts (the “ADR”) Program Agreement with ADR depositary bank (the “DB”) in July 2017 and the upfront payments received from Huizheng (Shanghai) Pharmaceutical Technology 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. Cash grants of $2,151, $7,289 and $4,113 were included in other income for the years ended December 31, 2019, 2020 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. Cash grants of $2,519 and $2,366 were recorded in deferred income as of December 31, 2020 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 detail assessment of the requirements and recognizes the reimbursements it expects to be entitled to over the five-year contract term as other income. For the years ended December 31, 2019, 2020 and 2021, $312, $312 and $312 were recorded in other income, respectively. $546 and $234 were recorded in deferred income as of December 31, 2020 and 2021, respectively.

In March 2020, the Company entered into an exclusive promotion agreement with Hanhui. 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 the hospital and community care facilities. In exchange for the exclusive promotion rights in mainland China, Hanhui has agreed to pay the Company a non-creditable, upfront payment in the amount of RMB230,000. The

Company received RMB90,000 in April 2020 and has the right to receive RMB70,000 in December 2021. The Company assessed and determined to record the upfront payment as deferred income and amortize by 10 years from the date when the income recognition criteria is met. In December 2021, the Company obtained the 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 monthly basis. For the years ended December 31 2019, 2020 and 2021, nil, nil and $207 were recorded in collaboration revenue. As of December 31, 2020 and 2021, a total amount of RMB90,000 ($13,793) and RMB158,667 ($24,886) was recorded in deferred income.

***(x) Comprehensive loss***

Comprehensive loss is defined as the changes in equity of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Company's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

***(y) Share-based compensation***

The Company grants share options and non-vested restricted shares to eligible employees, management and directors and accounts for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation.*

Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (i) immediately at grant date if no vesting conditions are required; or (ii) using graded vesting method over the requisite service period, which is the vesting period.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

The Company determined the fair value of the stock options granted to employees using the Black-Scholes option valuation model.

*Awards Granted to Non-Employees*

The Company grants share options to eligible Non-Employees and accounts for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation.* Non-Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (i) immediately at grant date if no vesting conditions are required; or (ii) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting

in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. The Company determined the fair value of the stock options granted to Non-Employees using the Black-Scholes option valuation model.

***(z) 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.

***(aa) 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.

***(ab) Segment information***

In accordance with ASC 280, *Segment Reportin*g, 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 hence, the Company has only one reportable segment. The Company does not distinguish between markets or segments for the purpose of internal reporting. As the majority of the Company’s long-lived assets are located in and derived from Greater China, no geographical segments are presented.

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**For the years ended December 31, 2019, 2020 and 2021**

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

***(ac) Concentration of risks***

*Concentration of customers*

The following customers accounted for 10% or more of revenue for the years ended December 31, 2019, 2020 and 2021:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| A | 5,397 | * | * |
| B | 4,682 | * | * |
| C | * | 15,774 | 40,634 |

* Represents less than 10% of revenue for the years ended December 31, 2019, 2020 and 2021.

*Concentration of suppliers*

The following suppliers accounted for 10% or more of research and development expenses and the inventory purchases for the years ended December 31, 2019, 2020 and 2021:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| F | 27,966 | * | * |
| G | 18,362 | * | * |
| H | * | 33,564 | * |
| I | * | 26,710 | * |
| J | * | * | 165,431 |
| K | * | * | 66,650 |

* Represents less than 10% of research and development expenses and the inventory purchases for the years ended December 31, 2019, 2020 and 2021.

*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, 2020 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.

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

The following debtors accounted for 10% or more of balances of accounts receivable as of December 31, 2020 and 2021:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2021 |
| | $ | $ |
| C | 2,070 | 10,293 |
| D | 726 | * |
| E | * | 10,979 |

* Represents less than 10% of accounts receivable as of December 31, 2020 and 2021.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangement. 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 the debtor's current credit worthiness. Historically, the Company collected the receivables from customers within the credit terms with no significant credit losses incurred.

During the year ended December 31, 2021, certain accounts receivable balances are settled in the form of notes receivable. As of December 31, 2021, notes receivable represents 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 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 RMB155,934 and RMB151,684, which were denominated in RMB, as of December 31, 2020 and 2021, respectively, representing 5% and 2% of the cash and cash equivalents as of December 31, 2020 and 2021, respectively.

***(ad) Recent accounting pronouncements***

**Adopted Accounting Standards**

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)*: Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, Income taxes, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied

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

prospectively. The Company adopted this standard on January 1, 2021. There was no material impact to the Company's financial position or results of operations upon adoption.

**Future Adoption of Accounting Standards**

In November 2021, the FASB issued ASU 2021-10, 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. Early application of the amendments is permitted. The Company does not expect this ASU would have a material impact on the consolidated financial statements.

## 3. Cash and cash equivalents

| | As of December 31, | |
|---|---|---|
| | 2020 | 2021 |
| | $ | $ |
| Cash at bank and in hand | 441,283 | 663,472 |
| Cash equivalents (note (i)) | 833 | 300,628 |
| | 442,116 | 964,100 |
| Denominated in: | | |
| US$ | 297,813 | 932,888 |
| RMB (note (ii)) | 23,898 | 23,791 |
| Hong Kong dollar ("HK$") | 119,695 | 6,674 |
| Australian dollar ("A$") | 710 | 475 |
| Taiwan dollar ("TW$") | — | 272 |
| | 442,116 | 964,100 |

Notes:

(i) Cash equivalents represent short-term and highly liquid investments in a money market fund.

(ii) Certain cash and bank balances denominated in RMB were deposited with banks in mainland China. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the Chinese government.

## 4. Restricted cash, non-current

The Company's restricted cash balance of $743 and $803 as of December 31, 2020 and 2021, respectively, was long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Company.

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## 5. Short-term investments

Short-term investments are primarily comprised of time deposits with original maturities between three months and one year. For the years ended December 31, 2019, 2020 and 2021, the Company recorded the interest income of $7,778, $4,860 and $799, respectively, from the short-term investments in the consolidated statements of operations.

As of December 31, 2020 and 2021, the Company's short-term investments consisted entirely of short-term held to maturity debt instruments with high credit ratings, which were determined to have remote risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of December 31, 2020 and 2021.

## 6. Accounts receivable

Accounts receivable include receivable due from the Company's customers and receivable arising from the Company's collaborative arrangement. Accounts receivable due from the Company's customers as of December 31, 2020 and 2021 were $5,165 and $36,495, respectively. Accounts receivable arising from the the Company's collaborative arrangement as of December 31, 2020 and 2021 were nil and $10,979, respectively.

The roll-forward of the allowance for credit losses related to accounts receivable for the year ended December 31, 2021 consists of the following activity:

| | Allowance for Credit Losses<br>$ |
|---|---|
| Balance as of December 31, 2020 | 1 |
| Current period provision for expected credit losses | 10 |
| Amounts written-off | — |
| Recoveries of amounts previously written-off | — |
| Balance as of December 31, 2021 | 11 |

The Company did not have any allowance for the year ended December 31, 2019.

## 7. Inventories

The Company's inventory balance of $13,144 and $18,951 as of December 31, 2020 and 2021, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline (GSK), for distribution in Hong Kong, from NovoCure Limited ("NovoCure") for distribution in Hong Kong and mainland China , and from Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong, mainland China and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China.

| | As of December 31, | |
|---|---|---|
| | 2020<br>$ | 2021<br>$ |
| Finished goods | 3,041 | 5,632 |
| Raw materials | 10,103 | 13,231 |
| Work in progress | — | 88 |
| Inventories | 13,144 | 18,951 |

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

The Company writes-down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. During the years ended December 31, 2019, 2020 and 2021, the Company recorded write-downs of nil, $29 and $1,368, respectively, in cost of revenues.

## 8. Long-term investments

In June 2017, the Company entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Company was RMB26,250 in cash, which was paid by the Company in 2017 and 2018, representing 20% and 18% of the equity interest of JING as of December 31, 2020 and 2021, respectively. The Company accounts for this investment using the equity method of accounting due to the fact that the Company can exercise significant influence on the investee. The Company recorded its gain on deemed disposal in this investee of nil, nil and $463 for the years ended December 31, 2019, 2020 and 2021, respectively. The Company recorded share of loss in this investee of $752, $1,119 and $1,520 for its portion of JING's net loss for the year ended December 31, 2019, 2020 and 2021, respectively.

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 (see Note17). The Company recorded this investment at acquisition cost and subsequently measured at fair value, with the changes in fair value recognized in other income (expenses), net in the consolidated statements of operations. The Company recognized its fair value loss of nil, nil and $14,617 for the years ended December 31, 2019, 2020 and 2021, respectively.

## 9. Property and equipment, net

Property and equipment consist of the following:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2021 |
| | $ | $ |
| Office equipment | 430 | 836 |
| Electronic equipment | 2,646 | 5,036 |
| Vehicle | 143 | 220 |
| Laboratory equipment | 11,933 | 17,069 |
| Manufacturing equipment | 12,198 | 14,600 |
| Leasehold improvements | 9,641 | 10,432 |
| Construction in progress | 2,423 | 11,334 |
| | 39,414 | 59,527 |
| Less: accumulated depreciation | (10,252) | (16,425) |
| Property and equipment, net | 29,162 | 43,102 |

Depreciation expenses for the years ended December 31, 2019, 2020 and 2021 were $3,372, $4,324 and $5,994, respectively.

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**For the years ended December 31, 2019, 2020 and 2021**

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## 10. Lease

The Company leases facilities for office, research and development and manufacturing facilities in mainland China, Hong Kong, Taiwan, and the United States. Lease terms vary based on the nature of operations and the market dynamics, however, all leased facilities are classified as operating leases with remaining lease terms between one and seven years.

Total lease expense related to short-term leases was insignificant for the years ended December 31, 2019, 2020 and 2021.

Supplemental information related to leases was as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Operating fixed lease cost | 3,245 | 4,539 | 6,263 |

Supplemental cash flow information related to leases was as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Cash paid for amounts included in measurement of lease liabilities | 2,778 | 4,056 | 5,840 |
| Non-cash operating lease liabilities arising from obtaining operating right-of-use assets | 10,876 | 6,393 | 2,183 |

The maturities of lease liabilities in accordance with *Leases (Topic 842)* in each of the next five years and thereafter as of December 31, 2021 were as follows:

| | Year ended December 31 |
|---|---|
| | $ |
| 2022 | 6,153 |
| 2023 | 2,571 |
| 2024 | 2,240 |
| 2025 | 2,186 |
| 2026 | 1,638 |
| Thereafter | 1,213 |
| Total lease payments | 16,001 |
| Less: imputed interest | (461) |
| Present value of minimum operating lease payments | 15,540 |

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**For the years ended December 31, 2019, 2020 and 2021**

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

Weighted-average remaining lease terms and discount rates are as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2020 | 2021 |
| Weighted-average remaining lease term | 5.0 years | 4.2 years |
| Weighted-average discount rate | 2.3% | 2.3% |

## 11. Product revenue, net

The Company’s product revenue is primarily derived from the sale of ZEJULA, Optune, QINLOCK and NUZYRA in mainland China and Hong Kong. The table below presents the Company’s net product sales for the years ended December 31, 2019, 2020 and 2021.

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Product revenue — gross | 12,985 | 57,355 | 190,180 |
| Less: Rebate and sales return | — | (8,397) | (46,075) |
| Product revenue — net | 12,985 | 48,958 | 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 sales rebates included $3,051 and $29,547 compensation to distributors for those products previously sold at the price prior to the National Reimbursement Drug List (“NRDL”) implementation, due to the inclusion of ZEJULA in the NRDL, for the years ended December 31, 2020 and 2021, respectively. There was no such compensation for the year ended December 31, 2019.

The following table disaggregates net revenue by product for the years ended December 31, 2019, 2020 and 2021:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| ZEJULA | 6,625 | 32,138 | 93,579 |
| Optune | 6,360 | 16,418 | 38,903 |
| QINLOCK | — | 402 | 11,620 |
| NUZYRA | — | — | 3 |
| Total product revenue — net | 12,985 | 48,958 | 144,105 |

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

## 12. Income Tax

*Cayman Islands (“Cayman”)*

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 (“BVI”)*

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 (“AUST”)*

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. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

*United States (“U.S.”)*

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 has no taxable income for all periods presented, therefore, no provision for income taxes is required.

*Taiwan (“TW”)*

Zai Lab (Taiwan) Limited is incorporated in Taiwan and is subject to corporate income tax at a rate of 20%. Zai Lab (Taiwan) Limited has no taxable income for all periods presented, therefore, no provision for income taxes is required.

*Hong Kong (“HK”)*

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, 2019, 2020 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.

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**For the years ended December 31, 2019, 2020 and 2021**

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

*People's Republic of China*

Under EIT Law, the statutory income tax rate is 25%, and the EIT rate will be reduced to 15% for state-encouraged High and New Technology Enterprises ("HNTE"). Zai Lab (Shanghai) Co., Ltd., first obtained a HNTE certificate in 2018 and began to enjoy the preferential tax rate of 15% from 2018 to 2021 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 Zai Lab Limited and all of its subsidiaries are in cumulative loss positions for all the periods presented.

Loss (income) before income taxes consists of:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Cayman | (3,241) | 2,612 | 28,401 |
| BVI | 2 | 3 | 2 |
| Mainland China | 185,239 | 220,813 | 340,865 |
| HK | 3,271 | 20,022 | 243,400 |
| US | 9,786 | 24,616 | 89,374 |
| AUST | 14 | 839 | 1,758 |
| TW | — | — | 671 |
| | 195,071 | 268,905 | 704,471 |

Reconciliations of the differences between the Chinese statutory income tax rate and the Company's effective income tax rate for the years ended December 31, 2019, 2020 and 2021 are as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| Statutory income tax rate | 25% | 25% | 25% |
| Share-based compensations | (1.51%) | (1.36%) | (0.92%) |
| Non-deductible expenses | (0.39%) | (1.17%) | (5.78%) |
| Prior year tax filing adjustment | 1.93% | 1.78% | 1.50% |
| Effect of different tax rate of subsidiary operation in other jurisdictions | 0.07% | (1.04%) | (4.60%) |
| Preferential tax rate | (9.14%) | (7.48%) | (4.30%) |
| Effect of change in tax rate | (9.15%) | — | — |
| Changes in valuation allowance | (6.81%) | (15.73%) | (10.90%) |
| Effective income tax rate | — | — | — |

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

The principal components of the deferred tax assets and liabilities are as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Deferred tax assets: | | | |
| Depreciation of property and equipment, net | 57 | 84 | 108 |
| Government grants | 325 | 400 | 496 |
| Deferred revenue | — | 2,069 | 3,733 |
| Public welfare donations | — | 7,627 | 10,246 |
| Net operating loss carry forwards | 62,833 | 94,954 | 175,101 |
| Less: valuation allowance | (63,215) | (105,134) | (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 2020 and 2021, the Company has determined that the deferred tax assets on temporary differences and net operating loss carry forwards are 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, 2020 and 2021. Amounts of operating loss carry forwards were $403,460, $605,226 and $1,089,745 for the years ended December 31, 2019, 2020 and 2021, respectively, which are expected to expire from 2022 to 2031.

Movement of the valuation allowance is as follows:

| | 2020 | 2021 |
|---|---|---|
| | $ | $ |
| Balance as of January 1, | (63,215) | (105,134) |
| Additions | (41,919) | (84,550) |
| Balance as of December 31, | (105,134) | (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

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

authorities subsequently determine that the Company and its subsidiaries registered outside mainland China should be deemed resident enterprises, the Company and its subsidiaries registered outside mainland China will be subject to the Chinese income taxes, at a rate of 25%. The Company is not subject to any other uncertain tax position.

## 13. Other current liabilities

Other current liabilities consist of followings:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2021 |
| | $ | $ |
| Payroll | 13,694 | 25,685 |
| Accrued professional service fee | 3,128 | 4,319 |
| Payables for purchase of property and equipment | 788 | 2,568 |
| Accrued rebate to distributors | 7,067 | 15,001 |
| Tax payables | 952 | 8,817 |
| Others (note (i)) | 4,567 | 4,421 |
| Total | 30,196 | 60,811 |

Note:

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

## 14. Loss per share

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

| | For the years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| Numerator: | | | |
| Net loss attributable to ordinary shareholders | (195,071) | (268,905) | (704,471) |
| Denominator: | | | |
| Weighted average number of ordinary shares- basic and diluted | 64,369,490 | 77,667,743 | 92,992,112 |
| Net loss per share-basic and diluted | (3.03) | (3.46) | (7.58) |

As a result of the Company's net loss for the three years ended December 31, 2019, 2020 and 2021, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

| | As of December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| Share options | 9,122,980 | 8,755,920 | 8,101,559 |
| Non-vested restricted shares | 743,268 | 541,750 | 956,736 |

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## 15. Related party transactions

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

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

For the years ended December 31, 2019, 2020 and 2021, the Company incurred $234, $678 and $680 research and development expenses with MEDx (Suzhou) Translational Medicine Co., Ltd. for product research and development services, respectively. All of the transactions are carried out with normal business terms and are on arms' length basis.

## 16. Share-based compensation

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Company to purchase an aggregate of no more than 4,140,945 ordinary shares of the Company ("Option Pool"). Subsequently, the Board of Directors approved the increase in the Option Pool to 7,369,767 ordinary shares.

In connection with the completion of the initial public offering (the "IPO"), the Board of Directors has approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan.

*Share options*

In 2019, the Company granted 1,067,385 share options to certain management, employees and individual advisors of the Company at the exercise price ranging from $27.23 to $41.59 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five or three-year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

In 2020, the Company granted 1,220,177 share options to certain management, employees and individual advisors of the Company at the exercise price ranging from $44.94 to $128.72 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five or three-year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

In 2021, the Company granted 733,893 share options to certain management, employees and individual advisors of the Company at the exercise price ranging from $66.92 to $180.00 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five, four or three-year period, with 20%, 25% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

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

The following table presents the assumptions used to estimate the fair values of the share options granted in the years presented:

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Risk-free rate of return | 1.6%-2.5% | 0.4%-0.8% | 0.9%-1.4% |
| Contractual life of option | 10 years | 10 years | 10 years |
| Expected term | 6 or 6.5 years | 6 or 6.5 years | 6, 6.25 or 6.5 years |
| Estimated volatility rate | 70% | 70% | 65% |
| Expected dividend yield | 0% | 0% | 0% |
| Fair value of underlying ordinary shares | $27.23-$41.59 | $44.94-$128.72 | $66.92-$180.00 |

A summary of option activity under the 2015 Plan and 2017 Plan during the years ended December 31, 2019, 2020 and 2021 is presented below:

| | Number of options | Weighted average exercise price | Weighted average remaining contractual term | Aggregate intrinsic value |
|---|---|---|---|---|
| | | $ | Years | $ |
| Outstanding at December 31, 2020 | 8,755,920 | 17.26 | 6.53 | 1,033,899 |
| Granted | 733,893 | 126.02 | — | — |
| Exercised | (1,235,340) | 6.00 | — | — |
| Forfeited | (152,914) | 64.22 | — | — |
| Outstanding at December 31, 2021 | 8,101,559 | 27.94 | 5.98 | 339,570 |
| Vested and exercisable as of December 31, 2021 | 5,174,961 | 9.25 | 4.89 | 279,783 |
| Vested or expected to vest as of December 31, 2021 | 8,101,559 | 27.94 | 5.98 | 339,570 |

The weighted-average grant-date fair value of the options granted in 2019, 2020 and 2021 were $20.98, $40.60 and $126.02 per share, respectively. The Company recorded compensation expense related to the options of $14,925, $18,695 and $27,194 for the years ended December 31, 2019, 2020 and 2021, respectively, which were classified in the accompanying consolidated statements of operations as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Selling, general and administrative | 6,931 | 11,492 | 15,568 |
| Research and development | 7,994 | 7,203 | 11,626 |
| Total | 14,925 | 18,695 | 27,194 |

As of December 31, 2021, there was $94,823 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 2.81 years based on the number of unvested shares and unrecognized years.

*Non-vested restricted shares*

In 2019, 50,000 ordinary shares were authorized for grant to the independent directors, respectively. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of an independent director’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In 2019, 121,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In 2020, 50,000 ordinary shares were authorized for grant to the independent directors. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors’ service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In 2020, 109,250 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In 2021, 19,260 ordinary shares were authorized for grant to the independent directors. These restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. In addition, 16,257 ordinary shares were authorized for grant to the independent directors. One third of these restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the independent directors’ service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In 2021, 359,242 ordinary shares were authorized for grant to certain management. 20% or 25% of these restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. In addition, 231,640 ordinary shares were authorized for grant to certain management. 50% of these restricted shares will vest and be released from the restrictions on Jan 1, 2024 and 50% will vested and be released from the restrictions on January 1, 2026. Also, 30,000 ordinary shares were authorized for grant to certain management. 50% of these restricted shares will vest and be released from the restrictions immediately and 50% will vest and be released from the restrictions on the first anniversary from the date of the agreement. Upon termination of the certain management’s service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

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

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

The following table summarized the Company's non-vested restricted share activity in 2021:

| | Numbers of non-vested restricted shares | Weighted average grant date fair value |
|---|---|---|
| | | $ |
| Non-vested as of December 31, 2020 | 541,750 | 37.36 |
| Granted | 656,399 | 105.54 |
| Vested | (205,450) | 37.17 |
| Forfeited | (35,963) | 74.82 |
| Non-vested as of December 31, 2021 | 956,736 | 82.62 |

As of December 31, 2021, there was $69,264 of total unrecognized compensation expense related to non-vested restricted shares. The Company recorded compensation expense related to the restricted shares of $5,366, $6,135 and $13,520 for the years ended December 31, 2019, 2020 and 2021, respectively, which were classified in the accompanying consolidated statements of operations as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| Selling, general and administrative | 3,643 | 4,226 | 7,626 |
| Research and development | 1,723 | 1,909 | 5,894 |
| Total | 5,366 | 6,135 | 13,520 |

## 17. Licenses and collaborative arrangement

The following is a description of the Company's significant ongoing collaboration agreements for the year ended December 31, 2021.

*License and collaboration agreement with GSK*

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

Under the terms of the agreement, the Company made an upfront payment of $15,000 and one milestone payment of $1,000, and accrued one development milestone payment of $3,500 and one sales-based milestone of $8,000 to GSK. On top of those, if the Company achieves other specified regulatory, development and commercialization milestones, the Company may be additionally required to pay further milestone payments up to $28,000 to GSK. In addition, the Company will pay GSK tiered royalties on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

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

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

Under the terms of the agreement, the Company made an upfront payment of $7,500 to Paratek and two milestone payments totaling $8,000, and accrued one milestone payment of $6,000 to Paratek, and the Company may be required to pay further milestone payments of up to an aggregate of $40,500 to Paratek for the achievement of certain development and sales milestone events. In addition, the Company will pay to Paratek tiered royalties on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

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

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

Under the terms of the agreement, the Company made an upfront payment of $5,000 and a milestone payment of $2,000 to Five Prime. Additionally, the Company may be required to pay further development and regulatory milestone payments of up to an aggregate of $37,000 to Five Prime. The Company is also be obligated to pay Five Prime a royalty, on a licensed product-by-licensed product and region-by-region basis, depending on the number of patients the Company enrolls in the bemarituzumab study, subject to reduction in certain circumstances, on net sales of each licensed product in the licensed territory until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan product or data exclusivity with respect to such licensed product expires in such region.

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

*License and collaboration agreement with Entasis Therapeutics Holdings Inc.(“Entasis”)*

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.

Under the terms of the agreement, the Company made an upfront payment of $5,000 and two development milestone payments totaling $7,000 to Entasis. Additionally, the Company may be required to pay Entasis development, regulatory and research milestone payments (other than existing ones) and commercial milestone payments of up to an aggregate of $91,600. 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 is also obligated to pay Entasis a royalty based on a percentage of net sales of licensed products, depending on the amount of net sales of licensed products in the territory, subject to reduction in certain circumstances, until, with respect to a licensed product in a region in the territory, the latest of (i) the 10th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan product or data exclusivity with respect to such licensed product expires in such region.

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”)*

In May 2018, the Company and Crescendo entered into an exclusive, worldwide licensing agreement, under which the Company will develop, commercialize, and manufacture a topical, innovative antibody VH domain therapeutic for potential application in inflammatory indications.

Under the terms of the agreement, Crescendo granted to the Company a worldwide exclusive license to develop and commercialize its product candidate for all indications. 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.

Under the terms of these two agreements, the Company paid two upfront fee payments totalling $4,500 and three milestone payments totalling $6,000, to Crescendo, and the Company will provide development, regulatory, and commercial milestones for multiple indications up to an aggregate of $298,075. Crescendo will also be eligible to receive tiered royalties on global sales.

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

*License and collaboration agreement with NovoCure*

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.

Under the terms of the agreement, the Company paid an upfront license fee in the amount of $15,000 and two milestone payments totaling $10,000 to Novocure. The Company also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $68,000, and tiered royalties at percentage rates on the net sales of the Licensed Products in the 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 agreement with MacroGenics*

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.

Under the terms of the agreement, the Company paid an upfront license fee of $25,000 and two milestone payments in total of $4,000, and accrued one milestone payment of $5,000 to MacroGenics. The Company also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of $131,000, and tiered royalties at percentage rates for net sales of Margetuximab, tebotelimab and TRIDENT molecule in the territory.

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

In June 2021, the Company entered into a 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.

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

Pursuant to the collaboration and license agreement, the Company also made an equity investment of $30,000 in MacroGenics’ common stock at $31.30 per share in July 2021 (see Note 8).

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*

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.

Under the terms of the agreement, the Company paid Deciphera an upfront license fee of $20,000 and three milestone payments totaling $12,000. The Company also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $173,000, and tiered royalties on the net sales of the licensed products in the 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”)*

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.

Under the terms of agreement, the Company paid Incyte an upfront license fee of $17,500. The Company also agreed to pay certain development, regulatory and commercial milestone payments of up to an aggregate of $60,000, and tiered royalties at percentage rates on the net sales of retifanlimab in Greater China.

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

*Collaboration agreement with Regeneron Pharmaceuticals, Inc (“Regeneron”)*

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 for Greater China the exclusive oncology development and commercialization rights for products containing odronextamab as the sole active ingredient. We also obtained a right of first negotiation for additional indications outside the field of cancer.

Under the terms of the agreement, the Company paid an upfront payment of $30,000 to Regeneron. Regeneron is also eligible to receive up to $160,000 in additional regulatory and sales milestones. Additionally, the Company will make payments to Regeneron based on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will be responsible for the manufacture and supply of odronextamab for the Company’s development and commercialization in the region.

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

*License agreement with Turning Point Therapeutics Inc (“Turning Point”)*

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

Under the terms of the agreements, the Company paid an upfront payment of $25,000 and three milestone payments totalling $5,000 to Turning Point. Turning Point is also eligible to receive up to $146,000 in development, regulatory and sales milestones. Turning Point will also be eligible to receive mid-to-high teen royalties based on annual net sales of repotrectinib in Greater China.

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

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

The Company paid an upfront license fee in the amount of $25,000 and accrued one milestone payment of $2,000 to Turning Point. The Company also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $334,000. Turning Point will also be eligible to receive certain tiered royalties (from mid-teens to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of TPX-0022 in Greater China. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology product candidate discovered by the Company.

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

*License agreement with Cullinan Pearl Corp. (“Cullinan”)*

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

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

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

*License agreement with Takeda Pharmaceutical Company Limited (“Takeda”)*

In December 2020, the 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 exploit products in the licensed field during the term.

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

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

*Collaboration and license agreement with argenx BV (“argenx”)*

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

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Company and argenx. As the upfront payment to argenx, the Company issued 568,182 ordinary shares of the Company to argenx with par value $0.00006 per share on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $62,250 in the aggregate. The Company recorded this upfront payment in research and development expenses.

In addition, the Company made a non-creditable, non-refundable development cost-sharing payment of $75,000 and a cash payment of $25,000 to argenx. Argenx is also eligible to receive tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed product in the territory.

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

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

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

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

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

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

Under the terms of the agreement, the Company paid an upfront payment of $5,000 to Schrödinger. Schrödinger is also eligible to receive up to $337,500 in research, development, and sales-based milestone payments. Schrödinger is also eligible to receive tiered royalties based on annual net sales of commercialized products in Greater China.

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

*Collaboration and license agreement with Blueprint Medicines Corporation (“Blueprint”)*

In November 2021, the Company entered into a collaboration and license agreement with Blueprint, for the development and commercialization of BLU-945 and BLU-701 for the treatment of patients with epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China.

Under the terms of the agreement, the Company paid an upfront payment of $25,000 to Blueprint. Blueprint is also eligible to receive up to $590,000 in development, and sales-based milestone payments. Blueprint is also eligible to receive tiered royalties based on annual net sales of commercialized products in Greater China.

The Company has the right to terminate this agreement after the second anniversary of the effective date by providing written notice of termination to Blueprint.

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

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

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

Under the terms of the agreement, the Company paid an upfront payment of $35,000 to Karuna. Karuna is also eligible to receive up to $152,000 in development and regulatory, and sales-based milestone payments. Karuna is also eligible to receive tiered royalties based on annual net sales of commercialized products in Greater China.

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

As noted above, the Company has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Company is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management’s evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Company up to an aggregate of approximately $5,589,506 in future contingent milestone payments dependent upon the achievement of contractually specified development milestones, such as regulatory approval for the product candidates, which may be before the Company has commercialized the product or received any revenue from sales of such product candidate. These milestone payments are subject to uncertainties and contingencies and may not occur.

## 18. Restricted net assets

The Company’s ability to pay dividends may depend on the Company receiving distributions of funds from its Chinese subsidiaries. Relevant Chinese statutory laws and regulations permit payments of dividends by the Company’s Chinese subsidiary 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 China Company Law, 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 is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise’s 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 invested enterprise and therefore is subject to the above-mentioned restrictions on distributable profits.

During the years ended December 31, 2019, 2020 and 2021, no appropriation to statutory reserves was made because the Chinese subsidiaries had substantial losses during such periods.

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

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

Foreign exchange and other regulation in mainland China may further restrict the Company's Chinese subsidiaries from transferring funds to the Company in the form of dividends, loans and advances. As of December 31, 2020, and 2021, amounts restricted are the paid-in capital of the Company's Chinese subsidiaries, which amounted to $255,858 and $406,010 respectively.

## 19. Employee defined contribution plan

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 Chinese subsidiary make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Company has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were $5,406, $4,373 and $17,606 for the years ended December 31, 2019, 2020 and 2021, respectively.

## 20. Commitments and Contingencies

### *(a) Purchase commitments*

As of December 31, 2021, the Company's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement were $20,413 which are expected to be incurred in the years ended December 31, 2022.

### *(b) Contingencies*

The Company is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 17).

## 21. Selected quarterly financial data (unaudited)

The following table summarizes the unaudited statements of operations for each quarter of 2021 and 2020. The unaudited quarterly information has been prepared on a basis consistent with the audited financial statements and includes all adjustments that the Company considers necessary for a fair presentation of the information shown. The operating results for any fiscal quarter are not necessarily indicative of the operating results for a full fiscal year or for any future period and there can be no assurances that any trend reflected in such results will continue in the future.

| | Quarter Ended, | | | |
|---|---|---|---|---|
| 2021 | March 31, | June 30, | September 30, | December 31, |
| | $ | $ | $ | $ |
| Product revenue, net | 20,103 | 36,935 | 43,103 | 43,964 |
| Collaboration revenue | — | — | — | 207 |
| Loss from operations | (227,092) | (170,571) | (83,205) | (219,196) |
| Net loss | (232,910) | (163,324) | (96,412) | (211,825) |
| Net loss attributable to ordinary shareholders | (232,910) | (163,324) | (96,412) | (211,825) |
| Basic and diluted net loss per share | (2.64) | (1.76) | (1.01) | (2.22) |

**Zai Lab Limited**

**Notes to the consolidated financial statements**

**For the years ended December 31, 2019, 2020 and 2021**

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

| | Quarter Ended, | | | |
|---|---|---|---|---|
| 2020 | March 31, | June 30, | September 30, | December 31, |
| | $ | $ | $ | $ |
| Product revenue, net | 8,218 | 10,995 | 14,651 | 15,094 |
| Loss from operations | (46,322) | (83,966) | (76,257) | (95,256) |
| Net loss | (47,988) | (80,629) | (63,741) | (76,547) |
| Net loss attributable to ordinary shareholders | (47,988) | (80,629) | (63,741) | (76,547) |
| Basic and diluted net loss per share | (0.66) | (1.08) | (0.84) | (0.88) |

## 22. Subsequent events

In January and February 2022, the Company granted totalling 45,092 share options to certain management and employees of the Company at the exercise price from $62.85 to $53.59 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a 5-year period, with 20 % of the awards vesting beginning on the anniversary date one year after the grant date.

In January and February 2022, totalling 20,224 ordinary shares were authorized for grant to certain management and employees of the Company. One-fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management and employees' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

In January and February 2022, totalling 38,815 ordinary shares were authorized for grant to independent directors of the Company. 100% of the restricted shares will vest and be released from the restrictions on the first anniversary of the date of the agreement. Upon termination of the independent directors' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

**Additional financial information of parent company -**

**Financial statements schedule I**

**Zai Lab Limited**

**Financial information of parent company**

**Condensed balance sheets**

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

| | As of December 31, | |
|---|---|---|
| | 2020 | 2021 |
| | $ | $ |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | 397,608 | 591,842 |
| Short-term investments | 744,676 | 445,000 |
| Prepayments and other current assets | 1,926 | 2,364 |
| Total current assets | 1,144,210 | 1,039,206 |
| Investment in subsidiaries | 28,090 | 341,980 |
| **Total assets** | **1,172,300** | **1,381,186** |
| **Liabilities and shareholders' equity** | | |
| **Liabilities** | | |
| Current liabilities: | | |
| Other current liabilities | 2,410 | 996 |
| Total current liabilities | 2,410 | 996 |
| Deferred income | 546 | 234 |
| **Total liabilities** | **2,956** | **1,230** |
| **Shareholders' equity** | | |
| Ordinary shares (par value of US$0.00006 per share; 500,000,000 shares authorized, 87,811,026 and 95,536,398 shares issued and outstanding as of December 31, 2020 and 2021, respectively) | 5 | 6 |
| Additional paid-in capital | 1,897,467 | 2,825,948 |
| Accumulated deficit | (713,603) | (1,418,074) |
| Additional other comprehensive income | (14,525) | (23,645) |
| Treasury stock | — | (4,279) |
| **Total shareholders' equity** | **1,169,344** | **1,379,956** |
| **Total liabilities and shareholders' equity** | **1,172,300** | **1,381,186** |

**Additional financial information of parent company -**

**Financial statements schedule I**

**Zai Lab Limited**

**Financial information of parent company**

**Condensed statements of operations and comprehensive loss**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| **Operating Expenses:** | | | |
| Research and development | (101) | (437) | (6) |
| General and administrative | (4,864) | (7,345) | (12,074) |
| **Loss from operations** | **(4,965)** | **(7,782)** | **(12,080)** |
| Interest income | 7,987 | 4,899 | 1,881 |
| Other income (expenses), net | 311 | 312 | (18,173) |
| **Profit (Loss) before income tax and equity in loss of subsidiaries** | **3,333** | **(2,571)** | **(28,372)** |
| Equity in loss of subsidiaries | (198,404) | (266,334) | (676,099) |
| Income tax expense | — | — | — |
| **Net loss attributable to Zai Lab Limited** | **(195,071)** | **(268,905)** | **(704,471)** |
| **Net loss** | (195,071) | (268,905) | (704,471) |
| Other comprehensive income (loss) , net of tax of nil: | | | |
| Foreign currency translation adjustment | 1,958 | (19,144) | (9,121) |
| **Comprehensive loss** | **(193,113)** | **(288,049)** | **(713,592)** |

**Additional financial information of parent company -**

**Financial statements schedule I**

**Zai Lab Limited**

**Financial information of parent company**

**Condensed statements of cash flows**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | $ | $ | $ |
| **Cash flows from Operating activities:** | | | |
| Net loss | (195,071) | (268,905) | (704,471) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | | |
| Amortization of deferred income | (312) | (312) | (312) |
| Share based compensation | 2,013 | 3,025 | 3,435 |
| Equity in loss of subsidiaries | 198,404 | 266,334 | 676,099 |
| Loss from fair value changes of equity investment of readily determinable fair value | — | — | 14,617 |
| Changes in operating assets and liabilities: | | | |
| Prepayments and other current assets | (1,267) | 2,253 | (439) |
| Other current liabilities | 102 | 738 | (376) |
| Net cash provided by (used in) operating activities | 3,869 | 3,133 | (11,447) |
| **Cash flows from investing activities:** | | | |
| Purchases of short-term investments | (277,640) | (949,161) | (445,000) |
| Proceeds from maturity of short-term investments | 277,990 | 405,000 | 743,902 |
| Purchase of investment in equity investee | — | — | (30,000) |
| Investment in subsidiaries | (165,924) | (256,097) | (884,342) |
| Net cash used in investing activities | (165,574) | (800,258) | (615,440) |
| **Cash flows from financing activities:** | | | |
| Proceeds from exercises of stock options | 1,055 | 6,664 | 7,418 |
| Proceeds from issuance of ordinary shares upon public offerings | 216,200 | 1,137,683 | 818,875 |
| Payment of public offering costs | (854) | (4,541) | (1,692) |
| Employee taxes paid related to settlement of equity awards | — | — | (4,253) |
| Net cash provided by financing activities | 216,401 | 1,139,806 | 820,348 |
| Effect of foreign exchange rate changes on cash and cash equivalent | — | (515) | 774 |
| Net increase in cash and cash equivalents | 54,696 | 342,166 | 194,234 |
| Cash and cash equivalents-beginning of the year | 746 | 55,442 | 397,608 |
| Cash and cash equivalents-end of the year | 55,442 | 397,608 | 591,842 |

**Additional financial information of parent company -**

**Financial statements schedule I**

**Zai Lab Limited**

**Financial information of parent company**

**Notes**

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

1. Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.

2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. For the parent company, Zai Lab Limited records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, Investments-Equity Method and Joint Ventures. Such investments are presented on the Condensed Balance Sheets as “Investment in subsidiaries”. Ordinarily under the equity, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.

3. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The footnote disclosures provide certain supplemental information relating to the operations of the Company and, as such, these statements should be read in conjunction with the notes to the accompanying consolidated financial statements.

4. As of December 31, 2020 and 2021, there were no material contingencies, significant provisions of long-term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of Zai Lab Limited.

**Exhibit 10.6**

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

As of November 19, 2021, each individual who provides services to Zai Lab Limited (the "Company") as a director, other than a director who is employed by the Company or an affiliate, (a "Non-Employee Director") shall be entitled to receive the following amounts of compensation:

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

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

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

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

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL**

***Confidential***
***Execution Version***

# LICENSE AND COLLABORATION AGREEMENT

by and between

Blueprint Medicines Corporation

and

Zai Lab (Shanghai) Co., Ltd

Dated as of November 8, 2021

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**Schedules**

# LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this "**Agreement**") is made as of November 8, 2021 (the "**Effective Date**") by and between Blueprint Medicines Corporation, a Delaware corporation ("**Blueprint**"), having a place of business at 45 Sidney Street, Cambridge MA 02139, USA, and Zai Lab (Shanghai) Co., Ltd, an exempted company organized and existing under the laws of P.R. of China ("**Zai**"), having a place of business at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210. Blueprint and Zai are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

## RECITALS

**WHEREAS**, Blueprint is a biopharmaceutical company that is developing (a) a mutant EGFR inhibitor known as BLU-701, and (b) a mutant EGFR inhibitor known as BLU-945, in each case, that are being studied by Blueprint for the treatment of NSCLC and other cancers with certain mutations;

**WHEREAS**, Blueprint Controls certain Know-How and Patent Rights relating to BLU-945 and BLU-701;

**WHEREAS**, Zai is a biopharmaceutical company engaged in the research, development, and commercialization of pharmaceutical and biologic products in the Territory;

**WHEREAS**, Zai wishes to obtain from Blueprint an exclusive license to develop, perform medical affairs for, manufacture (subject to the terms in the Agreement) and commercialize, the Blueprint Compounds and Licensed Products, in each case, in the Territory, and Blueprint is willing to grant such a license to Zai, all in accordance with the terms and conditions set forth herein; and

**WHEREAS**, Blueprint and Zai both recognize the importance of accelerating Global Clinical Trials to address patient needs and Zai is willing to commit to participation in certain Clinical Trials as agreed to by both Parties for each Licensed Product.

## AGREEMENT

**NOW**, **THEREFORE**, the Parties hereby agree as follows:

## Article 1
## DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

**1.1** "**Accounting Standards**" means GAAP for both Parties, unless a Party elects to change its general accounting principles to IFRS (or any change thereafter between IFRS and GAAP) and provides notice to the other Party of such change in accordance with Section 10.7 (Accounting Standards).

**1.2** "**Acquiree**" has the meaning set forth in Section 2.8.3(b).

**1.3** "**Acquiror**" has the meaning set forth in Section 2.8.3(a).

**1.4** "**Active Ingredient**" means those clinically active materials that provide pharmacological activity in a pharmaceutical or biologic product (excluding [****]).

**1.5** "**Affiliate**" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract, or otherwise.

**1.6** "**Agreement**" has the meaning set forth in the Preamble.

**1.7** "**Alliance Manager**" has the meaning set forth in Section 3.1 (Alliance Managers).

**1.8** "**Anti-Corruption Laws**" has the meaning set forth in Section 12.1.5 (Representations and Warranties of Each Party).

**1.9** "**Applicable Law**" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws.

**1.10** "**Approved Labeling**" means, with respect to a Licensed Product: (a) the Regulatory Authority-approved full prescribing information for such Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product.

**1.11** "**Arbitration Notice**" has the meaning set forth in Section 16.3.1 (Rules).

**1.12** "**Arbitrators**" has the meaning set forth in Section 16.3.2 (Selection of Arbitrator).

**1.13** "**Assigned Collaboration Know-How**" means any Collaboration Know-How that [****].

**1.14** "**Assigned Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Assigned Collaboration Know-How.

**1.15** "**Assigned Collaboration Technology**" means the Assigned Collaboration Know-How and the Assigned Collaboration Patent Rights.

**1.16** "**Average Patient Cost**" means with respect to additional patients enrolled in a Global Clinical Trial for a Licensed Product by a Party [****].

**1.17** "**BLU-701**" means (a) Blueprint's mutant [****] EGFR inhibitor known as "BLU-701"; (b) its named back-up forms [****] and any other backup form that Blueprint identifies and designates after the Effective Date as a back-up form for BLU-701 in accordance with Blueprint's then-current business practices; (c) prodrugs that convert to the compounds in (a) and (b); (d) stereoisomers and isotopic variants of the compounds in (a), (b), and (c); (e) [****]; (f) salt forms of the compounds in (a) through (e); and (g) solvates, hydrates, and solid forms (including crystalline, polymorphic, amorphous and co-crystalline forms) of the compounds in (a) through (f).

**1.18** [****]

**1.19** "**BLU-945**" means (a) Blueprint's mutant [****] EGFR inhibitor known as "BLU-945"; (b) its named back-up forms [****] and any other backup form that Blueprint identifies and designates after the Effective Date as a back-up form for BLU-945 in accordance with Blueprint's then-current business practices; (c) prodrugs that convert to the compounds in (a) and (b); (d) stereoisomers and isotopic variants of the compounds in (a), (b), and (c); (e) [****]; (f) salt forms of the compounds in (a) through (e); and (g) solvates, hydrates, and solid forms (including crystalline, polymorphic, amorphous and co-crystalline forms) of the compounds in (a) through (f).

**1.20** [****]

**1.21** "**Blueprint**" has the meaning set forth in the Preamble.

**1.22** "**Blueprint Collaboration Know-How**" means Collaboration Know-How, other than Blueprint/Zai Combination Know-How, developed or invented solely by Blueprint's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Collaboration Know-How (or Patent Rights Covering such Know-How) to Blueprint or any Affiliate of Blueprint, in each case, in the performance of activities under this Agreement during the Term.

**1.23** "**Blueprint Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Blueprint Collaboration Know-How.

**1.24** "**Blueprint Compound**" means BLU-701 or BLU-945 and includes [****].

**1.25** "**Blueprint Identified Rights**" has the meaning set forth in Section 2.6.1 (Blueprint Identified Rights).

**1.26** "**Blueprint Indemnitee(s)**" has the meaning set forth in Section 13.1 (By Zai).

**1.27** "**Blueprint In-Licensed Rights**" has the meaning set forth in Section 2.6.3 (Third Party IP Agreements).

**1.28** "**Blueprint Know-How**" means, subject to Section 2.6.5 (Right to Decline Blueprint In-Licensed Rights), all Know-How (excluding Blueprint's interest in the Blueprint/Zai Combination Know-How and other Joint Collaboration Know-How) that is (a) Controlled by Blueprint or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary or reasonably useful to Develop, perform Medical Affairs for, or Commercialize a Blueprint Compound or a Licensed Product in the Territory, including all Assigned Collaboration Know-How and Blueprint Collaboration Know-How, but expressly excluding Blueprint Manufacturing Know-How.

**1.29** "**Blueprint Manufacturing Know-How**" means all Know-How Controlled by Blueprint or any of its Affiliates as of the Effective Date or during the Term that is actually used for the Manufacture of each Licensed Product in the Field in the Territory.

**1.30** "**Blueprint Manufacturing Patent Rights**" means all Patent Rights Controlled by Blueprint or any of its Affiliates as of the Effective Date or during the Term that are actually practiced for the Manufacture of each Licensed Product in the Field in the Territory.

**1.31** "**Blueprint Manufacturing Technology**" means the Blueprint Manufacturing Know-How and the Blueprint Manufacturing Patent Rights.

**1.32** "**Blueprint Patent Rights**" means, subject to Section 2.6.5 (Right to Decline Blueprint In-Licensed Rights), all Patent Rights (excluding Blueprint's interest in the Blueprint/Zai Combination Patent Rights and other Joint Collaboration Patent Rights) that are (a) Controlled by Blueprint or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) to Develop, perform Medical Affairs for, or Commercialize a Blueprint Compound or a Licensed Product in the Territory, including all Assigned Collaboration Patent Rights and Blueprint Collaboration Patent Rights, but expressly excluding Blueprint Manufacturing Patent Rights. **Schedule 1.32** (Blueprint Patent Rights) includes the Blueprint Patent Rights that are owned or exclusively licensed by Blueprint in the Territory and that exist as of the Effective Date.

**1.33** "**Blueprint Publication**" has the meaning set forth in Section 11.5.1.

**1.34** "**Blueprint Specifications**" has the meaning set forth in Section 7.2.3 (Specifications).

**1.35** "**Blueprint Technology**" means Blueprint Know-How, Blueprint Patent Rights, and Blueprint's interest in the Joint Collaboration Technology.

**1.36** "**Blueprint/Zai Combination**" means any Combination Product or Combination Regimen that includes a Blueprint Compound together with any Zai Product.

**1.37** "**Blueprint/Zai Combination Know-How**" means any Collaboration Know-How that (a) [****] relates to any Blueprint/Zai Combination (and not to any Zai Product alone or any other Licensed Product that is not a Blueprint/Zai Combination), including any composition, method of use or method of Manufacturing, in each case, that is specific to a Blueprint/Zai Combination (including any composition, method of use, or method of Manufacturing that is [****]), or any Companion Diagnostic [****] for use with a Blueprint/Zai Combination, and (b) is developed or invented during the Term by a Party's or its Affiliates', licensees', Sublicensees', or Sublicensees' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Know-How (or Patent Rights Covering such Know-How) to a Party or any Affiliate of a Party, either alone or jointly with the other Party's or its Affiliates', licensees', Sublicensees', Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Know-How (or Patent Rights Covering such Know-How) to the other Party or any Affiliate of the other Party, in each case, in the performance of activities under this Agreement during the Term.

**1.38** "**Blueprint/Zai Combination Patent Rights**" means all Collaboration Patent Rights that Cover Blueprint/Zai Combination Know-How. For clarity, Blueprint/Zai Combination Patent Rights do not include any Patent Rights that Cover (a) a Zai Product alone or (b) any other Licensed Product that is not a Blueprint/Zai Combination or a Companion Diagnostic that is for use with a Zai Product alone or any other Licensed Product that is not a Blueprint/Zai Combination.

**1.39** "**Blueprint/Zai Combination Technology**" means the Blueprint/Zai Combination Know-How and the Blueprint/Zai Combination Patent Rights.

**1.40** "**Breach Notification**" has the meaning set forth in Section 15.2.2(a) (Notice and Cure Period).

**1.41** "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in Cambridge, Massachusetts or Shanghai, China are required by Applicable Law to remain closed.

**1.42** "**Buyers**" has the meaning set forth in Section 1.136 (Net Sales).

**1.43** "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.

**1.44** "**Calendar Year**" means each 12-month period commencing on January 1.

**1.45** "**cGMP**" means all applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.

**1.46** "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party that owned less than 50% of the outstanding voting securities of such Party immediately prior to such transaction, owning at least 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

**1.47** "**Clinical Development**" means, with respect to a pharmaceutical or biologic product, Development activities conducted from and after (and including) the filing of an IND for such pharmaceutical or biologic product specifically in connection with (a) Clinical Trials and (b) regulatory activities related to Clinical Trials, including filing of MAAs and obtaining, supporting, or maintaining Regulatory Approvals for such pharmaceutical or biologic product following completion of a Pivotal Trial for such pharmaceutical or biologic product.

**1.48** "**Clinical Supply Agreement**" has the meaning set forth in Section 7.1.1 (Development Supply).

**1.49** "**Clinical Trial**" means any clinical trial in humans that is conducted in accordance with GCP and is designed to generate data in support or maintenance of an IND or MAA, or other similar marketing application, including any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or any post-approval clinical trial in humans.

**1.50** "**CMO**" means a contract manufacturing organization.

**1.51** "**Collaboration Know-How**" means any Know-How developed or invented during the Term by a Party's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Know-How to a Party or any Affiliate of a Party, either alone or jointly with the other Party's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Know-How (or patent Rights Covering such Know-How) to the other Party or any Affiliate of the other Party, in each case, in the performance of activities under this Agreement during the Term.

**1.52** "**Collaboration Patent Rights**" means any Patent Rights that (a) (i) claim any Invention included in the Collaboration Know-How or (ii) disclose any Collaboration Know-How and (b) have a priority date that is after the Effective Date.

**1.53** "**Collaboration Technology**" means Collaboration Know-How and Collaboration Patent Rights.

**1.54** "**Combination Product**" means a Licensed Product that includes (a) BLU-701 or BLU-945, or both, on the one hand; and (b) another Active Ingredient, on the other hand, sold for a single price.

**1.55** "**Combination Regimen**" means any product or treatment regimen that comprises, or is a combination of (a) a Licensed Product containing a Blueprint Compound, and (b) any other product containing an Active Ingredient other than such Blueprint Compound, where (a) and (b) are labeled for use together either simultaneously or in a separate or sequential administration, whether or not sold for a single price.

**1.56** "**Commercial Supply Agreement**" has the meaning set forth in Section 7.1.2 (Commercial Supply).

**1.57** "**Commercialization**" means any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

**1.58** "**Commercialization Plan**" means, with respect to a Licensed Product, the written [****] strategic and tactical plans for the Commercialization activities for such Licensed Product to be conducted in the Territory that will be prepared and updated by Zai as provided in Section 9.2 (Commercialization Plans).

**1.59** "**Commercially Reasonable Efforts**" means, with respect to the Exploitation of a Blueprint Compound or a Licensed Product by a Party, those efforts and resources, including reasonably necessary personnel, equivalent to the efforts that a reasonable international biopharmaceutical company or a pharmaceutical company[****] based on conditions then prevailing and taking into account all relevant factors [****]. Commercially Reasonable Efforts requires, with respect to an obligation, that the Party: (a) promptly assign responsibility for such obligation to specific employees who are held accountable for progress and monitor such progress on an on-going basis, (b) set and seek to achieve specific and meaningful objectives for carrying out such obligation, and (c) make and implement decisions and allocate resources designed to advance progress with respect to such objectives. [****]

**1.60** [****]

**1.61** "**Companion Diagnostics**" has the meaning set forth in Section 5.18 (Development of Companion Diagnostics).

**1.62** "**Competitive Activities**" has the meaning set forth in Section 2.8.1 (Exclusivity Covenant).

**1.63** "**Competitive Product**" means [****] other than a Licensed Product, that [****].

**1.64** "**Confidential Information**" means (a) Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement), regardless of whether such information is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

(a) is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

(b) is generally available to the public before its receipt from the Disclosing Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or discloses in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

(e) is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

**1.65** "**Confidentiality Agreement**" means the Confidential Disclosure Agreement dated [****] by and between the Parties.

**1.66** "**Continuing Know-How Transfer**" has the meaning set forth in Section 4.3 (Continuing Know-How Transfer).

**1.67** "**Control**" or "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to reference or use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense and without being required to make any payment to any Third Party other than payment obligations related to Blueprint In-Licensed Rights or Zai In-Licensed Rights acquired or licensed in accordance with Section 2.6 (Third Party In-Licenses) under which the other Party elects to take a sublicense and agrees to reimburse the contracting Party as set forth in Section 2.6 (Third Party In-Licenses). Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Patent Right or Know-How that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party after the Effective Date as a result of such Change of Control unless (i) prior to the consummation of such Change of Control, such acquired Party or any of its Affiliates also Controlled such Patent Right or Know-How, or (ii) after the consummation of such Change of Control, such acquired Party or any of its Affiliates determines to use or uses any such Patent Rights or Know-How in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((i) and (ii)), such Patent Rights or Know-How will be "Controlled" by such Party for purposes of this Agreement.

**1.68** "**Controlling Party**" has the meaning set forth in Section 14.3.2(a)(ii) (Enforcement Rights; Zai First Right).

**1.69** "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of a claim in such Patent Right.

**1.70** [****]

**1.71** "**CRO**" means a contract research organization.

**1.72** "**Data Breach**" has the meaning set forth in Section 12.5.2.

**1.73** "**Debarred/Excluded**" means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

**1.74** "**Deficient Site**" has the meaning set forth in Section 5.14.2 (Deficient Sublicensees or Sites and Replacement).

**1.75** "**Development**" means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, (b) preparation, submission, review, and development of data or information (or reports relating thereto and analysis and review of such reports) for the purpose of reviewing the progress and status of the activities under subsection (a) or for the purposes of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product, but excluding activities directed to Manufacturing, Medical Affairs, or Commercialization, and (c) the design of future studies, non-clinical and preclinical activities, and Clinical Trials. Development will include development and regulatory activities for additional forms, formulations, or indications for a pharmaceutical or biologic product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or Indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic product in such region). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

**1.76** "**Development Milestone Events**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

**1.77** "**Development Milestone Payments**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

**1.78** "**Development Subcontractor**" has the meaning set forth in Section 2.2.3 (Right to Subcontract).

**1.79** "**Disclosing Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

**1.80** "**Dispute**" has the meaning set forth in Section 16.1 (General).

**1.81** "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

**1.82** "**Effective Date**" has the meaning set forth in the Preamble.

**1.83** "**EGFR**" means epidermal growth factor receptor.

**1.84** "**Examined Party**" has the meaning set forth in Section 10.11 (Financial Records and Audits).

**1.85** "**Excess Enrollment Reimbursement**" has the meaning set forth in Section 5.2.3 (Enrollment of Additional Patients).

**1.86** "**Executive Officers**" has the meaning set forth in Section 3.6.3 (Decisions of the JSC).

**1.87** "**Exploit**" means to make, have made, use, offer to sell, sell, import, export, Develop, Manufacture, perform Medical Affairs activities, or Commercialize. "**Exploitation**" will be construed accordingly.

**1.88** "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

**1.89** "**FDA**" means the United States Food and Drug Administration or any successor entity thereto having essentially the same function.

**1.90** "**Field**" means the prevention, treatment, and diagnosis of any indications in humans.

**1.91** "**First Commercial Sale**" means, with respect to any Licensed Product in any country or region, the first sale of such Licensed Product to a Third Party for distribution, use, or consumption in such country or region after receiving all necessary Regulatory Approval and Reimbursement Approval (if required) to do so. First Commercial Sale excludes [****].

**1.92** "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [****] per year) carrying out Development, Manufacturing, Medical Affairs activities, or other scientific or technical work under this Agreement. Overtime and work on weekends, holidays, and the like, in each case, will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable by a Party for one individual during a given accounting period will be determined by dividing the number of hours worked directly by such individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [****] per Calendar Year.

**1.93** "**FTE Rate**" means the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2021 will be [****].

**1.94** "**Fully Burdened Manufacturing Cost**" means, with respect to any Blueprint Compound, Licensed Product, or any Zai Product (or component thereof), in each case, supplied by or on behalf of the applicable Party to the other Party or its Affiliates hereunder:

(a) if and to the extent such Blueprint Compound, Licensed Product, or Zai Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Third Party manufacturer, (i) the actual Third Party costs of such Manufacturing incurred by the supplying Party, including the costs [****]; and

(b) if and to the extent such Blueprint Compound, Licensed Product, or Zai Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Party or its Affiliate, the actual, fully burdened costs [****], including the cost of [****] Such fully burdened costs will be calculated in accordance with applicable Accounting Standards, consistently applied.

**1.95** "**GAAP**" means United States generally accepted accounting principles, consistently applied.

**1.96** "**GCP**" means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the "**ICH Guidelines**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Law in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.97** [****]

**1.98** "**Global Brand Elements**" has the meaning set forth in Section 14.9.1 (Global Brand Elements).

**1.99** "**Global Brand Strategy**" has the meaning set forth in Section 9.2 (Commercialization Plan).

**1.100** "**Global Clinical Trial**" means a Clinical Trial for a Licensed Product the data from which, at the time of commencement, is intended to be used to obtain Regulatory Approval both inside the Territory and in any of the following: [****].

**1.101** "**Global Development Plan**" has the meaning set forth in Section 5.1 (Global Development Plan).

**1.102** "**GLP**" means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in the region in the Territory, each as may be amended and applicable from time to time.

**1.103** "**Governmental Authority**" means any federal, national, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, regulatory body, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division of any of the foregoing, or any governmental arbitrator or arbitral body). Governmental Authorities include all Regulatory Authorities.

**1.104** [****]

**1.105** "**ICC**" has the meaning set forth in Section 16.3.1 (Rules).

**1.106** "**ICH Guidelines**" has the meaning set forth in Section 1.96 (GCP).

**1.107** "**IDL**" has the meaning set forth in Section 1.131 (Marketing Authorization Application or MAA).

**1.108** "**IFRS**" means International Financial Reporting Standards, consistently applied.

**1.109** "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the U.S. required to commence human clinical trials in such country or region (such as an application for a Clinical Trial Authorization in the Territory), and all supplements or amendments that may be filed with respect to the foregoing.

**1.110** "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

**1.111** "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

**1.112** "**Indication**" means [****] that a Licensed Product is [****] in the indication section of the Approved Labeling for such Licensed Product, or that is the subject of a Clinical Trial and where it is [****]

**1.113** "**Initial Know-How Transfer**" has the meaning set forth in Section 4.1 (Initial Know-How Transfer).

**1.114** "**Invention**" means any process, method, composition, article of manufacture, discovery, or finding that is conceived or reduced to practice (whether or not patentable).

**1.115** "**Joint Collaboration Know-How**" means (a) Blueprint/Zai Combination Know-How, and (b) other Collaboration Know-How, excluding any Assigned Collaboration Know-How, developed or invented jointly by a Party's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the other hand, in the performance of activities under this Agreement during the Term.

**1.116** "**Joint Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Joint Collaboration Know-How, including Blueprint/Zai Combination Patent Rights.

**1.117** "**Joint Collaboration Technology**" means the Joint Collaboration Know-How and the Joint Collaboration Patent Rights.

**1.118** "**JPT**" has the meaning set forth in Section 3.3 (Joint Project Teams).

**1.119** "**JPT Chairperson**" has the meaning set forth in Section 3.3.1 (Formation; Composition; Meetings).

**1.120** "**JSC**" has the meaning set forth in Section 3.2.1 (Formation).

**1.121** "**JSC Chairperson**" has the meaning set forth in Section 3.2.1 (Formation).

**1.122** "**Know-How**" means any information and materials, including records, discoveries, improvements, modifications, processes, techniques, methods, assays, chemical or biological materials, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, Inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how and trade secrets (in each case, whether or not patentable, copyrightable or otherwise).

**1.123** "**Knowledge**" means [****] of (a) with respect to Blueprint, [****] and (b) with respect to Zai, [****].

**1.124** "**Licensed Product**" means any product containing a Blueprint Compound as an Active Ingredient, in any form, formulation, dosage form, or method of delivery[****]. [****]

**1.125** "**Listing Patents**" has the meaning set forth in Section 14.6 (Patent Listings).

**1.126** "**Local Manufacturing Approval**" means receipt of all approvals and authorizations necessary for Zai or its Affiliate or their respective CMOs to Manufacture a particular Licensed Product in a particular region in the Territory (including after validation and qualification of Zai's or such Affiliate's or CMO's applicable facilities in the Territory).

**1.127** "**Losses**" means damages, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).

**1.128** "**Manufacture**" means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, shipping, storage, or freight of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including quality assurance and stability testing, characterization testing, quality control release testing of drug substance and drug product, quality assurance batch record review and release of product, process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, and product characterization, but excluding activities directed to Development, Commercialization, or Medical Affairs. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

**1.129** "**Manufacturing Technology Transfer**" means the transfer of the Blueprint Manufacturing Know-How related to a Blueprint Compound and Licensed Products containing such Blueprint Compound in accordance with the Manufacturing Technology Transfer Plan for such Blueprint Compound, which includes the provision of any technical assistance to enable the Manufacture of such Licensed Products [****].

**1.130** "**Manufacturing Technology Transfer Plan**" means, for each Blueprint Compound, the plan for the transfer to Zai and its designees of Blueprint Manufacturing Know-How for the Licensed Products that include such Blueprint Compound, which plan, among other things, will set forth [****].

**1.131** "**Marketing Authorization Application**" or "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto). In the context of imported drugs, MAA is also known as the Import Drug License ("**IDL**") application.

**1.132** "**Medical Affairs**" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Products and are not conducted by a Party's medical affairs (or equivalent) departments.

**1.133** "**Medical Affairs Plan**" means, with respect to a Licensed Product, [****] for the Medical Affairs activities for such Licensed Product to be conducted in the Territory, which plan will include medical information that Zai will provide in the Territory, including [****] that will be prepared and updated by Zai as provided in Section 8.1 (Medical Affairs Plans).

**1.134** "**Milestone Events**" has the meaning set forth in Section 10.2.3(a) (Notification of Milestone Events).

**1.135** "**Milestone Payments**" has the meaning set forth in Section 10.2.3(a) (Notification of Milestone Events).

**1.136** "**Net Sales**" means with respect to a Licensed Product, the gross amount [****] by Zai and its Affiliates and Sublicensees (each of the foregoing, a "**Seller**") to independent, unrelated persons (including Third Party Distributors) ("**Buyers**") in *bona fide* arm's length transactions with respect to such Licensed Product, less the following deductions, in each case, to the extent [****] in connection with such Licensed Product:

(a) [****]

(b) [****]

(c) [****]

(d) [****]

(e) [****]

(f) [****].

If Seller receives non-cash consideration for a Licensed Product sold to a Buyer during the Term, then the Net Sales amount for such Licensed Product will be calculated based on [****].

No deduction will be made for any item of cost incurred by any Seller in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) to (f) of the foregoing sentence; *provided* that Licensed Products transferred to Buyers in reasonable quantities in connection with Clinical Trials, compassionate use or named-patient use, in each case, will give rise to Net Sales only to the extent [****]. If a single item falls into more than one of the categories set forth in clauses (a)-(f) above, then such item may not be deducted more than once.

All deductions in clauses (a) through (f) above will be fairly and equitably allocated between such Licensed Product and other products of Zai and its Affiliates and Sublicensees such that such Licensed Product does not bear a disproportionate portion of such deductions. Calculations of Net Sales will be consistently applied across all products of Seller and will be consistent between periods.

Such amounts will be determined from the books and records of Seller, and will be calculated in accordance with applicable Accounting Standards.

Transfers or sales between Zai and its Affiliates and Sublicensees will be disregarded for purposes of calculating Net Sales, except if such purchaser is an end user.

[****]

If a Licensed Product is a Combination Product, [****].

If a Licensed Product containing the Blueprint Compound as the sole Active Ingredient is sold as part of an Combination Product and is sold separately in finished form, but the other Active Ingredients included in the Combination Product are not sold separately in finished form, [****].

If a Licensed Product containing the Blueprint Compound as the sole Active Ingredient is sold as part of a Combination Product and is not sold separately in finished form, but the other Active Ingredients included in the Combination Product are sold separately in finished form, [****].

If Net Sales of the Licensed Product when included in an Combination Product cannot be determined using the methods above (as neither the Licensed Product containing the applicable Blueprint Compound as the sole Active Ingredient nor the other Active Ingredients are sold separately), [****]. At least [****] prior to the anticipated First Commercial Sale of any such Combination Product in a region in the Territory, Zai will propose such good faith estimate to Blueprint, and Blueprint will [****] consider such proposal, and the Parties will seek to reach agreement on such allocation. If the Parties are unable to reach such agreement within [****] after Zai provides such proposal, then the issue will be resolved in accordance with Article 16 (Dispute Resolution).

**1.137** "**New Affiliate**" has the meaning set forth in Section 2.8.3 (New Affiliate Exception).

**1.138** "**New Combination**" has the meaning set forth in Section 5.9 (New Development Proposed by Zai).

**1.139** "**New Development Activities**" has the meaning set forth in Section 5.9 (New Development Proposed by Zai).

**1.140** "**New Development Proposal**" has the meaning set forth in Section 5.9 (New Development Proposed by Zai).

**1.141** "**New Indication**" has the meaning set forth in Section 5.9 (New Development Proposed by Zai).

**1.142** [****]

**1.143** "**New Territory-Specific Development Activities**" has the meaning set forth in Section 5.9.1(a) (JSC Approval).

**1.144** "**NMPA**" means the National Medical Products Administration of the PRC, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

**1.145** "**Non-Clinical Development**" means all Development excluding Clinical Development.

**1.146** "**Non-Funding Party**" has the meaning set forth in Section 5.8.1(a) (JSC Approval).

**1.147** "**NSCLC**" means non-small cell lung cancer.

**1.148** "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

**1.149** "**Other Extensions**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

**1.150** "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

**1.151** "**Patent Challenge**" has the meaning set forth in Section 15.2.3 (Termination for Patent Challenge).

**1.152** "**Patent Prosecution**" means activities directed to (a) preparing, filing, or prosecuting applications (of all types) for any Patent Right, (b) maintaining any Patent Right, or (c) deciding whether to abandon or maintain any Patent Right.

**1.153** "**Patent Rights**" means (a) all patents and patent applications in any country or region, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, and (d) any and all substitutions, renewals, registrations, confirmations, extensions, or restorations, including revalidations, reissues, and re-examinations (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

**1.154** "**Patent Term Adjustment**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

**1.155** "**Patent Term Extension**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

**1.156** "**Patient Commitment**" has the meaning set forth in Section 5.2.1 (Enrollment in Committed Trials).

**1.157** "**Paying Party**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

**1.158** "**Permitted Zai Non-Clinical Development**" has the meaning set forth in Section 5.7 (Non-Clinical and Preclinical Studies).

**1.159** "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, joint stock company, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.

**1.160** "**Personal Information**" means information related to a reasonably identifiable natural person.

**1.161** "**Phase I Clinical Trial**" means a clinical trial in humans that is generally consistent with 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

**1.162** "**Phase II Clinical Trial**" means a clinical trial in humans that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

**1.163** "**Phase III Clinical Trial**" means a clinical trial in humans of a pharmaceutical or biologic product (including any Combination Regimen) that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

**1.164** "**Pivotal Trial**" means any (a) [****] or (b) [****] in humans of a pharmaceutical or biologic product (including any Combination Regimen), the results of which, together with prior data and information concerning such product, are [****] in any particular jurisdiction and that is intended to support, or otherwise supports, the filing of an MAA in such jurisdiction (including any bridging study).

**1.165** "**POC Trial**" means a clinical trial [****] in humans of a pharmaceutical or biologic product (including any Combination Regimen) performed to [****] of such product and that [****].

**1.166** "**PRC**" means the People's Republic of China, which, for purposes of this Agreement, does not include Hong Kong Special Administrative Region, Macau Special Administrative Region, or Taiwan.

**1.167** "**PRC Submission Estimated Timeline**" means, for each Licensed Product, a written timeline setting forth the estimated dates of achievement of key regulatory milestones and submission to applicable Regulatory Authorities in the PRC of key Regulatory Submissions (including each MAA) for such Licensed Product.

**1.168** "**Preapproved Subcontractor**" means any Subcontractor that the JSC has approved as a Subcontractor that Zai may engage to perform its obligations or exercise its rights under this Agreement as further described in Section 2.2.3 (Right to Subcontract).

**1.169** "**Privacy Laws**" has the meaning set forth in Section 12.5.2.

**1.170** "**Product Infringement**" has the meaning set forth in Section 14.3.1 (Patent Enforcement; Notice).

**1.171** "**Product Marks**" has the meaning set forth in Section 14.9.1 (Global Brand Elements).

**1.172** "**Proposed Blueprint/Zai Combination**" has the meaning set forth in Section 5.8.1 (Proposed Blueprint/Zai Combinations).

**1.173** "**Prosecuting Party**" has the meaning set forth under Section 14.2.3(a) (Blueprint/Zai Combination Technology).

**1.174** "**Public Official**" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

**1.175** "**Publication**" has the meaning set forth in Section 11.5 (Publications).

**1.176** "**Receiving Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

**1.177** "**Recipient**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

**1.178** "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, permit, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

**1.179** "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the NMPA, and any corresponding national or regional regulatory authorities.

**1.180** "**Regulatory Exclusivity**" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction that prohibits a Person from Commercializing [****].

**1.181** [****]

**1.182** "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents.

**1.183** "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

**1.184** "**Replacement Site**" has the meaning set forth in Section 5.14.2 (Deficient Sublicensees or Sites and Replacement).

**1.185** "**Review Period**" has the meaning set forth in Section 11.5 (Publications).

**1.186** "**Royalty Estimate**" has the meaning set forth in Section 10.3.4 (Royalty Reports and Payments).

**1.187** "**Royalty Patent Rights**" means the Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, and the Joint Collaboration Patent Rights.

**1.188** "**Royalty Payments**" has the meaning set forth in Section 10.3.1 (Royalty Rates).

**1.189** "**Royalty Report**" has the meaning set forth in Section 10.3.4 (Royalty Reports and Payments).

**1.190** "**Royalty Term**" has the meaning set forth in Section 10.3.2 (Royalty Term).

**1.191** "**Rules**" has the meaning set forth in Section 16.3.1 (Arbitration; Rules).

**1.192** "**Safety Agreement**" has the meaning set forth in Section 6.5.1 (Adverse Events Reporting; Safety Agreements).

**1.193** "**Sales Milestone Events**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

**1.194** "**Sales Milestone Payments**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

**1.195** "**Scientific Officers**" has the meaning set forth in Section 2.8.2 (Competitive Product Disputes).

**1.196** "**Seller**" has the meaning set forth in Section 1.136 (Net Sales).

**1.197** "**Shared Services Costs**" means [****] **1.197** [****].

**1.198** [****] has the meaning set forth in Section 5.2.2 [****].

**1.199** "**Subcontractor**" means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs and CMOs).

**1.200** "**Sublicensee**" means any Person, excluding any Subcontractor or Third Party Distributor, (a) with respect to Zai, to whom Zai grants a sublicense of, or other authorization or permission granted under, the rights granted to Zai in Section 2.1 (License Grants to Zai), and (b) with respect to Blueprint, to whom Blueprint grants a sublicense of, or other authorization or permission granted under, the rights granted to Blueprint in Section 2.3 (License Grants to Blueprint).

**1.201** "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), including value add taxes ("**VAT**").

**1.202** "**Technology Transfer**" has the meaning set forth in Section 4.3 (Continuing Know-How Transfer).

**1.203** "**Term**" has the meaning set forth in Section 15.1 (Term).

**1.204** "**Territory**" means the PRC, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan, each of which will be deemed a separate region for purposes of this Agreement.

**1.205** "**Territory Sponsor**" means, with respect to a Territory-Specific Clinical Trial or a Global Clinical Trial for a Licensed Product to be conducted at sites in the Territory, the Party that holds the IND from the applicable Regulatory Authority in the Territory for such Clinical Trial in its name.

**1.206** "**Territory-Specific Clinical Trial**" means a Clinical Trial for a Licensed Product, the data from which at the time of commencement is intended to be used to obtain, support, or maintain Regulatory Approval in the Territory but not to obtain, support, or maintain Regulatory Approval in any of the following: [****].

**1.207** "**Territory-Specific Development Plans**" has the meaning set forth in Section 5.4 (Territory-Specific Development Plans).

**1.208** "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

**1.209** "**Third Party Claims**" means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil, in contract, tort, or otherwise).

**1.210** "**Third Party Distributor**" means any Third Party that purchases Licensed Product from Zai or its Affiliates, or Sublicensees, takes title to such Licensed Product, and distributes such Licensed Product directly to customers, but does not Develop or Manufacture any Blueprint Compound or Licensed Product and does not make any royalty, profit-share, or other payment to Zai or its Affiliates or Sublicensees, other than payment for the purchase of Licensed Products for resale.

**1.211** "**Third Party IP Agreement**" means any agreement with a Third Party entered into by Blueprint or Zai respect to a grant of rights under any Blueprint Identified Rights or Zai Identified Rights.

**1.212** "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

**1.213** "**Upfront Payment**" has the meaning set forth in Section 10.1 (Upfront Payment).

**1.214** "**Valid Claim**" means with respect to a particular country or region, a claim in any (a) unexpired and issued Patent Right that has not been irretrievably lapsed or been abandoned, disclaimed, permanently revoked, dedicated to the public, or held invalid, unenforceable, or not patentable by a final non-appealable decision of a court of competent jurisdiction or Governmental Authority in such country or region, or (b) pending patent application that has been pending for [****]; *provided* that, if a claim ceases to be a Valid Claim by reason of foregoing subclause (b), then such claim would again be deemed a Valid Claim in the event such claim subsequently issues prior to the end of the then-current Royalty Term in such country or region.

**1.215** "**VAT**" has the meaning set forth in Section 1.201 (Tax).

**1.216** "**VAT Credit**" has the meaning set forth in Section 10.13 (VAT Credits).

**1.217** "**Working Group**" has the meaning set forth in Section 3.4 (Working Groups).

**1.218** "**Zai**" has the meaning set forth in the Preamble.

**1.219** "**Zai Collaboration Know-How**" means Collaboration Know-How, other than Blueprint/Zai Combination Know-How or Assigned Collaboration Know-How, developed or invented solely by Zai's or its Affiliates', licensees', Sublicensees', or Subcontractors' employees, agents, or independent contractors, or any Persons that are contractually required to assign or license such Collaboration Know-How (or Patent Rights Covering such Know-How) to Zai or any Affiliate of Zai, in each case, in the performance of activities under this Agreement during the Term.

**1.220** "**Zai Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Zai Collaboration Know-How. For clarity, Zai Collaboration Patent Rights do not include any Blueprint/Zai Combination Patent Rights or Assigned Collaboration Patent Rights.

**1.221** "**Zai Collaboration Technology**" means Zai Collaboration Know-How and Zai Collaboration Patent Rights.

**1.222** "**Zai Identified General Rights**" has the meaning set forth in Section 2.6.2 (Zai Identified Rights).

**1.223** "**Zai Identified Rights**" has the meaning set forth in Section 2.6.2 (Zai Identified Rights).

**1.224** "**Zai Indemnitee(s)**" has the meaning set forth in Section 13.2 (By Blueprint).

**1.225** "**Zai In-Licensed Rights**" has the meaning set forth in Section 2.6.2 (Zai Identified Rights).

**1.226** "**Zai Know-How**" means, subject to Section 2.6.6 (Right to Decline Zai In-Licensed Rights), all Know-How (excluding Zai's interest in Blueprint/Zai Combination Know-How and other Joint Collaboration Know-How) that is (a) Controlled by Zai or any of its Affiliates as of the Effective Date or during the Term, and (b) used by either Party in the Exploitation of a Blueprint Compound or a Licensed Product, including all Zai Collaboration Know-How.

**1.227** "**Zai Patent Rights**" means, subject to Section 2.6.6 (Right to Decline Zai In-Licensed Rights), all Patent Rights (excluding Zai's interest in Blueprint/Zai Combination Patent Rights and other Joint Collaboration Patent Rights) that are (a) Controlled by Zai or any of its Affiliates as of the Effective Date or during the Term; and (b) practiced by either Party in the Exploitation of a Blueprint Compound or a Licensed Product, including all Zai Collaboration Patent Rights.

**1.228** "**Zai Product**" means any pharmaceutical or biologic product with respect to which Zai or any of its Affiliates has exclusive rights to Exploit inside the Territory or outside of the Territory, including all forms, modifications, and variants thereof that are Controlled by Zai, in each case, at the time that the JSC agrees in writing to include a Blueprint/Zai Combination containing such Zai Product under this Agreement pursuant to Section 5.8.1 (Proposed Blueprint/Zai Combinations) or Section 5.9 (New Development Proposed by Zai).

**1.229** "**Zai Publication**" has the meaning set forth in Section 11.5.1.

**1.230** "**Zai Specifications**" has the meaning set forth in Section 7.2.3 (Specifications).

**1.231** "**Zai Technology**" means Zai Know-How, Zai Patent Rights, and Zai's interest in the Joint Collaboration Technology.

**1.232** "**Zai Third Party IP Agreement**" has the meaning set forth in Section 2.6.6(b) (Right to Decline Zai In-Licensed Rights).

## Article 2
## LICENSES

**2.1 License Grants to Zai**.

2.1.1 **In the Territory**. Subject to the terms of this Agreement, Blueprint hereby grants to Zai (a) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under the Blueprint Technology to Exploit (other than to conduct or have conducted Non-Clinical Development, or Manufacture or have Manufactured) the Blueprint Compounds and the Licensed Products in the Field in the Territory in accordance with the Territory-Specific Development Plans, Global Development Plans, the Medical Affairs Plans, and the Commercialization Plans or as otherwise expressly permitted by this Agreement and (b) a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under the Blueprint Technology to [****] in the Field in the Territory. Zai will not practice the Blueprint Technology licensed to Zai under this Section 2.1.1 (In the Territory) except as expressly set forth in the Territory-Specific Development Plans, Global Development Plan, Medical Affairs Plans, and Commercialization Plans or to conduct other activities expressly permitted under this Agreement. Notwithstanding any provision to the contrary set forth in this Agreement, [****].

2.1.2 **Manufacturing License**. Subject to the terms of this Agreement, effective upon the commencement of the Manufacturing Technology Transfer to Zai for the Manufacture of the Licensed Products in accordance with Section 7.2.2 (Clinical and Commercial Supply), Blueprint hereby grants to Zai [****] in accordance with and subject to the terms of this Agreement, including pursuant to Section 7.2 (Supply by Zai). Zai will not practice the Blueprint Manufacturing Technology licensed to Zai under this Section 2.1.2 (Manufacturing License) until the commencement of the Manufacturing Technology Transfer to Zai for the Manufacture of the Licensed Products in accordance with Section 7.2.2 (Clinical and Commercial Supply).

**2.2 Sublicensing and Subcontractors**.

2.2.1 **Right to Sublicense**. Subject to the terms of this Agreement, Zai will have the right to grant sublicenses of the rights granted under Section 2.1 (License Grants to Zai) to (a) its Affiliates, *provided* that any such sublicense will automatically terminate if such Person ceases to be an Affiliate of Zai, (b) Development Subcontractors and Third Party Distributors in accordance with this Section 2.2 (Sublicensing and Subcontractors), and (c) subject to Blueprint's prior written approval, not to be unreasonably withheld, conditioned, or delayed, Third Parties (other than Development Subcontractors and Third Party Distributors). Notwithstanding the foregoing, Zai will not grant a sublicense to a Third Party of all or substantially all of Zai's rights or obligations under this Agreement with respect to one or more regions within the Territory without Blueprint's prior written consent, which consent Blueprint may withhold, condition, or delay in its sole discretion. Each Sublicensee will hold its rights contingent on the rights licensed to Zai under the terms of this Agreement. Any termination of the licenses granted to Zai under Section 2.1 (License Grants to Zai) as a result of a termination of this Agreement with respect to one or more Licensed Products or in its entirety will, subject to Section 15.3.11 (Sublicense Survival), cause the Sublicensees to automatically lose the same rights under any sublicense.

2.2.2 **Terms of Sublicenses to Third Parties**. Zai will provide prior written notice to Blueprint identifying its intention to grant a sublicense under Section 2.2.1 (Right to Sublicense) to any Third Party (other than a sublicense granted by Zai to a Development Subcontractor or Third Party Distributor; *provided* that such engagement is otherwise in accordance with Section 2.2.3 (Right to Subcontract)), the purpose of such sublicense, and the identity of the Third Party to whom Zai intends to grant such sublicense. Each sublicense to a Third Party will be granted under a written agreement that is consistent with the terms of this Agreement and that (a) requires each such Third Party Sublicensee to which Zai grants a sublicense of the rights granted to Zai under Section 2.1 (License Grants to Zai) to comply with the terms of this Agreement that are applicable to such sublicense (including obligations of confidentiality and non-use at least as stringent as those set forth Article 11 (Confidentiality; Publication), as applicable, the Milestone Event and Royalty Payment reporting obligations set forth under Section 10.2 (Milestone Payments) and Section 10.3 (Royalty Payments to Blueprint), the record keeping and audit requirements set forth under Section 5.14 (Clinical Trial Audit Rights), Section 10.11 (Financial Records and Audits), and the intellectual property provisions set forth in Article 14 (Intellectual Property)), and (b) precludes the granting of further sublicenses in contravention with the terms of this Agreement. Without limiting the generality of the foregoing, each sublicense agreement with such a Third Party entered into after the Effective Date must include (i) [****], (ii) [****], and (iii) [****].

2.2.3 **Right to Subcontract**. Zai will not propose the engagement of any Subcontractor that is Debarred/Excluded. Zai may engage (a) Subcontractors solely to perform Zai's Development activities with respect to Licensed Products under this Agreement on Zai's behalf (each a "**Development Subcontractor**") or (b) Third Party Distributors to distribute Licensed Products in the Territory on behalf of Zai, in either case, without Blueprint's prior written consent, but subject to the requirements set forth in the first, the second to last, and the last sentence of this Section 2.2.3 (Right to Subcontract), Section 2.2.4 (Notices of Sublicensing and Subcontractors), Section 2.2.5 (Zai Audits of Sublicensees and Subcontractors), and Section 2.2.6 (Responsibility for Sublicensees and Subcontractors). Prior to Zai's engagement of the first Subcontractor (other than a Development Subcontractor or Third Party Distributor), Zai will provide to the JSC to review, discuss, and determine whether to approve as Preapproved Subcontractors a list of Subcontractors that Zai may engage to perform its obligations and exercise its rights under this Agreement. In addition, during the term, Zai may propose additional Subcontractors to be approved by the JSC as Preapproved Subcontractors and following the approval by the JSC of any such additional Subcontractors, such Subcontractors will be Preapproved Subcontractors. Zai may engage any such Preapproved Subcontractor to perform Zai's obligations and exercise of Zai's rights under this Agreement. In addition, if Zai wishes to engage a Subcontractor (other than a Development Subcontractor or Third Party Distributor) that is not a Preapproved Subcontractor to perform its obligations or exercise its rights under this Agreement related to the (i) Manufacture of a Licensed Product following completion of the Manufacturing Technology Transfer, or (ii) the Commercialization of such Licensed Product in a region in the Territory, then, in each case ((i) and (ii)), Zai will provide written notice to Blueprint at least [****] before engaging any such Subcontractor identifying Zai's intention to engage such Subcontractor, the purpose of engaging such Subcontractor, and the identity of such Subcontractor. Within [****] after the receipt of such written notice, Blueprint may provide written notice of its veto of Zai's engagement of such proposed Subcontractor and in such case, Zai will not engage such Subcontractor to perform its obligations or exercise its rights under this Agreement, *provided* that Blueprint will not unreasonably veto such engagement. If Blueprint does not provide written notice to Zai of Blueprint's veto of Zai's engagement of a particular proposed Subcontractor within [****] after Blueprint's receipt of such notice, then Zai may engage such proposed Subcontractor to perform its obligations or exercise its rights under this Agreement (subject to the terms set forth herein). Any agreement pursuant to which Zai engages any Subcontractor (including any Development Subcontractor or Third Party Distributor) must be consistent with the terms of this Agreement, including containing obligations of confidentiality and non-use at least as stringent as those set forth Article 11 (Confidentiality; Publication), and terms that are consistent with the intellectual property provisions set forth in Article 14 (Intellectual Property). Without limiting the generality of the foregoing, unless otherwise agreed by the Parties, each agreement pursuant to which Zai engages a Subcontractor (including any Development Subcontractor or Third Party Distributor) to Exploit Licensed Products hereunder must include [****].

2.2.4 **Notice of Sublicenses and Subcontracts**. Zai will provide Blueprint with a true and complete copy of each sublicense or subcontracting agreement (including all schedules, exhibits, and appendices thereto) with any Third Party (including any Development Subcontractor or Third Party Distributor) within [****] after it becomes effective[****] Any sublicense granted under this Agreement must either be in English or [****].

2.2.5 **Zai Audits of Sublicensees and Subcontractors**. Zai will provide Blueprint with copies of all quality oversight or audit reports from audits that Zai (or its agent) has conducted on any Sublicensees or Subcontractors that Zai engages to perform its obligations or exercise its rights under this Agreement with respect to any Licensed Product, as well as all corrective action plans resulting from any such audits, in each case, to the extent such reports and plans are relevant to such Sublicensees or Subcontractors' performance of such obligations or exercise of such rights no later than [****].

2.2.6 **Responsibility for Sublicensees and Subcontractors**. Zai will require that all Sublicensees and Subcontractors perform the activities that they are sublicensed or engaged to perform (as applicable) in accordance with GLP, cGMP, and GCP, as applicable, and otherwise in compliance with Applicable Law. Notwithstanding any sublicense or subcontracting, Zai will remain primarily liable to Blueprint for the performance of all of its obligations under, and Zai's compliance with all provisions of, this Agreement. Zai will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or Subcontractors to the same extent as if Zai itself has committed any such breach and will terminate the agreement with any Sublicensee or Subcontractor [****] if such Sublicensee or Subcontractor is in breach of this Agreement and neither Zai nor such Subcontractor cures such breach in a timely manner [****].

**2.3 License Grants to Blueprint**.

2.3.1 **Development Activities**. Subject to the terms of this Agreement, Zai hereby grants to Blueprint a worldwide, non-exclusive, royalty-free license, with the right to grant sublicenses through multiple tiers, under the Zai Technology to perform the Development activities for the Blueprint Compounds and the Licensed Products in the Field for which it is responsible under a Global Development Plan, including any Global Clinical Trial for a Licensed Product (including a POC Trial or other Development of any Blueprint/Zai Combination approved by the JSC pursuant to Section 5.8.1 (Proposed Combinations)).

2.3.2 **Outside of the Territory**. Subject to the terms of this Agreement, Zai hereby grants to Blueprint a perpetual, irrevocable, royalty-free license, with the right to grant sublicenses through multiple tiers, under the Zai Technology to Exploit the Blueprint Compounds and the Licensed Products in the Field outside of the Territory. Such license under this Section 2.3.2 (Outside of the Territory) will be (a) exclusive under the Zai Collaboration Technology and Zai's interest in the Joint Collaboration Technology and (b) non-exclusive under all other Zai Technology.

**2.4 Retained Rights**. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Blueprint Technology, Blueprint Manufacturing Technology, Joint Collaboration Technology, or Zai Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Blueprint by Zai under this Agreement are hereby retained by Zai. Any rights not expressly granted to Zai by Blueprint under this Agreement are hereby retained by Blueprint. In addition, Blueprint expressly retains (a) the exclusive right under the Blueprint Technology (on behalf of itself and its licensees and Sublicensees, other than Zai, Zai's Affiliates and Zai's Sublicensees) to conduct Non-Clinical Development involving Blueprint Compounds or Licensed Products anywhere in the world (including in the Territory[****]), (b) the right under the Blueprint Technology to perform Development activities for the Blueprint Compounds and the Licensed Products in the Territory in accordance with this Agreement, including to conduct Development activities under a Global Development Plan as provided hereunder (including in the event that Zai declines, through the JSC, to participate in a Global Clinical Trial proposed by Blueprint under Section 5.11 (New Development Proposed by Blueprint) or fails to satisfy the Patient Commitment with respect to one or more Committed Trials), (c) the right under the Blueprint Technology (on behalf of itself and its licensees and Sublicensees, other than Zai, Zai's Affiliates and Zai's Sublicensees) to Manufacture Licensed Products in the Territory itself or through its Affiliates or Third Parties (i) for use by Zai and its authorized Sublicensees in the Territory or (ii) for use by Blueprint, or its licensees, Sublicensees, Affiliates or Third Parties outside of the Territory, (d) the right to perform Blueprint's other obligations under this Agreement, (e) in the event that Zai does not participate in a Global Clinical Trial for one or more Licensed Products in one or more Indications or with respect to one or more Combination Products or Combination Regimens, the non-exclusive right to Develop Blueprint Compounds and Licensed Products through the use of clinical trial sites, CROs, and other Third Parties in the Territory in connection with the performance of such Global Clinical Trials, and (f) the exclusive right to Exploit the Blueprint Compounds and Licensed Products outside of the Territory. Zai will not practice the Blueprint Technology and Blueprint will not practice the Zai Technology, in each case, other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing.

**2.5** **Combination Products Rights**. Notwithstanding any other provision of this Agreement, for purposes of the license grants under Section 2.1 (License Grants to Zai) or Section 2.3 (License Grants to Blueprint), with respect to any Licensed Product that is a Combination Product or Combination Regimen, such license will only include rights with respect to any Blueprint Compound component of such Combination Product or Combination Regimen and not any other Active Ingredient Controlled by, as applicable, the Party granting such license (*e.g.*, with respect to Zai, any Zai Product or with respect to Blueprint, a compound Controlled by Blueprint other than BLU-701 or BLU-945) or any of its Affiliates except in the event that [****].

**2.6** **Third Party In-Licenses**.

2.6.1 **Blueprint Identified Rights**. Blueprint will remain solely responsible for the payment of all royalties, license fees, milestone payments, and other payment obligations under all agreements entered into by Blueprint prior to the Effective Date. If, after the Effective Date during the Term, Blueprint intends to obtain Control of any Know-How or Patent Rights from a Third Party (whether by acquisition or license) that may be necessary or useful to Exploit one or more Blueprint Compounds or Licensed Products in the Field anywhere in the world (other than a Change of Control of Blueprint or as a result of the acquisition by Blueprint of a Third Party by merger, acquisition, or similar transaction or series of related transactions) (such Know-How and Patent Rights, "**Blueprint Identified Rights**"), then Blueprint will notify Zai in writing of such Blueprint Identified Rights and Section 2.6.3 (Third Party IP Agreements) will apply.

2.6.2 **Zai Identified Rights**. If Zai determines that a license under any Know-How or Patent Rights controlled by a Third Party is [****] ("**Zai Identified Rights**"), then Zai will [****]. Blueprint will have the first right to acquire rights to any such Zai Identified Rights from such Third Party (whether by acquisition or license)[****]. If [****], then Blueprint will notify Zai of such intention within [****] and the terms of Section 2.6.3 (Third Party IP Agreements) will apply. If (a) Blueprint [****] within such [****] period or otherwise [****], or (b) [****], then Zai will have the right to acquire rights under such Zai Identified Rights from such Third Party solely for the Territory or any region therein and any such right obtained by Zai will be referred to as "**Zai In-Licensed Rights**."

2.6.3 **Blueprint In-Licensed Rights**. Prior to executing a Third Party IP Agreement with a Third Party to acquire or license any Blueprint Identified Rights or Zai Identified Rights (together, "**Blueprint In-Licensed Rights**"), Blueprint will (a) provide Zai an opportunity to review and comment on [****], including any [****] (b) take Zai's comments into consideration [****] prior to finalizing such Third Party IP Agreement, and (c) ensure that such Third Party IP Agreement includes [****]. Upon execution of such Third Party IP Agreement, Blueprint will notify Zai in writing and will provide [****].

2.6.4 **Responsibility for Costs of Blueprint In-Licensed Rights**. Subject to Zai's right to decline a license or sublicense of Blueprint In-Licensed Rights within [****] in accordance with the terms of Section 2.6.5 (Right to Decline Blueprint In-Licensed Rights), following Blueprint's execution of the applicable Third Party IP Agreement (a) such Blueprint In-Licensed Rights will be included in the Blueprint Know-How or the Blueprint Patent Rights (as applicable) and licensed or sublicensed (as applicable) to Zai under the licenses granted in Section 2.1 (License Grants to Zai), subject to the terms of this Agreement and the applicable Third Party IP Agreement, and (b) Zai will reimburse Blueprint (i) [****] of any such payments under the applicable Third Party IP Agreement that [****] pertain to, or arise [****] as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products in the Territory (for example, [****]) by Zai or its Affiliates or Sublicensees, and (ii) with respect to any [****] payments payable in consideration for any Blueprint In-Licensed Rights that pertain to, or arise as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products both inside and outside of the Territory or are non-Territory-specific (for example, [****]), [****]. Blueprint will bear [****] of amounts payable in consideration for any Blueprint In-Licensed Rights that pertain to any product other than a Blueprint Compound or Licensed Product or that [****] pertain to, or arise [****] as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products outside of the Territory (for example, [****]).

2.6.5 **Right to Decline Blueprint In-Licensed Rights**. Zai will have the right to decline a license or sublicense (as applicable) from Blueprint under Blueprint In-Licensed Rights under a Third Party IP Agreement by providing written notice to Blueprint [****]. Upon Blueprint's [****] receipt of such notice declining such a license or sublicense (as applicable) under any Blueprint In-Licensed Rights, Blueprint will not be deemed to Control such Blueprint In-Licensed Rights, the definitions of Blueprint Patent Rights and Blueprint Know-How will exclude such Blueprint In-Licensed Rights, as applicable, and such Blueprint In-Licensed Rights will not be included in the scope of the rights granted to Zai under Section 2.1 (License Grants to Zai).

2.6.6 **Right to Decline Zai In-Licensed Rights; Responsibility for Costs**.

(a) **Zai In-Licensed Rights**. Prior to executing a Third Party IP Agreement with a Third Party to acquire or license any Zai In-Licensed Rights, Zai will (i) provide Blueprint an opportunity to review and comment on [****], including any [****], (ii) take Blueprint's comments into consideration [****] prior to finalizing such Third Party IP Agreement, and (iii) ensure that such Third Party IP Agreement includes [****]. Upon execution of such Third Party IP Agreement, Zai will notify Blueprint in writing and will provide [****].

(b) **Right to Decline Zai In-Licensed Rights**. Blueprint will have the right to decline a license or sublicense (as applicable) from Zai under Zai In-Licensed Rights by providing written notice to Zai [****] (the "**Zai Third Party IP Agreement**") [****]. Upon Zai's [****] receipt of such notice declining such a license or sublicense (as applicable) under any Zai In-Licensed Rights, Zai will not be deemed to Control such Zai In-Licensed Rights, the definitions of Zai Patent Rights and Zai Know-How will exclude such Zai In-Licensed Rights, as applicable, and such Zai In-Licensed Rights will not be included in the scope of the rights granted to Blueprint under Section 2.3 (License Grants to Blueprint).

(c) **Responsibility for Costs of Zai In-Licensed Rights**. Subject to Blueprint's right to decline a license or sublicense of Zai In-Licensed Rights in accordance with the terms of Section 2.6.6(b) (Right to Decline Zai In-Licensed Rights), following Zai's execution of the applicable Zai Third Party IP Agreement: (i) such Zai In-Licensed Rights will be included in the Zai Know-How or the Zai Patent Rights (as applicable) and licensed or sublicensed (as applicable) to Blueprint under the licenses granted in Section 2.3 (License Grants to Blueprint), subject to the terms of this Agreement and the applicable Zai Third Party IP Agreement, and (ii) Blueprint will reimburse Zai (A) [****] of any such payments under the applicable Zai Third Party IP Agreement that [****]pertain to, or arise [****] as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products outside the Territory (for example, [****] by Blueprint, its Affiliates or (sub)licensees, and (B) with respect to [****] payments payable in consideration for any Zai In-Licensed Rights that pertain to, or arise as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products both inside and outside of the Territory or are non-Territory-specific (for example, [****]), a [****]. Zai will bear [****]of amounts payable in consideration for any Zai In-Licensed Rights that pertain to any product other than a Blueprint Compound or Licensed Product or that [****] pertain to, or arise [****] as a result of, the Exploitation of the Blueprint Compounds or the Licensed Products in the Territory (for example, [****]).

**2.7** [****]

**2.8** **Exclusivity**.

2.8.1 **Exclusivity Covenant**. Subject to Section 2.8.3 (New Affiliate Exception), during the Term neither Party will, and will ensure that its Affiliates and Sublicensees do not, independently or for or with any Third Party, [****] unless agreed in writing by the Parties (the "**Competitive Activities**").

2.8.2 **Competitive Product Disputes**. If a Party disputes whether a pharmaceutical or biologic product is a Competitive Product, then the Parties will refer the matter to the head of Research & Development of Zai and Blueprint (or, if a Party does not have a head of Research & Development, its most senior employee having the equivalent responsibilities) or their designees (the "**Scientific Officers**"). The Scientific Officers will meet [****] to discuss and resolve the matter within [****] after referral of such matter to such Scientific Officers. If the Scientific Officers cannot agree on a resolution to the matter within such [****] period, then the Parties will refer such matter for resolution to an independent Third Party expert agreed upon by the Parties within [****] after the Scientific Officers failed to resolve such matter. Such independent Third Party expert will be [****], and unless otherwise agreed in writing by the Parties, must not [****]. Such expert will make its determination as to whether the applicable pharmaceutical or biologic product is a Competitive Product [****]. The Party bringing a dispute pursuant to this Section 2.8.2 (Competitive Product Disputes) will [****] engage such expert and the Parties will share the out-of-pocket costs incurred in connection with the engagement of such expert [****]. Within [****] of the engagement of such expert by the disputing Party, such expert will deliver a written decision to the Parties on the matter as to whether such product is a Competitive Product (including a detailed report as to such expert's rationale for such decision), and such decision will be binding on the Parties.

2.8.3 **New Affiliate Exception**. Notwithstanding Section 2.8.1 (Exclusivity Covenant), if (1) a Third Party becomes an Affiliate of a Party during the Term through merger, acquisition, consolidation, Change of Control, or other similar transaction (any such Third Party, a "**New Affiliate**") and (2) such New Affiliate, as of the execution date of the definitive agreement with respect to such transaction, is engaged in Competitive Activities with respect to one or more Competitive Products, then:

(a) If such transaction results in a Change of Control of a Party, then such New Affiliate of such Party (the "**Acquiror**") and such Party and their respective Affiliates may continue to perform such Competitive Activities after such Change of Control and such Party will not be in violation of its exclusivity obligations set forth in Section 2.8.1 (Exclusivity Covenant), as long as (i) no Confidential Information of the other Party or Blueprint Technology (if the acquired Party is Zai) or Zai Technology (if the acquired Party is Blueprint) is used by or on behalf of such Party, its Acquiror and their respective Affiliates in connection with any such Competitive Activities, and (ii) such Party, its Acquiror and their respective Affiliates institute commercially reasonable [****] safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel working on such Competitive Activities and the personnel teams charged with working on the Blueprint Compounds and Licensed Products hereunder or having access to data from activities performed under this Agreement or to the Confidential Information of the other Party.

(b) If such transaction does not result in a Change of Control of a Party, then such Party (i) will provide to the other Party [****], (ii) unless the Parties agree otherwise in writing, such Party and its New Affiliate (an "**Acquiree**") will take one of the following actions set forth below in clauses (A) or (B) and (iii) no later than [****] following the date of consummation of the relevant acquisition transaction, such Party will notify the other Party of which of the actions in the following clauses (A) or (B), it will pursue: (A) divest, or cause its Acquiree to divest, whether by license or otherwise, its interest in the program of applicable Competitive Activities; or (B) terminate any further Competitive Activities. If such Party notifies the other Party in writing that it intends to divest the program of applicable Competitive Activities or terminate the performance of the applicable Competitive Activities, then such Party or its Acquiree will effect the consummation of such divestiture within [****] (or such other period as may be required to comply with Applicable Law), or effect such termination of the program of applicable Competitive Activities within [****], in each case, after the closing of the relevant transaction and will confirm to the other Party in writing when it completes such divestiture pursuant to clause (A) or termination pursuant to clause (B). Such Party will keep the other Party reasonably informed of its efforts and progress in effecting such divesture or termination until such Party or its Acquiree completes the same. During such [****] or [****] period, as applicable, such Party and its Acquiree's and their respective Affiliates' conduct of such Competitive Activities will not constitute a breach by such Party of its exclusivity obligations set forth in Section 2.8.1 (Exclusivity Covenant), as long as during such period, (I) no Confidential Information of the other Party or Blueprint Technology (if the acquiring Party is Zai) or Zai Technology (if the acquiring Party is Blueprint) is used by or on behalf of such acquiring Party, its Acquiree, and their respective Affiliates in connection with any such Competitive Activities, and (II) such acquiring Party, its Acquiree and their respective Affiliates institute commercially reasonable [****] safeguards to ensure the requirements set forth in the foregoing clause (I) are met, including by creating "firewalls" between the personnel working under such Competitive Activities and the personnel teams charged with working on the Blueprint Compounds and Licensed Products hereunder or having access to data from activities performed under this Agreement or Confidential Information of the other Party.

## Article 3
## GOVERNANCE

**3.1** **Alliance Managers**. Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, all of which communications between the Parties will be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC, JPT, and Working Group meetings, in each case, as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC, a JPT, or applicable Working Group if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

**3.2** **Joint Steering Committee**.

3.2.1 **Formation**. No later than [****] after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to monitor and coordinate the Exploitation of the Blueprint Compounds and the Licensed Products in the Territory. The JSC will be composed of [****] representatives from each Party (unless otherwise agreed by the Parties) who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [****] prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. The JSC will be chaired by one of the representatives ("**JSC Chairperson**") and will rotate between the Parties every 12 months during the Term. The initial JSC Chairperson of the JSC will be a representative of Zai for the period ending [****], and a Blueprint representative will become the JSC Chairperson of the JSC for the next [****] period during the Term. The role of the JSC Chairperson will be to convene and preside at meetings of the JSC and to ensure that the Alliance Managers prepare minutes, but the JSC Chairperson will have no additional powers or rights beyond those held by the other JSC representatives. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.

3.2.2 **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [****] in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.2.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JSC may meet in person or by means of teleconference, internet teleconference, videoconference, or other similar communication method; *provided* that, [****] meeting each Calendar Year will be conducted in person at a location selected alternatively by Blueprint and Zai or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within [****] after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [****] thereafter.

3.2.4 **JSC Roles and Responsibilities**. The responsibilities of the JSC will be to:

(a) provide a forum for the discussion of the Parties' activities under this Agreement;

(b) review, discuss, and determine whether to approve the initial list of Preapproved Subcontractors and any updates thereto, as described in Section 2.2.3 (Right to Subcontract);

(c) oversee the JPTs and establish and oversee Working Groups as necessary or advisable to further the purpose of this Agreement and settle any disputes that arise within any JPT or Working Groups, as described in Section 3.6.2 (Resolution of JPT and Working Group Disputes);

(d) oversee the implementation of, and the coordination between the Parties of activities to be performed under, the Clinical Supply Agreement, the Commercial Supply Agreement, the Safety Agreements, and any other written agreement between the Parties with respect to the subject matter hereof;

(e) review, discuss, and determine whether to approve each Manufacturing Technology Transfer Plan, as described in Section 4.2 (Manufacturing Technology Transfer);

(f) review, discuss, and determine whether to approve any change in the scope of Manufacturing activities to be transferred to Zai in connection with the Manufacturing Technology Transfer for any Blueprint Compound and any updates or amendments thereto, as described in Section 4.2 (Manufacturing Technology Transfer);

(g) review, discuss, and determine whether to approve the [****] PRC Submission Estimated Timeline for each Licensed Product and each update thereto for each Licensed Product, in each case, as described in Section 5.6.2 (Amendments and Obligations);

(h) review, discuss, and determine whether to approve the initial Territory-Specific Development Plan for each Licensed Product and each update thereto, in each case, as described in Section 5.4 (Territory-Specific Development Plans);

(i) review and discuss the initial Global Development Plan for each Licensed Product and each update thereto for any Licensed Product, in each case, as described in Section 5.1 (Global Development Plan);

(j) review, discuss, and determine whether to approve allocation to Zai of any new or additional activities under the Global Development Plan, including any additional Committed Trials proposed by Blueprint, as described in Section 5.1 (Global Development Plan);

(k) review, discuss, and determine whether to approve for Development under this Agreement [****];

(l) review, discuss, and determine whether to approve any New Development Proposal, and review, discuss, and determine whether to approve any New Territory-Specific Development Activities, in each case, as described in Section 5.9 (New Development Proposed by Zai);

(m) review, discuss, and determine whether to approve the regulatory strategy for the Territory with respect to each Licensed Product and each update thereto, as described in Section 6.1 (Regulatory Strategy);

(n) review and discuss Zai's plan for undertaking additional regulatory activities for any Licensed Product delegated by Blueprint or the JSC to Zai, as described in Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals);

(o) review, discuss, and determine matters that may have a material adverse impact upon the regulatory status of the Licensed Products pursuant to Section 6.7 (No Harmful Actions);

(p) discuss and determine whether to approve [****];

(q) review, discuss, and determine whether to approve each Medical Affairs Plan and each update thereto, as described in Section 8.1 (Medical Affairs Plans);

(r) review, discuss, and determine whether to approve each Commercialization Plan and each update thereto, as described in Section 9.2 (Commercialization Plans);

(s) determine whether a Product Mark is not appropriate for the Territory due to linguistic reasons or market research showing that such Product Mark is not appropriate, and review and comment on any alternative Product Marks selected by Zai, in each case, as described in Section 14.9.2 (Product Marks in the Territory);

(t) review, discuss, and determine whether to approve any brand strategy for a Licensed Product that is specific to the Territory (or any region therein) and that is inconsistent with the Global Brand Strategy for such Licensed Product, as described in Section 9.2 (Commercialization Plans);

(u) review, discuss, and determine whether to approve any alternative Licensed Product-specific trademark selected by Zai in accordance with Section 14.9.2 (Product Marks in the Territory); and

(v) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

**3.3 Joint Project Teams**.

3.3.1 **Formation; Composition; Meetings**. No later than [****], the Parties will form one or more joint project teams to coordinate and oversee the day-to-day performance of the activities and obligations of the Parties under this Agreement related to the Exploitation of each Blueprint Compound and the corresponding Licensed Products (each, a "**JPT**"). Each JPT will be composed of representatives from each Party who have direct knowledge and expertise in each of the following functional areas (as applicable depending on the stage of the applicable Licensed Products): clinical, clinical operations, pharmaceutical and biologic product development (including Companion Diagnostics, to the extent applicable), regulatory, safety, manufacturing, intellectual property, marketing, and commercial, in each case, as such functional areas relate to products similar to the applicable Licensed Product. Initially, only one JPT will be formed for all Licensed Products, but the JPT may during the Term elect to form separate JPTs for one or more Licensed Products. Each Party may replace any of its representatives on a JPT and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [****] prior to the next scheduled meeting of the applicable JPT. An individual may serve on more than one JPT and each Party will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. Each Party's representatives on the JPT will inform and coordinate within their respective organization to enable each Party to fulfill its obligations within the time frames as agreed upon between the Parties under this Agreement. Each JPT will be chaired by one of the representatives ("**JPT Chairperson**") and will rotate between the Parties every [****] during the Term. The initial JPT Chairperson of each JPT will be a representative of Blueprint for the period [****] and a Zai representative will become the JPT Chairperson of each JPT for the next [****] period during the Term. Each JPT will meet as frequently as, and will operate as, the JSC may determine [****]. The role of the JPT Chairperson will be to convene and preside at meetings of the applicable JPT and to ensure that the Alliance Managers prepare minutes, but the JPT Chairperson will have no additional powers or rights beyond those held by the other JPT representatives. The JPTs may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communications method, and the JPT for each Blueprint Compound and corresponding Licensed Products may hold meetings at the same time as one or more other JPTs if agreed by the Parties. All meetings of each JPT will be held in English. Each JPT and its activities will be subject to the oversight of, and will report to, the JSC. In no event will the authority of any JPT exceed the authority of the JSC. Each Party will be responsible for all of its own costs and expenses of participating in the JPTs. The Alliance Managers will jointly prepare and circulate minutes for each JPT meeting within [****] after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [****] thereafter.

3.3.2 **JPT Roles and Responsibilities**. The responsibilities of the JPT will be to:

(a) oversee the day-to-day performance of the activities and obligations of each Party under this Agreement related to the Exploitation of each Blueprint Compound and Licensed Product;

(b) discuss and develop the Manufacturing Technology Transfer Plan for each Blueprint Compound, as described in Section 4.2 (Manufacturing Technology Transfer);

(c) review and discuss updates of any Blueprint Know-How related to any Blueprint Compound or Licensed Product developed by Blueprint or its Affiliates or licensees since the previous meeting, as described in Section 4.3 (Continuing Know-How Transfer);

(d) review, discuss, and submit to the JSC the [****] PRC Submission Estimated Timeline for each Licensed Product and each update thereto for each Licensed Product, as described in Section 5.6.2 (Amendments and Obligations);

(e) review, discuss, provide comments on, and submit to the JSC the Territory-Specific Development Plan for each Licensed Product, and each update thereto, as described in Section 5.4 (Territory-Specific Development Plans);

(f) review, discuss, and determine whether to approve the inclusion of any Non-Clinical Development in the Territory-Specific Development Plan for a Licensed Product, as described in Section 5.7 (Non-Clinical and Preclinical Studies);

(g) review and discuss the Global Development Plan for each Licensed Product, and each update thereto, as described in Section 5.1 (Global Development Plans);

(h) discuss, develop, and submit to the JSC the Global Development Plan for any Proposed Blueprint/Zai Combination, as described in Section 5.8.1 (Proposed Blueprint/Zai Combinations);

(i) review, discuss, provide comments on, and submit to the JSC any update to the Territory-Specific Development Plan for any Licensed Product that includes any New Territory-Specific Development Activities that have been approved by the JSC, as described in Section 5.9.1(a) (JSC Approval);

(j) discuss, develop, and submit to the JSC the regulatory strategy for the Territory for each Licensed Product, as described in Section 6.1 (Regulatory Strategy);

(k) review and monitor the Parties' compliance with the Safety Agreements, as described in Section 6.5.1 (Safety Agreements);

(l) review and monitor the Parties' compliance with and performance under the Clinical Supply Agreement, the Commercial Supply Agreement, and any other written agreement between the Parties with respect to the subject matter hereof, and review and discuss Manufacturing of the Licensed Products by each Party for the Territory;

(m) review, discuss, and comment on the Medical Affairs Plan for each Licensed Product and each update thereto, as described in Section 8.1 (Medical Affairs Plans);

(n) review and discuss each report provided by Zai of the Medical Affairs activities performed by or on behalf of Zai in the Territory for each Licensed Product, as described in Section 8.3 (Medical Affairs Reports);

(o) review, discuss, and comment on the Commercialization Plan for each Licensed Product and each update thereto, as described in Section 9.2 (Commercialization Plans);

(p) review and discuss each report provided by Zai of the Commercialization activities performed by or on behalf of Zai in the Territory for each Licensed Product, as described in Section 9.4 (Commercialization Reports);

(q) coordinate activities between the Parties with respect to certain Commercialization and Medical Affairs activities for the Licensed Products inside and outside of the Territory, as described in Section 8.4 (Coordination of Medical Affairs Activities) and Section 9.5 (Coordination of Commercialization Activities; Blueprint Support), respectively;

(r) raise matters for which the JPT is responsible to the JSC for discussion or resolution as appropriate; and

(s) perform such other functions as expressly set forth in this Agreement or allocated to JPT by the Parties' written agreement or by the JSC.

**3.4** **Working Groups**. From time to time, the JSC may establish joint working groups (each, a "**Working Group**") on an "as-needed" basis to oversee specific functional areas or activities and coordinate the day-to-day performance of such activities under this Agreement, which establishment of Working Groups will be reflected in the minutes of the meetings of the JSC. Each such Working Group will have at least two representatives of each Party and will be otherwise constituted, will meet as frequently as, and will operate as the JSC may determine. Working Groups may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communications method. Each Working Group and its activities will be subject to the oversight of, and will report to, the JSC. In no event will the authority of any Working Group exceed the authority of the JSC. Each Party will be responsible for all of its own costs and expenses of participating in any Working Group. The Alliance Managers will jointly prepare and circulate minutes for each Working Group meeting within [****] after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [****] thereafter.

**3.5** **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of the JSC (in a non-voting capacity), a JPT, or any Working Group if such participants have expertise that is relevant to the planned agenda for such JSC, JPT, or Working Group meeting; *provided that* if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Notwithstanding anything to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a *bona fide* concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting *(i.e.*, a consultant that also provides services to a Third Party with a Competitive Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

**3.6 Decision-Making**.

3.6.1 **General Process**. The JSC, the JPTs, and any Working Group will only have the powers expressly assigned to it in this Article 3 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with the terms of this Agreement. All decisions of the JSC, a JPT, and any Working Group will be made by unanimous vote, with each Party's representatives having one vote (*i.e.*, one vote per Party). No action taken at any meeting of the JSC or any JPT or Working Group will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if two voting representatives of each Party are present or participating in such meeting. [****]

3.6.2 **Resolution of JPT and Working Group Disputes**. The JSC will [****] to resolve all disputes that arise within a JPT or any Working Group within [****] after any such matter is brought to the JSC for resolution.

3.6.3 **Decisions of the JSC**. The JSC [****] to promptly resolve any such matter for which it has authority. If [****] the JSC is unable to resolve any such matter referred to it by the JPT or any Working Group or any matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [****], then a Party may refer such matter for resolution in accordance with 3.7.1 (Referral to Executive Officers) to the Chief Executive Officer of Blueprint (or an executive officer of Blueprint designated by the Chief Executive Officer of Blueprint who has the power and authority to resolve such matter) and the Chief Executive Officer of Zai (or an executive officer of Zai designated by the Chief Executive Officer of Zai who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**").

**3.7 Resolution of JSC Disputes**.

3.7.1 **Referral to Executive Officers**. If a Party makes an election under Section 3.6.3 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will [****] to resolve any such matter so referred to them [****], and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.7.2 **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter referred to them [****] after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:

(a) **No Change; Status Quo**. Neither Party will have final decision-making authority [****] and all such matters set forth in the foregoing [****] must be decided by unanimous agreement of the Parties in order to take any action or adopt any change from the then-current *status quo*.

(b) **Zai Decisions**. Except for any decision listed in Section 3.7.2(a) (No Change; Status Quo), Zai will have final decision-making authority with respect to [****]; *provided* that:

(i) [****]; and

(ii) [****].

(c) **Blueprint Decisions**. Except for any decision listed in Section 3.7.2(a) (No Change; Status Quo), Blueprint will have final decision-making authority with respect to [****] *provided* that [****].

3.7.3 **Limitations on Decision-Making**. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, no decision of the JSC or a Party's Executive Officer (in the exercise of a Party's final decision-making authority on any such matters), in each case, may make a decision that could reasonably be expected to (a) result in a [****] in the other Party's obligations, costs, or expenses under this Agreement, or any Global Development Plan or Territory-Specific Development Plan, unless, in each case, such actions are necessary for Blueprint to comply with Applicable Law as the Territory Sponsor or as the owner and holder of any Regulatory Submission, Regulatory Approval, or Reimbursement Approval, as applicable, for a Licensed Product in the Territory, (b) require the other Party to take any action that such other Party [****] would (i) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other Party or (ii) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party, (c) conflict with, amend, interpret, modify, or waive compliance under this Agreement, or (d) impose any obligation on either Party that would be in violation of such Party's written standard operating procedures, written business policies, or written compliance policies or procedures.

**3.8** **Discontinuation of JSC**. The JSC will continue to exist until the first to occur of (a) the Parties agreeing to disband the JSC, or (b) Blueprint providing written notice to Zai of its intention to disband and no longer participate in the JSC. Once the JSC is disbanded, the JSC will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to decisions of the JSC will automatically become references to decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.7.2 (Final Decision-Making Authority).

## Article 4
## TECHNOLOGY TRANSFERS

**4.1** **Initial Know-How Transfer**. [****] Blueprint will provide and transfer to Zai copies of Blueprint Know-How (other than Blueprint Manufacturing Know-How, the transfer of which will be performed pursuant to Section 4.2 (Manufacturing Technology Transfer)) that exists on the Effective Date to the extent not previously provided to Zai, including data and results required for Zai to file an IND for the Licensed Products, in each case, in the Territory (the "**Initial Know-How Transfer**"). Blueprint may make such Blueprint Know-How available in such reasonable form as Blueprint determines, including, if Blueprint so elects, in the form such Blueprint Know-How is maintained by Blueprint.

**4.2 Manufacturing Technology Transfer**.

4.2.1 **Initiation of Manufacturing Technology Transfer**. In addition to the Blueprint Know-How provided to Zai pursuant to the Initial Know-How Transfer, unless otherwise agreed by the Parties, on a Blueprint Compound-by-Blueprint Compound basis, upon [****] commencing [****] and ending no later than [****], Blueprint and Zai will jointly develop a draft Manufacturing Technology Transfer Plan for such Licensed Products containing such Blueprint Compound. Notwithstanding the foregoing, Blueprint will have the right to elect to initiate a Manufacturing Technology Transfer with respect to a Blueprint Compound at any time during the Term by developing a draft Manufacturing Technology Transfer Plan for Licensed Products containing such Blueprint Compound.

4.2.2 **Approval of Manufacturing Technology Transfer Plans**. Following development thereof, either Party will submit each Manufacturing Technology Transfer Plan to the JPT to review and discuss, and thereafter to the JSC to review, discuss, and determine whether to approve no later than [****] following either Party's submission to the JPT of each such plan. Blueprint or Zai may propose updates or amendments to any Manufacturing Technology Transfer Plan from time to time, and such updates or amendments will become effective upon approval thereof by the JSC.

4.2.3 **Manufacturing Transfer Plan Requirements**. Unless otherwise agreed by the JSC, each initial Manufacturing Technology Transfer Plan will contemplate the transfer to Zai of, at minimum, all Manufacturing steps that are necessary for Zai to obtain all applicable Regulatory Approvals (including Local Manufacturing Approvals) required to market and sell a locally-Manufactured version of such Licensed Product in the PRC in the name of Zai or its Affiliate. If transfer of the Manufacture [****] of a Blueprint Compound is not [****] for Zai to obtain all applicable Regulatory Approvals (including Local Manufacturing Approvals) required to market and sell a locally-Manufactured version of such Licensed Product in the PRC in the name of Zai or its Affiliate, and Manufacture [****] is not otherwise transferred to Zai under the initial Manufacturing Technology Transfer Plan for such Blueprint Compound, then, if requested by Zai and agreed to by Blueprint, Blueprint will prepare and submit to the JSC for approval, a Manufacturing Technology Transfer Plan for the transfer of Manufacture to Zai [****] of such Blueprint Compound.

4.2.4 **Performance of Manufacturing Technology Transfers**. If the Manufacturing Technology Transfer Plan for a Blueprint Compound contemplates the Manufacturing of the applicable Licensed Product from [****], then Blueprint will supply to Zai each of such [****] in accordance with Article 7 (Manufacturing). [****] Blueprint will perform (or cause one or more applicable Third Parties (including any CMO engaged by Blueprint to Manufacture such Licensed Product) to perform) a Manufacturing Technology Transfer for such Licensed Products containing such Blueprint Compound in accordance with such plan. The Parties will [****] complete the Manufacturing Technology Transfer for Licensed Products containing each Blueprint Compound [****] following the approval of the applicable Manufacturing Technology Transfer Plan pursuant to the applicable Manufacturing Technology Transfer Plan, but in any event [****]. Without limiting the foregoing, the Parties will [****] to complete a Manufacturing Technology Transfer with respect to each Licensed Product [****]. Thereafter during the Term, Blueprint (a) will provide Blueprint Manufacturing Know-How as part of the Continuing Know-How Transfer in accordance with Section 4.3 (Continuing Know-How Transfer) and (b) may transfer additional Manufacturing steps with respect to a Blueprint Compound to Zai by proposing another Manufacturing Technology Transfer Plan (or an amendment or update to a prior Manufacturing Technology Transfer Plan) to the JSC.

**4.3** **Continuing Know-How Transfer**. Following the applicable Manufacturing Technology Transfer for each Blueprint Compound and the Licensed Products containing such Blueprint Compound and the Initial Know-How Transfer for each Licensed Product, Blueprint will provide to the JPT in advance of its meeting [****] a summary of any additional Blueprint Manufacturing Know-How and other Blueprint Know-How, in each case, developed by Blueprint or its Affiliates or licensees since the previous quarterly summary that was provided to the JPT. Upon Zai's reasonable request during the Term, Blueprint will (a) make available to Zai all Blueprint Manufacturing Know-How and other Blueprint Know-How, in each case, in Blueprint's possession and not previously provided to Zai hereunder and that is necessary or reasonably useful for Zai's Exploitation of any Blueprint Compound or Licensed Product (as applicable) in accordance with this Agreement, (b) provide a schedule of applicable Blueprint Manufacturing Patent Rights following delivery of a Manufacturing Technology Transfer Plan, (c) transfer any such Blueprint Know-How or Blueprint Manufacturing Know-How, or provide such schedule, to Zai no later than [****] after Zai's request therefor, and (d) [****] after the Initial Know-How Transfer or Manufacturing Technology Transfer for a Blueprint Compound or Licensed Product (as applicable), provide Zai with reasonable access to Blueprint personnel involved in the Development or Manufacture of such Blueprint Compound or Licensed Product (as applicable) (and the corresponding Blueprint Compound), either in-person at Blueprint's facility or by teleconference (the "**Continuing Know-How Transfer**," and together with the Initial Know-How Transfer and the Manufacturing Technology Transfer, the "**Technology Transfers**"). Zai may only use the Blueprint Know-How to perform its obligations or exercise its rights under this Agreement and in accordance with the terms hereof. Notwithstanding anything to the contrary set forth in this Agreement, the terms of this Section 4.3 (Continuing Know-How Transfer) will not apply to any data or results of any Global Clinical Trial (including a Global Clinical Trial for a Licensed Product in a New Indication or for a Combination Product or Combination Regimen) unless [****]

**4.4** **Conduct of Technology Transfer**. Blueprint personnel will not be obligated to travel to Zai's (or its designee's) facilities in connection with the performance of any Technology Transfer. Any materials provided by Blueprint to Zai in connection with the transfer of Blueprint Know-How (including pursuant to any Technology Transfer) will remain the sole property of Blueprint.

**4.5** **Technology Transfer Costs**. Blueprint will provide consultation and assistance with qualified personnel in connection with the Technology Transfer for each Blueprint Compound and the Licensed Products containing such Blueprint Compound as reasonably requested by Zai, subject to personnel availability. Blueprint will be responsible for the internal costs of up to [****] of such consultation and assistance for each Blueprint Compound. Zai will reimburse Blueprint for (a) internal costs (at the FTE Rate) in excess of [****] of such consultation and assistance for each Blueprint Compound and (b) all out-of-pocket costs, in each case ((a) and (b)), reasonably incurred by or on behalf of Blueprint in connection with such assistance within [****] after receiving Blueprint's invoice therefor.

## Article 5
## DEVELOPMENT PROGRAM

**5.1** **Global Development Plan**. The global Development of Licensed Products that involves activities both inside and outside of the Territory will be conducted pursuant to a written Development plan (as updated from time to time in accordance with this Section 5.1 (Global Development Plan), the "**Global Development Plan**"). The initial Global Development Plan has been agreed by the Parties in writing on or prior to the Effective Date and is attached hereto as **Schedule 5.1** (Global Development Plan). [****] With respect to the Licensed Products, the Global Development Plan will be consistent with the overall global development synopsis for each such Licensed Product provided by Blueprint to Zai prior to the Effective Date, and will include, as applicable to each Licensed Product, all Global Clinical Trials (including Clinical Trials that Blueprint has determined will include trial sites both inside and outside of the Territory) for the Licensed Products. Zai will support the global Development of each Licensed Product by conducting certain Development activities in the Territory as set forth in, and in accordance with, the Global Development Plan, including by satisfying the enrollment requirements for the Committed Trials as required under Section 5.2 (Enrollment in Global Clinical Trials). The Global Development Plan will include for each Licensed Product [****]. From time to time, Blueprint (or the JPT, with respect to any Blueprint/Zai Combination) may make and implement updates to the then-current Global Development Plan for one or more Licensed Products, including to contemplate the conduct of the Development of any Licensed Product for a New Indication or a new Combination Product or Combination Regimen. To the extent such amendments (i) are [****], and (ii) include activities to be conducted in the Territory, Blueprint will submit such proposed updates to the JSC for review and discussion before adopting such updates, *provided*, *however*, that if the updates to the Global Development Plan include [****] in the Territory, including any additional proposed Committed Trials, then such update must be approved by the JSC.

**5.2** **Enrollment in Committed Trials**.

5.2.1 **Enrollment in Committed Trials**. Zai will, in accordance with the Global Development Plan for each Licensed Product, enroll and treat [****].

5.2.2 **Failure to Satisfy Patient Commitments**. On a Committed Trial-by-Committed Trial basis, unless the Parties otherwise agree in writing, if Zai fails to enroll the Patient Commitment in such Committed Trial, other than due to [****] then Zai will reimburse Blueprint for [****]. Zai will pay each Shortfall Reimbursement to Blueprint within [****] after receiving Blueprint's invoice therefor. For example, [****].

5.2.3 **Enrollment of Additional Patients in Committed Trials**. If requested by Blueprint for one or more Committed Trials and agreed to by Zai, then Zai will enroll and treat additional patients in each such Committed Trial in excess of the Patient Commitment and Blueprint will reimburse Zai for [****]. Blueprint will pay each Excess Enrollment Reimbursement to Zai within [****] after receiving Zai's invoice therefor. For example, [****]

5.2.4 **Data Access Criteria**. Subject to the terms of this Agreement, Blueprint and Zai will share in a timely fashion and allow the other Party to utilize data generated from each Party's on-going and future Clinical Trials and Regulatory Submissions for all Indications for the Licensed Products, including as set forth in Section 4.3 (Ongoing Know-How Transfer), Section 5.16 (Development Reports), Section 5.17 (Data Exchange and Use), and Section 6.4 (Right of Reference). [****] If Zai does not satisfy the criteria set forth in the foregoing clause (a) or (b), then Zai will not have any rights with respect to any data or results generated from such Global Clinical Trial for such Licensed Product, including pursuant to Section 4.3 (Ongoing Know-How Transfer), Section 5.17 (Data Exchange and Use) or pursuant to Section 6.4 (Right of Reference), except as necessary for Zai to comply with Applicable Law or safety reporting requirements of the applicable Regulatory Authorities in the Territory [****].

**5.3** **Zai Decision to Use a CRO**. If Zai decides to engage a Development Subcontractor to perform one or more Clinical Trials with respect to Licensed Products in the Territory assigned to Zai under the Global Development Plan on Zai's behalf, then, if applicable, Zai will [****] engaging a local Affiliate of the same contract research organization that Blueprint has engaged or plans to engage, in each case, to perform such Clinical Trials outside of the Territory (including if such Clinical Trial is a Committed Trials).

**5.4** **Territory-Specific Development Plans**. Except for the activities allocated to Zai under the Global Development Plan for a Licensed Product pursuant to Section 5.1 (Global Development Plan), all Development of each Licensed Product in the Territory under this Agreement will be conducted pursuant to a written development plan for each such Licensed Product (each, as updated from time to time in accordance with this Section 5.4 (Territory-Specific Development Plans) and Section 3.2 (Joint Steering Committee), a "**Territory-Specific Development Plan**"). At least [****] prior to Zai's planned initiation of any Development activities for a Licensed Product in the Territory that are not contemplated under the Global Development Plan, Zai will provide the applicable JPT with an initial draft of the Territory-Specific Development Plan for such Licensed Product for the JPT's review and comment. Each such Territory-Specific Development Plan will contain [****] (a) [****], (b) all major Clinical Development activities for such Licensed Product and all Territory-Specific Clinical Trials and the trial design thereof, in each case, to be conducted solely in furtherance of obtaining Regulatory Approval of such Licensed Product in the Territory (and not outside of the Territory) for the upcoming [****] period, (c) [****] timelines for achieving such activities described in (a) and (b), and (d) [****] key elements involved in obtaining Regulatory Approval of such Licensed Product from all applicable Regulatory Authorities throughout the Territory and the regulatory strategy for each Licensed Product for the Territory approved by the JSC pursuant to Section 6.1 (Regulatory Strategy). Each Territory-Specific Development Plan will include all Clinical Development required to obtain and maintain Regulatory Approval for the applicable Licensed Product in each region of the Territory. Zai will take the applicable JPT's comments [****] and incorporate such comments where appropriate prior to finalizing the initial Territory-Specific Development Plan for each Licensed Product. From time to time thereafter, [****] to include any New Territory-Specific Development Activities, Zai will propose updates to each Territory-Specific Development Plan in consultation with Blueprint through the applicable JPT and submit each initial Territory-Specific Development Plan and each such proposed updated Territory-Specific Development Plan to the JSC. The JSC will review, discuss, and determine whether to approve the initial Territory-Specific Development Plan for each Licensed Product and each update thereto. Once approved by the JSC, each update to a Territory-Specific Development Plan for a Licensed Product will become effective and supersede the then-current Territory-Specific Development Plan for such Licensed Product.

**5.5** **Development Diligence**. Subject to the terms of this Agreement, Zai will be responsible for and will use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval, and, if applicable, Reimbursement Approval, for [****] each Licensed Product that is the subject of a Territory-Specific Development Plan or Global Development Plan in the Field in the Territory. Without limiting the generality of the foregoing, Zai will use Commercially Reasonable Efforts to [****].

**5.6** **PRC Submission Estimated Timeline**.

5.6.1 **Other Licensed Products**. [****] the Parties have finalized the PRC Submission Estimated Timeline [****], in each case, such PRC Submission Estimated Timeline is included in the initial Global Development Plan. In addition, the JPT will develop a PRC Submission Estimated Timeline for any additional Licensed Products at the appropriate time. The JPT will submit each such PRC Submission Estimated Timeline to the JSC to review, discuss, and determine whether to approve.

5.6.2 **Amendments and Obligations**. The JPT will update, and will provide to the JSC to review, discuss, and determine whether to approve, the PRC Submission Estimated Timeline for each Licensed Product annually to include in detail the anticipated key regulatory activities for such Licensed Product [****] in the Territory and the dates on which such activities are estimated to occur. Without limiting the obligations set forth in Section 5.5 (Development Diligence), Zai will use Commercially Reasonable Efforts to: (a) make all Regulatory Submissions to the NMPA pursuant to and in accordance with Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals) for each Licensed Product and in accordance with the applicable PRC Submission Estimated Timeline (as may be amended by the JSC from time to time) [****] and (b) promptly obtain all approvals from the applicable Regulatory Authorities required to dose the first patient with each Licensed Product in Clinical Trials in the Territory.

**5.7** **Non-Clinical and Preclinical Studies**. Blueprint will be responsible for [****] Non-Clinical Development for all Licensed Products, other than specific Non-Clinical Development for any Licensed Product that (a) is required specifically in support of [****] for such Licensed Product in the Territory, which additional Non-Clinical Development will, subject to approval by the JPT [****] be included under the Territory-Specific Development Plan for such Licensed Product or (b) that the JPT otherwise agrees to include in a Territory-Specific Development Plan, and in each case ((a) or (b)), for which Zai will be responsible (such Non-Clinical Development, "**Permitted Zai Non-Clinical Development**"). Notwithstanding any provision to the contrary set forth in this Agreement, in no event will the JPT be permitted to withhold consent to Zai's performance of any specific Non-Clinical Development in the Territory that is required specifically in support of [****] for such Licensed Product in the Territory, unless[****]. Blueprint will provide support and cooperation as reasonably requested by Zai in connection with any such Permitted Zai Non-Clinical Development. In addition, Zai will provide support and cooperation as reasonably requested by Blueprint in connection with any Non-Clinical Development for any Blueprint/Zai Combination that is required to support [****] for such product outside of the Territory. The Party generating data and results (or on whose behalf such data and results are generated) in the course of conducting such Non-Clinical Development for any Licensed Product will provide such data and results to the other Party in accordance with Section 5.17 (Data Exchange and Use).

**5.8** **Proposed Blueprint/Zai Combination Products**.

5.8.1 **Proposed Combinations**. If the JPT wishes to include, under the Global Development Plan, Development of any Blueprint/Zai Combination (each, a "**Proposed Blueprint/Zai Combination**"), then the JPT will develop a Global Development Plan for such Proposed Blueprint/Zai Combination, which plan will include the conduct of a POC Trial for such Proposed Blueprint/Zai Combination and a regulatory strategy for the applicable Proposed Blueprint/Zai Combination and the conduct those Clinical Trials contemplated in such Global Development Plan. Thereafter, the JPT will submit such plans, along with details regarding the scope of intellectual property rights relating to the applicable Active Ingredient Controlled by Zai or its Affiliates that will be licensed or sublicensed (as applicable) to Blueprint (where any license for Blueprint to obtain any right to any Zai Product beyond the conduct of Clinical Trials in accordance with this Section 5.8.1 (Proposed Combinations) will only be as contemplated under an agreement or amendment to this Agreement entered into by the Parties pursuant to Section 5.8.2 (Further Exploitation of Proposed Blueprint/Zai Combinations)), to the JSC for its review, discussion, and approval.

(a) **JSC Approval**. If the JSC approves the Development under this Agreement of the applicable Proposed Blueprint/Zai Combination under the Global Development Plan, then [****].

(b) **No JSC Approval**. If the JSC does not approve the Development under this Agreement of a Proposed Blueprint/Zai Combination, then such Proposed Blueprint/Zai Combination will not be a Blueprint/Zai Combination for purposes of this Agreement and the Parties may not Exploit such Proposed Blueprint/Zai Combination under this Agreement unless and until the JSC approves the Development such Proposed Blueprint/Zai Combination hereunder.

5.8.2 **Further Exploitation of Proposed Blueprint/Zai Combinations**. If the JSC determines to approve the conduct of a Pivotal Trial as a Global Clinical Trial for any Blueprint/Zai Combination that was a Proposed Blueprint/Zai Combination approved by the JSC pursuant to Section 5.8.1 (Proposed Blueprint/Zai Combinations), then:

(a) the JSC will determine which Party will conduct such Pivotal Trial as a Global Clinical Trial;

(b) following completion [****];

(c) (i) Zai will not be required to grant any license to Blueprint to seek Regulatory Approval for, or Commercialize the Zai Product included in such Blueprint/Zai Combination, and (ii) Blueprint will not be required to grant any license to Zai to seek Regulatory Approval for, or Commercialize, the Blueprint Compound included in such Blueprint/Zai Combination, in each case ((i) and (ii)), unless the Parties reach agreement on the terms and conditions for such commercial arrangement under this Section 5.8.2 (Further Exploitation of Proposed Blueprint/Zai Combinations);

(d) notwithstanding any provision to the contrary set forth in this Agreement, no license will be deemed to have been granted to Blueprint or its Affiliates or (sub)licensees to Exploit any Zai Product, except that the license grant to Blueprint under Section 2.3 (License Grants to Blueprint) will include the right to Develop Blueprint/Zai Combinations solely through POC Trials if approved by the JSC pursuant to Section 5.8.1 (Proposed Combinations);

(e) the Parties will [****] reach agreement on such commercial arrangement prior to commencement of such Pivotal Trial or any further Development of such Blueprint/Zai Combination after completion of the POC Trial for such Blueprint/Zai Combination; and

(f) neither Party will conduct further Development or other Exploitation of the applicable Blueprint/Zai Combination inside or outside of the Territory, unless and until the Parties enter into a written agreement setting forth such terms as described above in Section 5.8.2(a) through Section 5.8.2(c).

**5.9** **New Development Proposed by Zai**. Notwithstanding Zai's final decision-making authority with respect to Development activities for a Licensed Product that are Territory-specific as set forth in Section 3.7.2(b) (Zai Decisions), if [****], then, in either case ((a) or (b)), Zai will present to the JSC to review, discuss, and determine whether to approve, a proposal to add such Development activities for such New Indication or such New Combination to the Territory-Specific Development Plan for the applicable Licensed Product, including the regions in the Territory in which such activities would be conducted (a "**New Development Proposal**"). Each New Development Proposal will describe [****] the applicable Non-Clinical Development and Clinical Trials that Zai desires to conduct with respect to such New Indication or such New Combination, including [****] (the "**New Development Activities**"), as well as [****] anticipated to result from such New Development Activities, and [****].

5.9.1 **JSC Decision Regarding New Development Activities**. The JSC will review, discuss, and determine whether to approve a New Development Proposal within [****] after receipt thereof from Zai.

(a) **JSC Approval**. If the JSC approves a New Development Proposal, then upon such an approval, (i) the New Development Activities set forth in such New Development Proposal will be "**New Territory-Specific Development Activities**" for purposes of this Agreement, and (ii) the JPT will update the Territory-Specific Development Plan for such Licensed Product to include such New Territory-Specific Development Activities for those regions in the Territory agreed by the JSC, including the proposed timelines, in each case, for such New Development Activities set forth in such New Development Proposal (as may be amended by the JSC upon such approval). Any New Territory-Specific Development Activities included in a Territory-Specific Development Plan pursuant to this Section 5.9.1(a) (JSC Approval) will be Development activities for all purposes under Section 5.5 (Development Diligence).

(b) **No JSC Approval**. If the JSC fails to approve a New Development Proposal, then upon such a failure, the New Development Activities proposed in the New Development Proposal will not be included in any Territory-Specific Development Plan and Zai will not perform any such New Development Activities.

**5.10** **Standard of Conduct**. Each Party will perform, and will cause its Affiliates, sublicensees (or Sublicensees, as applicable), and subcontractors (or Subcontractors, as applicable) to perform, all Development activities for the Licensed Products under this Agreement (including under each Territory-Specific Development Plan and each Global Development Plan and any New Territory-Specific Development Activities) in good scientific manner, in a timely, professional manner, and in compliance with the applicable Territory-Specific Development Plan or Global Development Plan, as applicable, in accordance with GLP, cGMP, and GCP, as applicable, and in compliance with Applicable Law and with applicable FDA and EMA requirements to the extent necessary for the submission of data generated from such activities in Regulatory Submissions in the U.S. and the European Union. In addition, each Party will conduct its obligations with respect to any Global Clinical Trial under a Global Development Plan or (with respect to Zai) Territory-Specific Clinical Trial under a Territory-Specific Development Plan (as applicable) in strict adherence with the study design set forth in the applicable protocol therefor and as set forth in such Global Development Plan or such Territory-Specific Development Plan, each as may be amended from time to time, and will comply with each statistical analysis plan implemented by the other Party (as applicable) in connection therewith. Zai will not perform any Development of Blueprint Compounds or Licensed Products except for those activities set forth in a Territory-Specific Development Plan or set forth in, and allocated to Zai under, a Global Development Plan.

**5.11** **New Development Proposed by Blueprint**. At anytime during the Term, Blueprint may propose additional Committed Trials in addition to those identified on **Schedule 1.60** (Committed Trials) by adding additional Global Clinical Trials for Licensed Products in New Indications or as new Combination Products or Combination Regimens (beyond the Indications, Combination Products, and Combination Regimens contemplated by the then-current Committed Trials) to the Global Development Plan in accordance with Section 5.1 (Global Development Plan).

5.11.1 **Zai Election Not to Sponsor**. If the JSC does not approve the allocation of responsibility to Zai to serve as the Territory Sponsor or regulatory agent in the Territory for, or to otherwise implement in the Territory, such additional Global Clinical Trials added to the Global Development Plan by Blueprint for a Licensed Product for any New Indication or new Combination Product or Combination Regimen (beyond the Indications, Combination Products, and Combination Regimens contemplated by the then-current Committed Trials), then:

(a) **Not A Committed Trial**. The proposed Global Clinical Trial will not be considered a Committed Trial under this Agreement and Zai will not be obligated to implement such Global Clinical Trials in the Territory;

(b) **Right to Develop**. Notwithstanding any provision to the contrary set forth in this Agreement (including the terms of Section 2.1 (License Grant to Zai)), Blueprint will have the right to implement such Global Clinical Trials for such Licensed Product for such New Indication or for such new Combination Product or Combination Regimen globally (including in the Territory) [****]; and

(c) **Zai Assistance**. Zai will provide reasonable assistance to Blueprint to recruit and enroll patients from the Territory for such Global Clinical Trials [****].

5.11.2 **Patient Commitment for Data Access**. If Zai wishes to be granted rights with respect to any data or results generated in such Global Clinical Trials for such Licensed Product for such New Indication or for such new Combination Product or Combination Regimen added to the Global Development Plan by Blueprint (beyond the Indications, Combination Products, and Combination Regimens contemplated by the then-current Committed Trials), including pursuant to Section 4.3 (Continuing Know-How Transfer), Section 5.17 (Data Exchange and Use) or Section 6.4 (Right of Reference), then: (a) each Global Clinical Trial for such Licensed Product for such New Indication or such new Combination Product or Combination Regimen will be considered a Committed Trial for all purposes under this Agreement, (b) Zai will be obligated to satisfy the Patient Commitment with respect to all Global Clinical Trials for such Licensed Product for such New Indication or such new Combination Product or Combination Regimen, and (c) the terms of Section 5.2 (Enrollment in Global Clinical Trials) will apply to all Global Clinical Trials for such Licensed Product for such New Indication or for such new Combination Product or Combination Regimen.

**5.12** **Development of Co-Formulated Products**. Unless otherwise agreed by the Parties, in the course of performing their obligations and exercising their rights under this Agreement, neither Party will (independently or for or with any Third Party) Develop any co-formulated pharmaceutical or biologic product that includes a Blueprint Compound together with any Zai Product.

**5.13 Responsibility for Development Costs**.

5.13.1 **Territory-Specific Development Costs**. Except as otherwise set forth in this Agreement, [****].

5.13.2 **Global Development Costs**. Except as otherwise set forth in this Agreement, and otherwise subject to Section 5.1 (Global Development Plan), Zai will be responsible for and will pay (a) all Third Party out-of-pocket costs [****] (b) all other costs and expenses [****], (c) costs of [****], and (d) the internal costs (at the FTE Rate) of Blueprint personnel incurred [****]. Blueprint will invoice Zai quarterly for the foregoing costs incurred by or on behalf of Blueprint in such Calendar Quarter, and Zai will pay the undisputed invoiced amounts within [****] after the date of any such invoice.

5.13.3 **Shared Services**. Zai will be responsible for and will pay [****] of the Shared Services Costs incurred by Blueprint in connection with any Committed Trials. Blueprint will invoice Zai quarterly for the foregoing costs incurred by or on behalf of Blueprint in each Calendar Quarter, and Zai will pay the undisputed invoiced amounts within [****] after the date of any such invoice. Blueprint will be responsible for and will pay [****] of the Shared Services Costs incurred by Zai in the performance of any Committed Trials, if any. Zai will invoice Blueprint quarterly for the foregoing costs incurred by or on behalf of Zai in each Calendar Quarter, and Blueprint will pay the undisputed invoiced amounts within [****] after the date of any such invoice.

**5.14 Clinical Trial Audit Rights**.

5.14.1 **Conduct of Audits**. Upon reasonable notification by Blueprint [****], Blueprint or its representatives may conduct an audit of Zai, its Affiliates, or any Sublicensees, Subcontractors, and all Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees to perform Zai's obligations under any Global Development Plan or Territory-Specific Development Plan, in each case, to ensure that the applicable Global Clinical Trials and Territory-Specific Clinical Trials are conducted in compliance with the applicable Global Development Plan or Territory-Specific Development Plan, GCP, and Applicable Law and meet Blueprint's global Clinical Trial standards provided by Blueprint from time to time during the Term. [****] Blueprint will provide Zai with a written summary of Blueprint's findings of any deficiencies or other areas of remediation that Blueprint identifies during any such audit. Zai will use Commercially Reasonable Efforts to remediate any such deficiencies within [****] following Zai's receipt of such report[****]. Without limiting the foregoing, Zai will have the right to be present at any such audit conducted by Blueprint pursuant to this Section 5.14.1 (Conduct of Audits) of any Sublicensees, Subcontractors, or Clinical Trial sites.

5.14.2 **Deficient Sites and Replacement**. With respect to any Global Clinical Trial or Territory-Specific Clinical Trial, if either Party reasonably determines that any deficiencies with respect to a Clinical Trial site identified pursuant to Section 5.14.1 (Conduct of Audits) (each, a "**Deficient Site**") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) at such Deficient Site, then such Party will notify the other Party of such Deficient Site and the Parties will discuss and attempt to agree upon a remediation plan for such Deficient Site. If the Parties cannot agree to such a remediation plan for a Deficient Site that is participating in a Global Clinical Trial, then Zai will promptly remove such Deficient Site from the applicable Global Clinical Trial or Territory-Specific Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") within the Territory[****] (unless not permitted by Applicable Law or for ethical reasons). Any such Replacement Site will be compliant in all respects with Applicable Law and Blueprint's global Clinical Trial standards.

5.14.3 **Zai Audits**. Zai will provide Blueprint with copies of all quality oversight or audit reports prepared in connection with any audit that Zai or its Affiliates or Sublicensees conduct of any Sublicensee, Subcontractor, or Clinical Trial site that Zai or its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill Zai's obligations under a Global Development Plan or a Territory-Specific Development Plan no later than [****] after receiving or preparing any such report (as applicable), including English translations thereof. If Blueprint believes in good faith that any such quality oversight or audit report may be necessary in connection with obtaining, supporting, or maintaining one or more Regulatory Approvals for a Licensed Product or for other communications with Regulatory Authorities outside of the Territory, then upon Blueprint's request, Zai will provide a certified translation thereof [****].

**5.15** **Development Records**. Zai will, and will cause its Affiliates, Sublicensees, and Subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of Zai, and its Affiliates, Sublicensees, and Subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with 21 C.F.R. §11 and in accordance with Applicable Law of both the United States and the Territory. [****] Zai will maintain all such records relating to the Development of Licensed Products for a period of [****]. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Products in good scientific manner appropriate for regulatory and patent purposes. Zai will document all Non-Clinical Development and Clinical Trials in formal written study reports in accordance with GLP, cGMP, and GCP, as applicable, and in compliance with Applicable Law. Upon Blueprint's reasonable request, not more frequently than [****] during which Zai or its Affiliates, Sublicensees, or Subcontractors are performing or having performed Development activities for any Licensed Product, Zai will, and will cause its Affiliates, Sublicensees, and Subcontractors to, allow Blueprint to access, review, and copy such records (including access to relevant databases). Blueprint will have the right to use the data and results generated by or on behalf of Zai and its Affiliates, Sublicensees, and Subcontractors hereunder to Exploit the Blueprint Compounds and Licensed Products outside of the Territory and to perform Development activities under a Global Development Plan that are allocated to Blueprint thereunder. Each Party will ensure that all records or other documents that it transmits to the other Party electronically under this Agreement are transmitted over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

**5.16** **Development Reports**. No later than [****] during which Zai is performing, or having performed, Development activities for any Licensed Product, Zai will provide Blueprint[****] with [****] written reports [****] the Development activities performed during the period since the preceding report, the Development activities in process, and the future activities that Zai or its Sublicensees or Subcontractors expect to initiate, including a summary of the data, timelines, and results of such Development activities. Such reports will be in English. Zai will also establish a secure link that includes adequate encryption safeguards to provide Blueprint with electronic access to, and secure file transfer of, such information. Without limiting the foregoing, such reports will contain sufficient detail to enable Blueprint to assess Zai's compliance with its Development diligence obligations set forth in Section 5.5 (Development Diligence). Zai will [****] respond to Blueprint's [****] requests from time to time for additional information regarding significant Development activities for any Licensed Product performed by or on behalf of Zai or its Affiliates, Sublicensees, or Subcontractors. The Parties will discuss the status, progress, and results of all Development activities at each JSC meeting. Such reports will be the Confidential Information of Zai and subject to the terms of Article 11 (Confidentiality; Publication).

**5.17** **Data Exchange and Use**. Subject to Section 5.2.4 (Data Access Criteria) and Section 5.8.1(a) (JSC Approval), in addition to its adverse event and safety data reporting obligations set forth in Section 6.5 (Adverse Events Reporting), each Party will [****] provide the other Party with copies of all data and results and all supporting documentation (*e.g.*, protocols, investigator's brochures, case report forms, and analysis plans) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates, Sublicensees, or Subcontractors, if applicable, in the Development of each Licensed Product or any Companion Diagnostic, *provided, however*, that Blueprint may decline to receive copies of data and results of Development of a Blueprint/Zai Combination Product or other Combination Product or Combination Regimen. Zai will have the right to use and reference such data and results provided by Blueprint for the purpose of obtaining, supporting, and maintaining Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approval, as applicable, of the Licensed Products and Companion Diagnostics in the Territory, without additional consideration. Blueprint and its designees will have the right to use and reference such data and results provided by Zai for the purpose of obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of any Licensed Product or Companion Diagnostic (a) outside of the Territory during the Term, or (b) anywhere in the world following termination of this Agreement, in each case ((a) and (b)), without additional consideration.

**5.18** **Development of Companion Diagnostics**. In connection with the Development or Commercialization of any Licensed Product for which the JSC has approved a Territory-Specific Development Plan (as applicable) contemplating the Development of one or more companion diagnostic products to be used in connection with such Licensed Product (each a "**Companion Diagnostic**"), Zai may elect to Develop one or more Companion Diagnostics solely in the Territory. Unless otherwise allocated to Zai under a Global Development Plan for a Licensed Product, Blueprint will be responsible for Developing Companion Diagnostics for Licensed Products if such Companion Diagnostics are to be used with one or more Licensed Products inside and outside of the Territory. If JSC determines that Zai will Develop a Companion Diagnostic for use with the Commercialization of any Licensed Product in the Territory, then Zai will be responsible [****]. Without limiting Zai's reimbursement obligations under Section 5.13 (Responsibility for Development Costs) (which obligations pertain to the Development of each Licensed Product, including the cost to purchase Companion Diagnostics [****] to screen patients in connection with the Development of such Licensed Products), Blueprint will be responsible for [****] Notwithstanding Blueprint's responsibility for [****] if Zai wishes to use any Companion Diagnostic Developed by Blueprint in connection with Zai's Commercialization of any Licensed Product in the Territory, then Zai will reimburse Blueprint for: (a) [****] that are related to the Development of Companion Diagnostics for use with a Licensed Product solely in the Territory [****] and (b) with respect to [****] that are related to the Development of Companion Diagnostics for use [****] the Territory [****].

## Article 6
## REGULATORY

**6.1** **Regulatory Strategy**. [****] the JPT will discuss and develop a regulatory strategy for the Territory for each Licensed Product and will submit the same to the JSC to review, discuss, and determine whether to approve. From time to time the JPT may update the regulatory strategy for the Territory for any Licensed Product and submit the same to the JSC to review, discuss, and determine whether to approve. Once approved by the JSC, each update to a regulatory strategy for such a Licensed Product will become effective and supersede the then-current regulatory strategy for the Territory for such Licensed Product and such approved regulatory strategy will be included in the Territory-Specific Development Plan. The Parties will reasonably coordinate with respect to the implementation of the regulatory strategy for each Licensed Product in the Territory.

**6.2** **Zai's Regulatory Responsibilities**.

6.2.1 **Obtaining and Maintaining Regulatory Approvals**. Each Party will keep the other Party informed of regulatory developments related to the Licensed Products in each region in the Territory and will promptly notify the other Party in writing of any decision by any Regulatory Authority in the Territory regarding any Licensed Product.

(a) **In the PRC**. Prior to [****], Zai or one of its Affiliates will be responsible for undertaking all regulatory activities and interactions with Regulatory Authorities in the PRC for such Licensed Product in Blueprint's name as the express and authorized regulatory agent of record for Blueprint in the Territory and will take such actions on behalf of and for the benefit of Blueprint in the PRC in accordance with the applicable regulatory strategy approved by the JSC (including performing any and all regulatory activities assigned to Zai in this Agreement or by the JSC during the Term in connection with the Development or Commercialization of a Licensed Product in the Territory). Following [****] Zai or one of its Affiliates will be responsible for all regulatory activities and interactions with Regulatory Authorities in the PRC leading up to and including obtaining (to the extent not already obtained) and thereafter maintaining, Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approvals, as applicable, for such Licensed Product in the PRC in Zai's or its Affiliate's own name in accordance with the applicable regulatory strategy approved by the JSC. Prior to undertaking any such activities and interactions relating to obtaining and maintaining Local Manufacturing Approvals, Regulatory Approvals, or Reimbursement Approvals for any Licensed Product in the PRC, whether prior to or after [****] for the applicable Licensed Product, Zai will submit a [****] plan for undertaking the same to the JSC for review and discussion. Following [****] Zai or one of its Affiliates will continue to be responsible for all regulatory activities and interactions with Regulatory Authorities in the PRC with respect to any imported version of such Licensed Product as the express and authorized regulatory agent of record for Blueprint in the PRC and will continue to take such actions with respect to the imported Licensed Product on behalf of and for the benefit of Blueprint in the PRC in accordance with the applicable regulatory strategy approved by the JSC.

(b) **Obtaining and Maintaining Regulatory Approvals outside the PRC**. Zai will be responsible for all regulatory activities with respect to Licensed Products leading up to and including obtaining, and thereafter maintaining, Regulatory Approvals and any Reimbursement Approvals in all regions of the Territory other than the PRC in its own name or in the name of its Affiliate, Sublicensee, or Third Party Distributor, in each case, in accordance with the regulatory strategy approved by the JSC.

6.2.2 **Consultation with NMPA**. If Blueprint determines in its reasonable discretion that a consultation meeting with the NMPA may be necessary to conduct any Development of Licensed Products in the Territory contemplated under this Agreement, then at Blueprint's reasonable request, Zai will request a consultation meeting with the NMPA to discuss such Development in advance of commencing such Development. In such event, the Parties will coordinate with each other regarding the contents of any materials to be shared with the NMPA in connection with such meeting.

6.2.3 **Review of Regulatory Submissions**. Zai will provide to Blueprint for review and comment drafts of all Regulatory Submissions in the Territory for the Licensed Products. Zai will incorporate any [****] comments received from Blueprint on such Regulatory Submissions. In addition, each Party will notify the other Party of any Regulatory Submissions for the Licensed Products and any comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and will provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [****] after submission or receipt thereof (or such longer time period as may be necessary to obtain translations thereof). If any such Regulatory Submission, comment, or correspondence is not in English, then Zai will provide Blueprint with a certified English translation [****] after receipt of such Regulatory Submission, comment, or correspondence[****]. Blueprint will have the right to review and comment on all such Regulatory Submissions, and Zai will [****] and incorporate such comments [****]

6.2.4 **Notice of Meetings**. Each Party will provide the other Party with notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product no later than [****] after receiving notice thereof [****] Zai will lead any such meeting or discussion and Blueprint or its designee will have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. At Zai's request, Blueprint will reasonably cooperate with Zai in preparing for any such meeting or discussion. If Blueprint elects not to attend such meeting or discussion, then Zai will provide to Blueprint a written summary thereof in English [****] following such meeting or discussion.

6.2.5 **Zai Responsibility for Costs and Expenses**. Zai will be responsible for all costs and expenses incurred in connection with the performance of all regulatory activities leading up to and including obtaining and thereafter maintaining, Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approvals, as applicable, for each Licensed Product from Regulatory Authorities in the Territory.

**6.3** **Blueprint's Regulatory Responsibilities**. Other than with respect to a locally-Manufactured version of a Licensed Product following [****] therefor (if applicable), Blueprint will own and hold all Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals, as applicable, for all Licensed Products in the PRC, and upon Zai's reasonable request Blueprint will provide Zai with access to and copies of the applicable Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for such Licensed Products in the PRC. Following [****] with respect a locally-Manufactured version of a Licensed Product, Zai will own and hold the Local Manufacturing Approvals, Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals, as applicable, for such locally-Manufactured version of such Licensed Product (and any Combination Regimen of which such Licensed Product is a part) in the PRC, and upon Blueprint's reasonable request Zai will provide Blueprint with access to and copies of the applicable Local Manufacturing Approvals, Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for such locally-Manufactured version of such Licensed Product (and each Combination Regimen of which it is a part) in the PRC. For clarity, following [****], Blueprint will continue to own and hold the IDL and other Regulatory Submissions, Regulatory Approvals, and other approvals and authorizations in the PRC, as applicable, with respect to imported Licensed Products. Subject to Section 5.2.4 (Data Access Criteria) and Section 5.8.1(a) (JSC Approval), Blueprint will reasonably cooperate with Zai in obtaining any Regulatory Approvals and any Reimbursement Approvals, as applicable, for each Licensed Product in the Territory by providing access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for the Licensed Products, both inside and outside of the Territory, in each case, to the extent Controlled by Blueprint. Zai [****] in connection with providing any such access or further assistance to Zai.

**6.4** **Right of Reference**. Subject to Section 5.2.4 (Data Access Criteria) and Section 5.8.1(a) (JSC Approval), each Party will grant, and hereby does grant, to the other Party and its Affiliates, licensees, and Sublicensees a right of reference to all Regulatory Submissions pertaining to the Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates, including any Zai Product as necessary in relation to any Blueprint/Zai Combination. Subject to Section 5.8.1(b) (No JSC Approval), Section 5.8.2 (Further Exploitation of Proposed Additional Blueprint/Zai Combinations that are Blueprint/Zai Combinations), and Section 5.11 (New Development Proposed by Blueprint), Zai and its Affiliates and Sublicensees may use such right of reference to Blueprint's Regulatory Submissions solely for the purpose of seeking, obtaining, supporting, and maintaining Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approvals, as applicable, for the applicable Licensed Product in the Field in the Territory, as Blueprint's authorized regulatory agent of record, or on its own behalf for a locally-Manufactured version of a Licensed Product following [****] for such Licensed Product. Subject to Section 5.8.1(b) (No JSC Approval) and Section 5.8.2 (Further Exploitation of Proposed Additional Blueprint/Zai Combinations that are Blueprint/Zai Combinations), Blueprint and its Affiliates, licensees, and Sublicensees may use such right of reference to Zai's Regulatory Submissions, if any, solely for the purpose of seeking, obtaining, supporting, and maintaining Regulatory Approval and any Reimbursement Approvals of Licensed Products outside of the Territory. Each Party will bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 6.4 (Right of Reference). Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 6.4 (Right of Reference) and to give the other Party the benefit of the granting Party's Regulatory Submissions in the other Party's territory as provided herein. Such actions may include (a) providing to the other Party copies of correspondence and communications received from the applicable Regulatory Authorities related to such Party's application for Regulatory Approval of the Licensed Products in the Territory or outside of the Territory, as applicable, or (b) providing the other Party with any underlying raw data or information submitted by the granting Party to the Regulatory Authority with respect to any Regulatory Submissions Controlled by such granting Party or its Affiliates that relates to any Licensed Product.

**6.5 Adverse Events Reporting**.

6.5.1 **Safety Agreements**. [****] the Parties will enter into one or more written agreements setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to each Licensed Product (each a "**Safety Agreement**"). Each Safety Agreement will describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting, and exchange of information between the Parties concerning any adverse event experienced by a subject or, in the case of non-clinical studies, an animal in a toxicology study, and the seriousness thereof, whether or not determined to be attributable to any Blueprint Compound or Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) and will be sufficient to permit each Party and its Affiliates, licensees, or Sublicensees (as applicable) to comply with its legal obligations with respect thereto, including each Party's obligations as the owner or holder of Regulatory Approvals and Regulatory Submissions for such Licensed Product in the Territory or outside the Territory, as applicable. Each Safety Agreement will also detail each Party's responsibilities with respect to recalls and withdrawals of the applicable Licensed Product inside and outside of the Territory. If required by changes in Applicable Law, then the Parties will make appropriate updates to the applicable Safety Agreements. Each Party will comply with its respective obligations under each Safety Agreement and cause its Affiliates, licensees, and Sublicensees to comply with such obligations. Each Party will notify the other Party of any new planned Clinical Trials for any Licensed Product and the Parties will update the Safety Agreement to the extent necessary to comply with any applicable requirements set forth under Applicable Law or of any Regulatory Authorities related to adverse event reporting, drug safety, patient safety, pharmacovigilance, and risk management. Notwithstanding anything to the contrary in this Agreement or the Safety Agreement, each Party and its Affiliates, licensees, and Sublicensees will have the right to disclose information related to the safety of one or more Blueprint Compounds or Licensed Products to the extent that such disclosure is required for such Party to comply with its obligations under Applicable Law or the safety requirements of the applicable Regulatory Authorities. To the extent that there is a conflict between the terms of this Agreement and the terms of any Safety Agreement, the terms of the applicable Safety Agreement will govern with respect to the subject matter set forth therein.

6.5.2 **Safety Databases**. Zai will maintain a safety database in English for Clinical Trials for the Licensed Products conducted in the Territory under a Territory-Specific Development Plan[****]. During such time that Blueprint is the holder of Regulatory Approvals and Regulatory Submissions for a Licensed Product in the Territory, Zai will be responsible for, on Blueprint's behalf: (a) reporting to the applicable Regulatory Authorities in the Territory all quality complaints, adverse events, and safety data related to such Licensed Product for all Territory-Specific Clinical Trials or Global Clinical Trials conducted in the Territory; and (b) responding to safety issues and to all requests of Regulatory Authorities related to such Licensed Product in the Territory. Zai will provide Blueprint (i) secure, real-time access to Zai's safety database for the Licensed Products in the Territory, and (ii) upon Blueprint's request, query results from Zai's worldwide safety database for each Zai Product solely for the purpose of Developing Blueprint/Zai Combinations. Blueprint will maintain a global safety database for Global Clinical Trials for the Licensed Products conducted under each Global Development Plan [****].

6.5.3 **Notification Obligations**. Without limiting the provisions of Section 6.5.1 (Safety Agreements), Zai will be responsible for complying with all Applicable Law governing adverse events (including the reporting thereof) in the Territory and will comply fully with all applicable adverse event reporting recommendations and requirements in all regions in the Territory where Zai intends to Commercialize the applicable Licensed Product. Zai will notify Blueprint on a timely basis of any adverse events related to one or more Licensed Products occurring in the Territory. Zai will submit copies of reports of adverse events related to the Licensed Products to Blueprint simultaneously with submission thereof to the applicable Regulatory Authorities in the Territory, including any single case reports, together with an appropriate medical evaluation, as well as aggregate data, such as Periodic Safety Update Reports (PSURs) required by authorities. Each Party will notify the other in a timely manner and in any event [****] (or such shorter period as may be required for a Party to comply with its obligations under Applicable Law) of receiving any (a) serious adverse event reports from Clinical Trials for a Licensed Product that the applicable Party is monitoring, (b) notice from a Regulatory Authority, independent review committee, data safety monitoring board, or another similar clinical trial or post-marketing monitoring body alleging significant concern regarding a patient safety issue related to a Licensed Product, or (c) other material information relevant to the safety or efficacy of any Licensed Product.

**6.6** **Regulatory Audits**. In addition to its rights to conduct audits pursuant to Section 5.14 (Clinical Trial Audit Rights), upon reasonable notification, Blueprint or its representatives will be entitled to conduct audits of safety and regulatory systems, procedures, or practices of Zai or its Affiliates, Sublicensees, or Subcontractors (including Clinical Trial sites) relating to any Licensed Product. With respect to any inspection of Zai or its Affiliates, Sublicensees or Subcontractors (including Clinical Trial sites) by any Governmental Authority relating to any Licensed Product, Zai will notify Blueprint of such inspection (a) no later than [****] after Zai receives notice of such inspection [****] or (b) within [****] after the completion of any such inspection of which Zai did not receive prior notice. Zai will promptly provide Blueprint with all information related to any such inspection. To the extent permitted by Applicable Law, Zai will also permit Governmental Authorities outside of the Territory to conduct inspections of Zai or its Affiliates, Sublicensees, or Subcontractors (including Clinical Trial sites) relating to any Licensed Product, and will ensure that all such Affiliates, Sublicensees, and Subcontractors permit such inspections. Blueprint will have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection. Following any such regulatory inspection related to one or more Licensed Products, Zai will provide Blueprint with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to a Licensed Product) within [****] of Zai receiving the same, and (ii) an English translation of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to a Licensed Product) within [****] after receiving the same [****].

**6.7** **No Harmful Actions**. If either Party believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that could [****] of any Licensed Product in such Party's territory, then such Party will have the right to bring the matter to the attention of the JSC and the JSC will [****]. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth in this Agreement or in the applicable Global Development Plan), neither Party will communicate with any Regulatory Authority having jurisdiction outside of its respective territory with respect to any Licensed Product, unless for the purpose of seeking Regulatory Approval or so ordered by such Regulatory Authority, in which case, such Party will immediately notify the other Party of such order.

**6.8** **Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Zai relating to any Licensed Product, then Zai will notify Blueprint of such contact, inspection, notice, or action within [****] after receipt of such notice (or, if action is taken without notice, within [****] of Zai becoming aware of such action). If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Blueprint relating to any Licensed Product that is reasonably likely to have a material adverse impact on Zai's activities with respect to the Licensed Product in the Territory, then Blueprint will notify Zai of such contact, inspection, notice, or action within [****] after receipt of such notice (or, if action is taken without notice, within [****] of Blueprint becoming aware of such action), *provided* that, except to the extent disclosure is required pursuant to Applicable Law, Blueprint will not be required to disclose any information that is subject to a confidentiality restriction and will not be required to delay any response or action as a result of such notification requirement. Blueprint will have the final decision-making authority with respect to [****], but and will consider Zai's reasonable comments to such responses. Zai will have the final decision-making authority with respect to [****], but will incorporate Blueprint's reasonable comments to any such responses. [****] Upon Zai's request, Blueprint will provide an update on material regulatory actions taken with respect to the Licensed Products outside the Territory at regularly scheduled meetings of the JSC.

**6.9** **Notice of Other Actions**. In addition, each Party will promptly notify the other of any information that it receives regarding any threatened or pending action, inspection, or communication by or from a Third Party that would reasonably be expected to materially affect the Development of the Licensed Products.

## Article 7
## MANUFACTURING

**7.1** **Supply by Blueprint**.

7.1.1 **Development Supply**. [****] the Parties will enter into a clinical supply agreement for the supply to Zai of Licensed Products containing each Blueprint Compound (together with the corresponding quality agreement, each a "**Clinical Supply Agreement**") pursuant to which Zai will purchase from Blueprint its requirements of each such Licensed Product [****] as necessary for Zai to fulfill its obligations under this Agreement related to the Development of Licensed Products. [****] Pursuant to each Clinical Supply Agreement:

(a) **Sole Supply**. Blueprint will, subject to Section 7.2 (Supply by Zai) and any right for Zai to procure its own supply as set forth in such Clinical Supply Agreement, have the sole right to, either by itself or through a CMO, Manufacture and supply to Zai all Blueprint Compounds and Licensed Products containing such Blueprint Compounds, required by Zai for Development use in the Territory as set forth in a Territory-Specific Development Plan and to perform Zai's Development responsibilities under a Global Development Plan [****].

(b) **Supply Price**. Blueprint will supply the Blueprint Compounds and Licensed Products to Zai pursuant to this Section 7.1.1 (Development Supply) at a transfer price equal to [****], and Zai will pay such invoice, based on a payment schedule to be set forth in the Clinical Supply Agreement and in accordance with Section 7.1.3 (Shipment and Delivery).

7.1.2 **Commercial Supply**. [****] the Parties will enter into a commercial supply agreement (together with the corresponding quality agreement, the "**Commercial Supply Agreement**"), for the supply to Zai of (a) the [****] of each Licensed Product or such other form of such Licensed Product as the JSC may agree, in either case, until [****], and (b) until [****] Licensed Product, pursuant to which Zai will purchase from Blueprint its requirements of the same as necessary for Zai to fulfill its obligations under this Agreement related to the Manufacture and Commercialization of each Licensed Product in the Territory. Notwithstanding the entrance into any Commercial Supply Agreement, [****]. The Parties may also elect to amend the terms of a Commercial Supply Agreement into which the Parties have entered to contemplate the commercial supply to Zai of one or more additional Licensed Products in lieu of entering into a separate Commercial Supply Agreement for such Licensed Product. [****] Pursuant to all Commercial Supply Agreements for Licensed Products in the Territory:

(a) **Sole Supply**. Subject to Section 7.2 (Supply by Zai) and any right for Zai to procure its own supply as set forth in such Commercial Supply Agreement, Blueprint will have the sole right to, either by itself or through an Affiliate, CMO, or licensee, Manufacture and supply to Zai all such Licensed Products as required by Zai for Commercialization in the Territory in accordance with this Agreement. The Commercial Supply Agreement will [****].

(b) **Supply Price**. Blueprint will supply to Zai pursuant to this Section 7.1.2 (Commercial Supply) each Licensed Product (or Active Ingredient thereof, as applicable) at a transfer price equal to [****]. Blueprint will invoice Zai for such Licensed Products, and Zai will pay such invoice, based on a payment schedule to be set forth in the Commercial Supply Agreement and in accordance with Section 7.1.3 (Shipment and Delivery).

7.1.3 **Shipment and Delivery**. Delivery of all Blueprint Compounds and Licensed Products supplied by Blueprint under any Clinical Supply Agreement or Commercial Supply Agreement will take place [****].

**7.2 Supply by Zai**.

7.2.1 **Restriction on Manufacturing by Zai**. Zai will not Manufacture or have Manufactured any Blueprint Compound or any Licensed Product that contains such Blueprint Compound until the completion of a Manufacturing Technology Transfer for the applicable Blueprint Compound in accordance with Section 4.2 (Manufacturing Technology Transfer). Notwithstanding any provision to the contrary in this Agreement, unless otherwise subsequently agreed by Blueprint in a Clinical Supply Agreement or Commercial Supply Agreement, or otherwise in writing, in no event will Zai perform any step in the Manufacturing process for any Licensed Product [****].

7.2.2 **Clinical and Commercial Supply**. Following [****], Zai will Manufacture locally-Manufactured Licensed Products in the Territory for Development purposes or commercial use, as applicable, and will be responsible for all Manufacturing steps transferred to Zai under a Manufacturing Technology Transfer Plan, in each case, in the Territory [****]. Zai agrees that Zai's Manufacturing process with respect to each locally-Manufactured Licensed Product will at all times be in accordance with the Zai Specifications for such Licensed Product approved by Blueprint pursuant to Section 7.2.3 (Specifications) and cGMP and ICH Guidelines, and in compliance with Applicable Law.

7.2.3 **Specifications**. Unless the JSC determines that Zai will be granted rights only to package and label, but not otherwise Manufacture, a particular Licensed Product for Development or Commercialization purposes in the Territory, as part of the Manufacturing Technology Transfer for each Blueprint Compound and the Licensed Products containing such Blueprint Compound, Blueprint will provide Zai with Blueprint's written process and quality specifications for the Manufacturing drug product of such Licensed Product (the "**Blueprint Specifications**"). Zai will prepare written process and quality specifications for the Manufacture of drug product of such Licensed Products applicable to Zai's Manufacturing facilities, systems, processes, and capabilities, including how the foregoing relate to drug substance, drug product, in-process intermediates, raw materials, and reference material (the "**Zai Specifications**"), which Zai Specifications will be consistent in all respects with the Blueprint Specifications for such Licensed Product, unless the requirements of any Regulatory Authority or Applicable Law in the Territory necessitate any deviations from such Blueprint Specifications. Zai will provide to Blueprint all such Zai Specifications (and any subsequent changes thereto) for Blueprint's review, comment and approval. In addition, Zai will promptly provide to Blueprint for its review and approval any changes to the Zai Specifications for any Licensed Product at any time following Blueprint's approval of the Zai Specifications for such Licensed Product, and will provide such proposed amendment to Blueprint for Blueprint's review, comment and approval in accordance with the procedure described below. [****] Blueprint will either (a) approve the Zai Specifications for such Licensed Product (or any changes thereto), or (b) provide Zai with a written response to the Zai Specifications for such Licensed Product (or such changes thereto) that includes a description of any deficiencies or limitations that Blueprint has identified with respect thereto, and the Parties will cooperate to develop a plan for remediation with respect to any such deficiencies or limitations within a reasonable period of time thereafter. Following Zai's remediation of all deficiencies, Zai will provide Blueprint with a revised draft of the Zai Specifications for the applicable Licensed Product (or any subsequent changes to any Zai Specifications) for Blueprint's review and approval. Thereafter, and on a continuing basis for so long as Zai Manufactures a particular Licensed Product, Zai will (i) Manufacture and require its Affiliates and CMOs to Manufacture such Licensed Product is at all times in accordance with the Blueprint-approved Zai Specifications for such Licensed Product and cGMP and ICH Guidelines, and (ii) complete any additional studies or testing required to maintain any qualifications and Regulatory Approvals (including manufacturing licenses) from any Regulatory Authorities or other Governmental Authorities necessary to continue to Manufacture such Licensed Product in the Territory and provide to Blueprint copies of reports from any such additional studies or testing in English[****].

7.2.4 **Second Source of Supply**. Blueprint will have the right at any time during the Term to request that Zai serve as a back-up supplier of one or more Licensed Products for use by Blueprint inside or outside of the Territory. Upon Blueprint's request, and Zai's agreement, following completion of the Manufacturing Technology Transfer with respect to a Blueprint Compound and the Licensed Products containing such Blueprint Compound, Zai will supply such Licensed Products to Blueprint for Blueprint's Exploitation of such Licensed Products outside of the Territory, as a second source of supply, at a price equal to [****].

**7.3** **Product Tracking in the Territory**. Zai will, and will ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Licensed Products to hospitals and pharmacies in the Territory.

## Article 8
## MEDICAL AFFAIRS

**8.1** **Medical Affairs Plans**. [****] Zai will develop and provide an initial draft of the Medical Affairs Plan for such Licensed Product to the JPT for its review and discussion. The Medical Affairs Plan for a Licensed Product will contain a [****] of the major Medical Affairs activities to be undertaken for such Licensed Product in the Territory and the estimated timelines for performing such activities, including all key opinion leaders that Zai plans to engage. The JPT will have the right to comment on each such Medical Affairs Plan and each update thereto, and Zai will consider such comments [****] and incorporate such comments [****] prior to finalizing each such Medical Affairs Plan (or any update thereto). Thereafter, from time to time, [****] Zai will propose updates to the Medical Affairs Plan for each Licensed Product in consultation with the JPT to reflect changes in such plans, including to account for relevant factors that may influence such plan and the Medical Affairs activities set forth therein. Zai submit each initial Medical Affairs Plan and each such proposed updated Medical Affairs Plan to the JSC. The JSC will review, discuss, and determine whether to approve each initial Medical Affairs Plan for each Licensed Product and each update thereto. Once approved by the JSC, each update to a Medical Affairs Plan for a Licensed Product will become effective and supersede the then-current Medical Affairs Plan for such Licensed Product.

**8.2** **Conduct of Medical Affairs Activities**. Zai will conduct all Medical Affairs activities for Licensed Products in the Territory in accordance with the applicable Medical Affairs Plan. Zai will not conduct any Medical Affairs activities with respect to Licensed Products except for those activities set forth in an applicable Medical Affairs Plan. Zai will, subject to Applicable Laws, conduct such activities in compliance with its internal policies on engaging and sponsoring healthcare providers.

**8.3** **Medical Affairs Reports**. For each Calendar Year following the first Regulatory Approval for a Licensed Product in the Territory, [****] Zai will provide to Blueprint a report (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities performed by or on behalf of Zai and its Affiliates and Sublicensees in the Territory for each Licensed Product in each region in the Territory since the prior report provided by Zai. Such reports will be Confidential Information of Zai and subject to the terms of Article 11 (Confidentiality; Publication). Zai will provide [****] updates [****] to any such report at each meeting of the JSC, JPT, and any Working Group established by the JSC to oversee Medical Affairs activities under this Agreement.

**8.4** **Coordination of Medical Affairs Activities**. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the Licensed Products inside and outside of the Territory. Accordingly, the Parties will coordinate such activities through the JPT where appropriate, including to ensure that medical information provided by each Party in their respective territories is consistent inside and outside of the Territory. Upon Zai's request, Blueprint will provide an update on Blueprint's material planned key Medical Affairs activities with respect to the Licensed Products outside the Territory at regularly scheduled meetings of the JSC.

## Article 9
## COMMERCIALIZATION

**9.1** **Commercialization Diligence Obligations**. Zai will be solely responsible for and will use Commercially Reasonable Efforts to Commercialize each Licensed Product in each region in the Territory after receiving Regulatory Approval and, if applicable, Reimbursement Approval for such Licensed Product in such region. Zai will conduct all Commercialization of each Licensed Product in the Territory in accordance with the Commercialization Plan for such Licensed Product, at its sole cost and expense. [****]

**9.2** **Commercialization Plans**. [****] Zai will develop and provide an initial draft of the Commercialization Plan for such Licensed Product to the JPT for its review and discussion. The Commercialization Plan for a Licensed Product will contain [****] Commercialization activities to be undertaken (including [****]) for such Licensed Product in the Territory and the estimated timelines for achieving such activities. The JPT will have the right to comment on each such Commercialization Plan and Zai will consider such comments [****] and incorporate such comments [****] prior to finalizing each such Commercialization Plan. Thereafter, from time to time, [****] Zai will propose updates to the Commercialization Plan for each Licensed Product in consultation with the JPT to reflect changes in such plans, including those in response to changes in the marketplace, relative commercial success of the applicable Licensed Product, and other relevant factors that may influence such plan and the Commercialization activities set forth therein. Zai will submit each proposed updated Commercialization Plan for a Licensed Product to the JPT for review and discussion and will consider [****] and incorporate [****] any comments thereon provided by the JPT before finalizing any such update. Zai submit each initial Commercialization Plan and each such proposed updated Commercialization Plan to the JSC. The JSC will review, discuss, and determine whether to approve each initial Commercialization Plan for each Licensed Product and each update thereto. Once approved by the JSC, each update to a Commercialization Plan for a Licensed Product will become effective and supersede the then-current Commercialization Plan for such Licensed Product. Each Commercialization Plan for a Licensed Product (including each update thereto) must be consistent with Blueprint's global brand strategy and global key messaging, and Global Brand Elements for such Licensed Product (each, a "**Global Brand Strategy**"), if and as provided to Zai by Blueprint from time to time during the Term; *provided*, *however*, that if the JSC agrees upon brand strategy for a Licensed Product that is specific to the Territory (or any region therein) and that is inconsistent with the Global Brand Strategy for such Licensed Product (including any product positioning or messaging for the Territory or any region therein), then Zai will have the right to implement such Territory-specific brand strategy within the Territory and to incorporate such inconsistent strategies in the Commercialization Plan for such Licensed Product.

**9.3** **Conduct of Commercialization Activities**. Zai will conduct all Commercialization of Licensed Products in the Territory in accordance with the applicable Commercialization Plan. Zai will not conduct any Commercialization activities with respect to Licensed Products except for those activities set forth in an applicable Commercialization Plan.

**9.4** **Commercialization Reports**. For each Calendar Year following the first Regulatory Approval for a Licensed Product in the Territory, [****] Zai will provide to Blueprint a report [****] summarizing the Commercialization activities performed by or on behalf of Zai and its Affiliates and Sublicensees in the Territory for each Licensed Product in each region in the Territory since the prior report provided by Zai. Each such report will contain sufficient detail to enable Blueprint to assess Zai's compliance with its Commercialization diligence obligations set forth in Section 9.1 (Commercialization Diligence Obligations). Such reports will be Confidential Information of Zai and subject to the terms of Article 11 (Confidentiality; Publication). Zai will provide updates to any such report at each meeting of the JSC, JPT, and any Working Group established by the JSC to oversee Commercialization activities under this Agreement.

**9.5** **Coordination of Commercialization Activities**. The Parties recognize that each Party may benefit from the coordination of certain Commercialization activities for the Licensed Products inside and outside of the Territory (other than pricing for the Licensed Products inside and outside of the Territory, the responsibilities for which are set forth in Section 9.6 (Pricing; Reimbursement Approvals)). Accordingly, the Parties will coordinate such activities through the JPT where appropriate, which coordination may include communications regarding product positioning.

**9.6** **Pricing; Reimbursement Approvals**. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to determine the price of the Licensed Products sold in its territory and neither Party will have the right to direct, control, or approve the pricing of the Licensed Products in the other Party's territory. Zai will keep Blueprint timely informed on (a) any [****] changes to the [****] pricing strategies with respect to any Licensed Product in the Territory, and (b) the status of any application for Reimbursement Approval for a Licensed Product in the Territory, including any discussion with any Regulatory Authority with respect thereto.

**9.7** **Diversion**. Each Party agrees that it will not, and will ensure that its Affiliates and licensees and subcontractors (or Sublicensees and Subcontractors, as applicable) will not, either directly or indirectly, promote, market, distribute, import, sell, or have sold any Licensed Products to any Third Party or to any address or Internet Protocol address or the like outside of such Party's respective territory, including via the Internet or mail order. Neither Party will engage, and each Party will not permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of the Licensed Products located in any country or jurisdiction outside of such Party's respective territory, or solicit orders from any prospective purchaser located in any country or jurisdiction outside of such Party's respective territory. If either Party or its respective Affiliates or licensees (or Sublicensees, as applicable) receives any order for any Licensed Products from a prospective purchaser located in a country or jurisdiction outside of such Party's respective territory, then such Party will immediately refer that order to the other Party and will not accept any such orders. Neither Party will, and neither Party will permit its Affiliates, licensees (or Sublicensees, as applicable), or subcontractors (or Subcontractors, as applicable) to, deliver or tender (or cause to be delivered or tendered) any Licensed Products to Third Parties for use outside of such Party's respective territory, except in accordance with a Global Development Plan or Territory-Specific Development Plan, or except in connection with a Manufacturing Technology Transfer pursuant to Section 4.2 (Manufacturing Technology Transfer) and Article 7 (Manufacturing). For purposes of this Section 9.7 (Diversion), (a) Zai's territory will be the Territory and (b) Blueprint's territory will be worldwide except for the Territory.

## Article 10
## PAYMENTS

**10.1** **Upfront Payment**. Within [****] after the Effective Date, Zai will pay to Blueprint by wire transfer of immediately available funds a non-refundable, non-creditable upfront payment of $25,000,000 in U.S. Dollars (the "**Upfront Payment**").

**10.2** **Milestone Payments**.

10.2.1 **Development Milestone Events and Payments**. No later than [****] after the earliest achievement of each development milestone event set forth below [****], Zai will pay to Blueprint the corresponding non-refundable, non-creditable development milestone payment set forth below (the development milestone events set forth in Table 10.2.1 the "**Development Milestone Events**" and the development milestone payments set forth in Table 10.2.1 the "**Development Milestone Payments**").

**Table 10.2.1 – LICENSED PRODUCT DEVELOPMENT MILESTONES**

| | *Development Milestone Events For Licensed Products* | *Development Milestone Event Payment (in U.S. Dollars)* |
|---|---|---|
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |

[****]

[****]

10.2.2 **Sales Milestone Events and Payments**. On a Licensed Product-by-Licensed Product basis, no later than [****] after the end of the first Calendar Quarter in which each sales milestone event set forth below for such Licensed Product is achieved, Zai will pay to Blueprint with respect to each Licensed Product the corresponding non-refundable, non-creditable sales milestone payment set forth below in Table 10.2.2 (the sales milestone events set forth in Table 10.2.2, the "**Sales Milestone Events**" and the sales milestone payments set forth in Table 10.2.2, the "**Sales Milestone Payments**"). If in a given Calendar Year more than one of the Sales Milestone Events set forth in Table 10.2.2 below is achieved with respect to a particular Licensed Product, then Zai will pay to Blueprint a separate Sales Milestone Payment with respect to each such Sales Milestone Payment that is achieved for the first time in such Calendar Year. For purposes of this Section 10.2.2 (Sales Milestone Events and Payments), (a) Licensed Products containing [****] and (b) Combination Products containing [****].

**Table 10.2.2 –SALES MILESTONES FOR LICENSED PRODUCTS**

| | *Sales Milestone Event* | *Sales Milestone Payment (in U.S. Dollars)* |
|---|---|---|
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |
| [****] | [****] | [****] |

[****]

10.2.3 **Milestone Conditions**.

(a) **Notification of Milestone Events**. Zai will promptly notify Blueprint in writing, but in no event later than (i) [****] after the achievement of each Development Milestone Event and (ii) [****]after the end of the Calendar Quarter in which each Sales Milestone Event is achieved (together with the Development Milestone Events, the "**Milestone Events**"). However, in no event will a failure by Zai to deliver such notice of achievement of a Milestone Event relieve Zai of its obligation to pay Blueprint the corresponding Development Milestone Payment or Sales Milestone Payment (collectively, the "**Milestone Payments**").

(b) **Skipped Milestone Events**. If Zai achieves any of the Development Milestone Events for a particular Licensed Product [****] but without the prior achievement of any corresponding earlier listed Development Milestone Events for such Licensed Product [****], then Zai will pay to Blueprint the applicable Milestone Payment to be made with respect to such earlier Development Milestone Events for such Licensed Product [****] at the same time as Zai pays the applicable Development Milestone Payment due upon achievement of such Development Milestone Event. For example, [****].

(c) **Maximum Milestone Payment Example.** For example: [****].

**10.3 Royalty Payments to Blueprint**.

10.3.1 **Royalty Rates**. Subject to the remainder of this Section 10.3 (Royalty Payments to Blueprint), Zai will make non-refundable royalty payments to Blueprint, on a Licensed Product-by-Licensed Product basis for Licensed Products sold in the Territory during the applicable Royalty Term, calculated by multiplying the applicable royalty rate set forth below in Table 10.3.1 by [****]. The royalty payments due with respect to Net Sales of each Licensed Product pursuant to this Section 10.3 (Royalty Payments to Blueprint), collectively the "**Royalty Payments**." For purposes of this Section 10.3 (Royalty Payments to Blueprint), (a) Licensed Products [****] and (b) Combination Products [****].

**Table 10.3.1 – LICENSED PRODUCT ROYALTY PAYMENTS**

| *Portion of Aggregate Calendar Year Net Sales of the same Licensed Product in the Territory (in U.S. Dollars)* | *Royalty Rate* |
|---|---|
| [****] | [****] |
| [****] | [****] |
| [****] | [****] |
| [****] | [****] |
| [****] | |

10.3.2 **Royalty Term**. Zai will pay to Blueprint the Royalty Payments on a Licensed Product-by-Licensed Product and region-by-region basis beginning on the date of the First Commercial Sale of such Licensed Product in such country or region and lasting until the later of: (a) [****] (b) [****] and (c) [****] ("**Royalty Term**").

10.3.3 **Royalty Reductions**.

(a) **Expiration of Valid Claims.** Subject to Section 10.3.3(c) (Cumulative Reductions Floor), on a Licensed Product-by-Licensed Product and region-by-region basis, if there is no Valid Claim of a Royalty Patent Right that Covers the Licensed Product [****] in such region, then, commencing [****] after the date on which this Section 10.3.3(a) (Expiration of Valid Claims) applies and for all [****] thereafter during which this Section 10.3.3(a) (Expiration of Valid Claims) applies, the applicable royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such region under Section 10.3.1 (Royalty Payments to Blueprint) will be [****]; *provided* that if such Licensed Product [****] subsequently becomes Covered by a Valid Claim within the Royalty Patent Rights in such region prior to [****], then the applicable royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such region will no longer be subject to the aforementioned reduction beginning at [****].

(b) **Offset For Third Party Licensing Payments**. Subject to Section 2.6 (Third Party In-Licenses) and Section 10.3.3(c) (Cumulative Reductions Floor), Zai will be entitled to, on a country-by-country basis, credit against the royalties due to Blueprint upon Net Sales of a Licensed Product in such country an amount equal to [****]of the total royalties paid by Zai to Third Parties with respect to license rights to Patent Rights, or Patent Rights together with Know-How, controlled by Third Parties that are necessary to avoid infringement of such Third Party rights in the Territory (i) [****] or (ii) [****].

(c) **Cumulative Reductions Floor**. In no event will the aggregate amount of Royalty Payments due to Blueprint for a Licensed Product in a region in the Territory in any given [****] during the Royalty Term for such Licensed Product in such region be reduced to less than [****] of the amount that otherwise would have been due and payable to Blueprint in such [****] for such Licensed Product in such region but for the reductions set forth in Section 10.3.3(a) (Expiration of Valid Claims) and Section 10.3.3(b) (Offset For Third Party Licensing Payments).

10.3.4 **Royalty Reports and Payments**. Commencing with the [****] during which the First Commercial Sale of a Licensed Product is made anywhere in the Territory, [****] Zai will provide Blueprint with [****] the amount of royalties payable by Zai for the applicable [****], on a Licensed Product-by-Licensed Product and region-by-region basis (each, a "**Royalty Estimate**"). [****] Zai will provide Blueprint with a detailed report for the applicable [****], on a Licensed Product-by-Licensed Product and region-by-region basis (each, a "**Royalty Report**") containing: (a) the amount of gross sales and Net Sales of each Licensed Product sold by Zai and its Affiliates and Sublicensees in each region and all deductions used to determine such Net Sales of each such Licensed Products for such [****], (b) a calculation of the Royalty Payment due on such Net Sales of each Licensed Product in each region, including any royalty reduction made in accordance with Section 10.3.3(a) (Expiration of Valid Claims) and Section 10.3.3(b) (Offset For Third Party Licensing Payments), (c) the exchange rate used for converting any Net Sales recorded in a currency other than Dollars, (d) any withholding taxes required to be made from such Royalty Payments, and (e) the quantity and description of each Licensed Product sold by Zai or its Affiliate or Sublicensee in each region in the Territory during such [****] comprising such Net Sales, including detailed sales reports for each Licensed Product for [****] in each region in the Territory. Concurrent with the delivery of the applicable Royalty Report, [****], Zai will pay the amount of the Royalty Payments set forth in the applicable Royalty Report to Blueprint in Dollars. If requested by Blueprint, the Parties will seek to resolve any questions or issues related to a Royalty Report within [****] following receipt by Blueprint of each Royalty Report.

**10.4** **Payments to Third Parties Under Existing Agreements**. Each Party will be solely responsible for any payments due to Third Parties under any agreement entered into by such Party prior to the Effective Date.

**10.5** **Other Amounts Payable**. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, within [****] after the end of each [****], each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such [****]. The owing Party will pay any undisputed amounts within [****] of receipt after the invoice, and any disputed amounts owed by a Party will be paid within [****] after resolution of the dispute. As used throughout this Agreement, a disputed amount owed by one Party to the other Party will be considered "undisputed" hereunder following a final, unappealable determination in accordance with Article 16 (Dispute Resolution) that such amount is owed.

**10.6** **No Refunds**. Except as expressly provided herein or in the case of an overpayment of Royalty Payments [****], all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

**10.7** **Accounting Standards**. If a Party changes its general accounting principles from the then-current standard (*e.g.*, from GAAP to IFRS) at any time during the Term, then at least [****] prior to adopting such change in principles, such Party will provide written notice to the other Party of such change.

**10.8** **Currency; Exchange Rate**. All payments to be made by Zai to Blueprint or Blueprint to Zai under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Blueprint or Zai, as applicable. Conversion of Net Sales recorded in local currencies will be converted to Dollars at the exchange rate set forth in *Wall Street Journal* or any successor thereto for [****].

**10.9** **Blocked Payments**. If by reason of Applicable Law in any country or region, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [****], in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

**10.10** **Late Payments**. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [****] as published by *The Wall Street Journal* or any successor thereto on the [****] in which such payments are overdue; or (b) the maximum rate permitted by Applicable Law; in each case, calculated on the number of days such payment is delinquent, compounded monthly.

**10.11** **Financial Records and Audits**. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount of royalty payments and other amounts payable under this Agreement. Upon reasonable prior notice, such records will be open during regular business hours for a period of [****] from the creation of individual records for examination by an independent certified public accountant selected by the examining Party and reasonably acceptable to the other Party for the sole purpose of verifying for the examining Party the accuracy of the financial reports furnished by the other Party (the "**Examined Party**") pursuant to this Agreement or of any payments made, or required to be made, by such Examined Party pursuant to this Agreement; *provided that* such independent accounting firm is subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Such audit will not be (a) performed more frequently than [****] during the Term or [****] after the expiration or termination of this Agreement, (b) conducted for any Calendar Year [****] after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records (unless a material discrepancy with respect to such records is discovered during a prior audit). Such auditor will not disclose the Examined Party's Confidential Information to the examining Party or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the Examined Party or the amount of payments by the Examined Party under this Agreement. The Examined Party will pay any amounts shown to be owed to the examining Party but unpaid within [****] after the accountant's report, *plus* interest (as set forth in Section 10.10 (Late Payments)) from the original due date. The examining Party will bear the full cost of such audit unless such audit reveals an underpayment by the Examined Party of [****], in which case the Examined Party will reimburse the examining Party for the reasonable audit fees for such examination.

**10.12** **Taxes**.

10.12.1 **Taxes on Income**. Except as set forth in this Section 10.12 (Taxes) or Section 10.13 (VAT Credits), each Party will be solely responsible for the payment of any and all Taxes levied on account of all payments it receives under this Agreement.

10.12.2 **Tax Cooperation**. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "**Paying Party**") is required to deduct and withhold Taxes on any payment to the other Party (the "**Recipient**"), the Paying Party will (a) pay the amount of such Taxes to the proper Governmental Authority in a timely manner, and (b) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient's applicable tax returns. The Paying Party will provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and will, to the extent practicable, provide the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. The Recipient will provide the Paying Party any tax forms that may be reasonably necessary in order for the Paying Party to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty, to the extent the Paying Party is legally able to do so. The Recipient will use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Paying Party if the Paying Party is the Party bearing such withholding Tax under this Section 10.12 (Taxes). In addition, the Parties will cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax, and other similar Taxes) in connection with this Agreement. In the event of any inconsistency between this Section 10.12 (Taxes) and Section 10.13 (VAT Credits), Section 10.13 (VAT Credits) will take precedence.

10.12.3 **Changes in Domicile**. Notwithstanding anything to the contrary in this Agreement, if the Paying Party assigns, transfers or otherwise disposes of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Law with respect to payments under this Agreement is increased, then any amount payable to the Recipient under this Agreement will be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Recipient receives an amount equal to the sum it would have received had no such withholding been made.

10.12.4 **Returns**. All transfer, documentary, sales, use, stamp, registration, and other such Taxes, and any conveyance fees, recording charges, and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, will be borne and paid by the Paying Party. The Paying Party will prepare and timely file all tax returns required to be filed in respect of any such Taxes. The Parties will reasonably cooperate in accordance with Applicable Law to minimize transfer Taxes in connection with this Agreement.

**10.13** **VAT Credits**. All payments due to Blueprint from Zai pursuant to this Agreement will be paid without any deduction for any VAT that Zai may be required to pay to any tax authorities in the Territory. Blueprint will use Commercially Reasonable Efforts to assist Zai to minimize and obtain all available exemptions from such VAT or other taxes, but if applicable, Zai will pay any such VAT to the proper taxing authorities upon receipt of a valid VAT invoice (where such invoice is required under local VAT laws). If Zai is required to pay or Blueprint is required to report, any such VAT, then [****]. Zai will promptly provide to Blueprint applicable receipts evidencing payment of such VAT and other documentation reasonably requested by Blueprint.

## Article 11
## CONFIDENTIALITY; PUBLICATION

**11.1** **Duty of Confidence**. Subject to the other provisions of this Article 11 (Confidentiality; Publication):

11.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for the Term and for [****] thereafter;

11.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

11.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

11.1.4 a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, licensees and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided that* such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, licensees, and Sublicensees, and its and its Affiliates', licensees', and Sublicensees' respective employees, directors, officers, agents, consultants, attorneys, accountants, banks, investors, advisors, and contractors, in each case, to treat such Confidential Information as required under this Section 11.1 (Duty of Confidence) (as if such Affiliates, licensees, Sublicensees, employees, directors, officers agents, consultants, advisors, attorneys, accountants, banks, investors, and contractors were Parties directly bound to the requirements of this Section 11.1 (Duty of Confidence)); and

11.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

**11.2** **Confidential Information**. The Blueprint Know-How and Blueprint Manufacturing Know-How will be the Confidential Information of Blueprint notwithstanding the fact that certain of such information may be developed or invented and disclosed to Blueprint by Zai. The Joint Collaboration Know-How and the terms of this Agreement will be the Confidential Information of each Party. The Zai Know-How will be the Confidential Information of Zai. Except as provided in Section 11.3 (Authorized Disclosures) and Section 11.7 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

**11.3 Authorized Disclosures**.

11.3.1 **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 11.1 (Duty of Confidence) and Section 11.6 (Publication and Listing of Clinical Trials), a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) (i) the Patent Prosecution, enforcement, and defense of Blueprint Patent Rights, Joint Collaboration Patent Rights, or Zai Collaboration Patent Rights, in each case, as contemplated by this Agreement; or (ii) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary or reasonably useful for the Exploitation of a Licensed Product;

(b) disclosure of this Agreement, its terms, and the status and results of Exploitation of one or more Licensed Products to actual or *bona fide* [****] solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 11 (Confidentiality; Publication) or otherwise customary for such type and scope of disclosure and that any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(c) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission, the Stock Exchange of Hong Kong Limited, or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider [****] comments provided by the non-disclosing Party; *provided* that [****]. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 11.3.1(c), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 11 (Confidentiality; Publication) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least [****] (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 11.3.1(c) (Permitted Circumstances);

(d) to prosecute or defend litigation [****];

(e) to present, disclose, and discuss general information about the existence of the Agreement and the general progress of the Licensed Products at investor press conferences or similar events; or

(f) disclosure pursuant to Section 11.6 (Publication and Listing of Clinical Trials) and Section 11.7 (Publicity; Use of Name).

11.3.2 **Confidential Treatment**. Notwithstanding anything to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 11.3.1 (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

**11.4** **Tax Treatment**. Nothing in Section 11.1 (Duty of Confidence) or 11.3 (Authorized Disclosures) will limit either Party in any way from disclosing to any Third Party such Party's U.S. or foreign income Tax treatment and the U.S. or foreign income Tax structure of the transactions relating to such Party that are based on or derived from this Agreement, or materials of any kind (including opinions or other Tax analyses) relating to such Tax treatment or Tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

**11.5** **Publications**.

11.5.1 Zai will not publicly present or publish any Clinical Trial data, non-clinical or preclinical data, clinical case study or review article, or any associated results or conclusions generated by or on behalf of Zai with respect to Licensed Products pursuant to this Agreement (each such proposed abstract, presentation or publication, a "**Zai Publication**"), except [****] with respect to the applicable Licensed Product as provided to Zai [****] during the Term upon Zai's request therefor, and subject to the additional limitations set forth in this Section 11.5 (Publications) and Section 11.6 (Publication and Listing of Clinical Trials). Blueprint will comply with this Section 11.5 (Publications) with respect to any presentation or publication of solely containing Clinical Trial data, non-clinical or preclinical data, clinical case study or review article, or any associated results or conclusions that were generated by or on behalf of Zai with respect to Licensed Products pursuant to this Agreement (each such proposed abstract, presentation or publication, a "**Blueprint Publication**" and together with a Zai Publication, a "**Publication**").

11.5.2 If Zai desires to publicly present or publish a Zai Publication or Blueprint desires to publicly present or publish a Blueprint Publication, then the publishing Party will provide the other Party (including the Alliance Manager and all of the other Party's members of the JSC) with a copy of such proposed Publication at least [****] prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). The publishing Party agrees that it will not submit or present any Publication until (a) [****]or (b) [****] in which case the publishing Party may proceed and the Publication will be considered approved in its entirety. If the publishing Party receives written comments from the other Party on any Publication during the applicable Review Period, then it will consider the other Party's comments [****] and incorporate such comments [****], but will retain the sole authority to publish the Publication.

11.5.3 Notwithstanding any provision to contrary set forth in this Agreement, each Party will (i) delete any Confidential Information of the other Party that the other Party identifies for deletion in the other Party's written comments, (ii) at the request of Blueprint, delete any Clinical Trial data, results, conclusions, or other related information for a Licensed Product the publication of which Blueprint determines, [****] would conflict with Blueprint's global publication strategy with respect to the applicable Licensed Product, except where required by Applicable Law to publicly disclose such information, (iii) at the request of the other Party, delete the structure or generic or internal name of the Licensed Product if such structure or name has not yet been publicly disclosed, and (iv) delay such Publication for a period of up to an additional [****] after the end of the applicable Review Period to enable the other Party, if applicable, to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. The publishing Party will provide the other Party a copy of the Publication at the time of the submission or presentation thereof. The publishing Party agrees to acknowledge the contributions of the other Party and the employees of the other Party, in each case, in all Publications as scientifically appropriate. Without limiting the foregoing, Blueprint agrees to acknowledge the contributions of Zai and the employees of Zai, in each case, in all presentations and publications as scientifically appropriate to the extent related to any Global Clinical Trials in which Zai assists in the enrollment of patients from the PRC. Each Party will require its Affiliates and licensees and Sublicensees, as applicable, to comply with the obligations of this Section 11.5 (Publications) as if they were such Party, and such Party will be liable for any non-compliance of such Persons.

**11.6 Publication and Listing of Clinical Trials**. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 11.6 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 11.5 (Publications).

**11.7 Publicity; Use of Names**.

11.7.1 **Press Release**. The Parties have agreed on a joint press release announcing this Agreement, set forth on **Schedule 11.7.1** (Press Release), to be issued by the Parties on such date and time as may be agreed by the Parties. Other than the press release set forth on **Schedule 11.7.1** (Press Release) and the public disclosures permitted by this Section 11.7 (Publicity; Use of Names), and Section 11.3 (Authorized Disclosures), the Parties agree that [****]. However, the Parties agree that after (a) a disclosure pursuant to Section 11.7 (Publicity; Use of Names) or Section 11.3 (Authorized Disclosures) or (b) the issuance of a press release (including the initial press release) or other public announcement pursuant to this Section 11.7.1 (Press Release) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate web site (or any website managed by such Party in connection with a Clinical Trial for a Licensed Product, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein.

11.7.2 **Authorized Disclosures**. Notwithstanding any provision to the contrary set forth in this Agreement, each Party has the right to publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) the commencement, completion, material data, or key results of any Territory-Specific Clinical Trials for the Licensed Products; (c) any information relating to any Global Clinical Trial, including the commencement, completion, material data, or key results of any such Global Clinical Trial; and (d) the achievement of Regulatory Approval for any Licensed Product in the Territory; *provided*, that, in each case of (a) – (d), any such public disclosure will (i) to the extent feasible, be provided to the other Party for review and comment [****] and (ii) in any event, be provided to the other Party for review and comment no later than [****] prior to public disclosure (unless a shorter timeframe is required under Applicable Law).

11.7.3 **Use of Names**. Each Party will have the right to use the other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 11.7 (Publicity; Use of Names); *provided* that each Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators. Except as permitted under this Section 11.7 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party's corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases issued pursuant to the terms of this Agreement. Zai will, to the extent consistent with Applicable Law, include explanatory text such as (a) "*Discovered by Blueprint Medicines Corporation*" in all publicity, promotion, news releases, or similar disclosures relating to the Licensed Products that are not Blueprint/Zai Combinations, and (b) "*Discovered in Collaboration by Blueprint Medicines Corporation and Zai Pharmaceuticals*" in all publicity, promotion, news releases, or similar disclosures relating to any Blueprint/Zai Combinations, in each case ((a) and (b)), or such other similar text provided by Blueprint and reasonably acceptable to Zai.

**11.8** **Attorney-Client Privilege**. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges. Notwithstanding the foregoing, nothing in this Section 11.8 (Attorney-Client Privilege) will apply with respect to a Dispute between the Parties (including their respective Affiliates).

## Article 12
## REPRESENTATIONS, WARRANTIES, AND COVENANTS

**12.1** **Representations and Warranties of Each Party**. Each Party represents and warrants to the other Party as of the Effective Date as follows:

12.1.1 It is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder.

12.1.2 It has not been Debarred/Excluded and no proceeding that could result it in being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Products, any employee, Subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded.

12.1.3 All consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

12.1.4 This Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

12.1.5 To its Knowledge, neither it nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on its behalf or any of its Affiliates:

(a) has taken any action in violation of any local and other anti-corruption laws (including the provisions of the United States Foreign Corrupt Practices Act, collectively "**Anti-Corruption Laws**"); or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

**12.2** **Representations and Warranties of Blueprint**. Blueprint represents and warrants to Zai as of the Effective Date with respect to itself and its Affiliates as follows:

12.2.1 It has the right under the Blueprint Technology to grant to Zai the licenses set forth in this Agreement, and it has not granted any license or other right under the Blueprint Technology that is inconsistent with the licenses purported to be granted to Zai hereunder.

12.2.2 [****]

12.2.3 There is no pending or, to Blueprint's Knowledge, threatened (in writing) litigation, nor has Blueprint received any written notice from any Third Party, asserting or alleging that the Exploitation of the Blueprint Compounds or the Licensed Products prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party.

12.2.4 There are no legal claims, judgments, or settlements against or owed by Blueprint or any of its Affiliates, or pending or, to Blueprint's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations.

12.2.5 To Blueprint's Knowledge, the Exploitation of the Blueprint Compounds as contemplated under this Agreement does not infringe any issued Patent Right of any Third Party.

12.2.6 [****]

12.2.7 Each employee of Blueprint and its Affiliates involved in the programs related to the Blueprint Compounds is bound by an agreement or policy requiring such employee to assign Inventions invented by such employee to Blueprint or such Affiliate.

12.2.8 Blueprint does not have agreements with any Third Parties under which Blueprint Controls any Blueprint Patent Rights or Blueprint Know-How as of the Effective Date.

12.2.9 All information provided by Blueprint to Zai for due diligence purposes in relation to this Agreement, to Blueprint's Knowledge, is complete and accurate in all material respects.

**12.3** **Representations and Warranties of Zai**. Zai represents and warrants to Blueprint as follows (a) [****], and (b) [****]:

12.3.1 It has the right under the Zai Technology to grant to Blueprint the licenses set forth in this Agreement, and it has not granted any license or other right under the Zai Technology that is inconsistent with the licenses purported to be granted to Blueprint hereunder.

12.3.2 There is no Zai Technology in existence as of the Effective Date.

12.3.3 There is no pending or, to Zai's Knowledge, threatened (in writing) litigation, nor has Zai received any written notice from any Third Party, asserting or alleging that the Exploitation of any Zai Product as part of any Blueprint/Zai Combination in the Territory as contemplated under this Agreement will infringe or misappropriate the intellectual property rights of such Third Party.

12.3.4 There are no legal claims, judgments, or settlements against or owed by Zai or any of its Affiliates, or pending or, to Zai's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations.

12.3.5 Zai has sufficient financial wherewithal to perform all of its obligations set forth under this Agreement as they come due.

12.3.6 Each employee of Zai and its Affiliates is bound by an agreement or policy requiring such employee to assign Inventions invented by such employee to Zai or such Affiliate.

12.3.7 Zai has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Manufacturing, Medical Affairs, Commercialization, and obtaining Regulatory Approvals, in each case, of the Blueprint Compounds and Licensed Products as contemplated under this Agreement.

12.3.8 None of the officers, directors, or employees of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case, that are employed or reside outside the United States, is a Public Official.

12.3.9 Zai or its Affiliate that will serve as Blueprint's regulatory agent (as applicable) in the PRC as contemplated by this Agreement has met all qualification requirements required under Applicable Law to be Blueprint's regulatory agent in the PRC as contemplated by this Agreement.

**12.4 Covenants of Zai**. Zai covenants to Blueprint that:

12.4.1 In the course of performing its obligations or exercising its rights under this Agreement, it will comply with all Applicable Law, including, as applicable, cGMP, GCP, and GLP standards, and all ethics policies agreed upon by the Parties in good faith, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded. Zai will make all related disclosures with respect to and record all transfers of value to health care providers in the Territory to the extent required by Applicable Laws. Zai will require any Affiliate, Sublicensee, Subcontractor, or other Person that provides services to or on behalf of Zai in connection with this Agreement to comply with Zai's obligations under this Section 12.4.1.

12.4.2 Zai will perform, and will cause its Affiliates and Sublicensees and their respective Subcontractors to, perform all necessary or required record filings with, and obtain all necessary or required licenses, approvals and permits from, all applicable Governmental Authorities in the Territory [****] for the conduct of activities, including Development activities and data sharing, under this Agreement, and provide Blueprint with copies of such record filings, licenses, approvals, and permits.

12.4.3 Throughout the Term, Zai or its Affiliate who will serve as Blueprint's regulatory agent in the PRC will at all times meet all qualification requirements required under Applicable Law to be Blueprint's regulatory agent in the PRC as contemplated by this Agreement. Zai will promptly notify Blueprint of any significant change to these qualification requirements and upon receiving any notice from any Third Party indicating, or otherwise becoming aware, that Zai or its Affiliate may not meet these requirements.

**12.5** **Mutual Covenants**. Each Party covenants to the other Party that:

12.5.1 Notwithstanding any provision to the contrary in this Agreement, each Party agrees as follows:

(a) It will not, in the performance of this Agreement, perform any actions that are prohibited by Anti-Corruption Laws that may be applicable to one or both Parties.

(b) It will not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws.

(c) At the request of the other Party, not more than [****], it will verify in writing to the requesting Party that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates or Sublicensees, or persons employed by or Subcontractors used by it or its Affiliates or Sublicensees in the performance of this Agreement, or will provide details of any exception to the foregoing.

(d) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Section 12.5 (Mutual Covenants) in order to document or verify compliance with the provisions of this Section 12.5 (Mutual Covenants), and upon request of the other Party upon reasonable advance notice, will provide to such requesting Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 12.5 (Mutual Covenants).

12.5.2 It and its Affiliates will, and will cause its and their licensees subcontractors (or Sublicensees and Subcontractors, as applicable) to, comply with all Applicable Laws pertaining to Personal Information (the "**Privacy Laws**") to which it is subject in connection with such Party's and its Affiliate's, licensees (or Sublicensee's, as applicable) or subcontractors (or Subcontractor's, as applicable) activities related to this Agreement. To the extent that such Party or its Affiliates, licensees (or Sublicensees, as applicable), or subcontractors (or Subcontractors, as applicable) access or come into possession of Personal Information in connection with activities related to this Agreement, such Party and its Affiliates agree, and will cause its and their licensees (or Sublicensees, as applicable) and subcontractors (or Subcontractors, as applicable), to comply with applicable Privacy Laws to which it may be subject as a result thereof. Any processing (including the collection, storage, use, transfer, provision, publication, and deletion) by such Party or its Affiliates, licensees (or Sublicensees, as applicable), or subcontractors (or Subcontractors, as applicable) of Personal Information obtained in connection with activities under this Agreement will be done solely for the purpose of performing such Party's obligations or exercising such Party's rights in connection with the Development of Licensed Products consistent with the terms of this Agreement, will be in accordance with notices provided to and consents obtained from the data subjects whose Personal Information is being processed, and will be in accordance with all applicable Privacy Laws. From and after the Effective Date, each Party and its Affiliates will take, and ensure that its licensees (or Sublicensees, as applicable) and subcontractors (or Subcontractors, as applicable) take, commercially reasonable and appropriate technical and organizational measures to protect Personal Information (including the results and any clinical data obtained in connection with any Clinical Trials conducted by or on behalf of such Party) in its possession against unauthorized access, accidental loss or damage, and unauthorized destruction. Such Party and its Affiliates will further maintain, and ensure that its licensees (or Sublicensees, as applicable) and subcontractors (or Subcontractors, as applicable) maintain, a commercially reasonable program for protecting against unauthorized access to or loss, misuse, alteration, destruction, damage or disclosure of Personal Information (including the results and any clinical data obtained in connection with Clinical Trials conducted by or on behalf of such Party) in its possession pursuant to its activities under this Agreement ("**Data Breach**"). In the event of a Data Breach, such Party will (i) promptly, and in any event so as to allow the other Party to comply with its obligations under Applicable Law, notify the other Party by phone and email after becoming aware of such Data Breach, and (ii) comply with the relevant requirements and procedures of the applicable Privacy Laws in resolving such Data Breach. With respect to all activities performed by such Party and its Affiliates under the Agreement, such Party and its Affiliates will use reasonable efforts to, and to ensure that its subcontractors (or Subcontractors, as applicable), implement multi-factor authentication and encryption promptly following the Effective Date. Prior to transferring any data, files, or results containing any Personal Information to the other Party its Affiliate, subcontractor (or Subcontractor, as applicable) or licensee (or Sublicensee, as applicable) hereunder, the Parties will agree upon the manner and format of such transfer and the transferring Party will provide any required notices to and obtain any necessary consents from Governmental Authorities and data subjects prior to a transfer. With respect to such transferred data, each Party will promptly notify the other Party by phone and email after receiving a data subject request from an individual whose Personal Information was transferred to the other Party or its Affiliate, subcontractor (or Subcontractor, as applicable) or licensee (or Sublicensee, as applicable), and will comply with, and inform its Affiliates, subcontractors (or Subcontractors, as applicable) or licensees (or Sublicensees, as applicable) of the need to comply with, the relevant requirements and procedures of the applicable Privacy Laws in responding to such data subject request. Each Party will have the right, upon reasonable advance notice and at a time agreed by the Parties, to audit the other Party's and its Affiliates' compliance with the requirements of this Section 12.5.2. To the extent permitted under Zai's agreements with its Sublicensees or Subcontractors, Blueprint will have the right to audit the data privacy and information security measures implemented by Zai's Sublicensees and Subcontractors performing activities under this Agreement. If such audit is not permitted under Zai's one or more agreements with its Sublicensees or Subcontractors, Zai will use reasonable efforts to obtain the right to conduct such an audit of the data privacy and information security measures of any such Sublicensees and Subcontractors.

**12.6 Covenants of Blueprint**. Blueprint covenants to Zai that:

12.6.1 Neither Blueprint nor any of its Affiliates will grant any license, sublicense, or other rights in or to the Blueprint Technology that is inconsistent with the terms and conditions of this Agreement.

12.6.2 During the Term Blueprint will comply with all Applicable Law applicable to its Development and Manufacture of the Blueprint Compounds and the Licensed Products pursuant to this Agreement, including, as applicable, cGMP, GCP, and GLP standards, and all ethics policies agreed upon by the Parties in good faith, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

**12.7** **NO OTHER WARRANTIES**. EXCEPT AS EXPRESSLY STATED IN THIS Article 12 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF BLUEPRINT OR ZAI; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT. ANY INFORMATION PROVIDED BY BLUEPRINT OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

**12.8** **Time for Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) the representations and warranties of the Parties contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Blueprint), and Section 12.3 (Representations and Warranties of Zai) will survive, with respect to direct claims made by one Party against the other Party, until the date that is [****] and (b) no claim may be made or suit instituted seeking indemnification pursuant to Article 13 (Indemnification) for any breach of, or inaccuracy in, any representation or warranty contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Blueprint), or Section 12.3 (Representations and Warranties of Zai) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [****].

## Article 13

## INDEMNIFICATION

**13.1** **By Zai**. Zai will indemnify, defend, and hold harmless Blueprint and its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Blueprint Indemnitee(s)**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to (a) the Exploitation of the Blueprint Compounds or the Licensed Products by or on behalf of Zai or any of its Affiliates, Sublicensees, or Subcontractors, including product liability claims arising from such Exploitation, (b) Zai's actions (or omissions) in the performance of its obligations with respect to Regulatory Submissions or interactions with Regulatory Authorities, in each case, as the authorized regulatory agent of record for Blueprint in the PRC, (c) the negligence or willful misconduct of Zai or any of its Affiliates, Sublicensees, or Subcontractors, (d) Zai's or its Affiliate's, Sublicensee's, or Subcontractor's breach of any of its representations, warranties, covenants, or obligations set forth in this Agreement, (e) the failure of Zai or any of its Affiliates, Sublicensees, or Subcontractors to abide by any Applicable Law, or (f) any claim or demand from any employee or contractor of Zai or its Affiliate who is an inventor of any Assigned Collaboration Technology or Joint Collaboration Technology with respect to the ownership thereof, in each case of clauses (a) through (f) above, except to the extent such Third Party Claims arise out of a Blueprint Indemnitee's negligence or willful misconduct, breach of its representations, warranties, covenants, or obligations set forth in this Agreement, or failure to abide by any Applicable Law.

**13.2** **By Blueprint**. Blueprint will indemnify, defend, and hold harmless Zai, its Affiliates, and their directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Zai Indemnitee(s)**") from and against all Losses incurred in connection with any Third Party Claims to the extent from or relating to (a) the Exploitation of the Blueprint Compounds or the Licensed Products, by or on behalf of Blueprint or any of its Affiliates, licensees (not including Zai or its Affiliates, Sublicensees, or its Subcontractors), Sublicensees, or Subcontractors, including product liability claims arising from such Exploitation, and including such Exploitation prior to the Effective Date or after the effective date of termination of this Agreement (including when acting as an exclusive distributor pursuant to Section 15.3.2 (Appointment as Exclusive Distributor), if applicable), (b) the negligence or willful misconduct of Blueprint or any of its Affiliates, licensees (not including Zai or its Affiliates, Sublicensees, or its Subcontractors), Sublicensees, or Subcontractors, (c) Blueprint's or its Affiliate's, licensee's (not including Zai or its Affiliates, Sublicensees, or its Subcontractors), Sublicensee's, or Subcontractor's breach of any of its representations, warranties, covenants, or obligations set forth in this Agreement, (d) the failure of Blueprint or any of its Affiliates, licensees (not including Zai or its Affiliates, Sublicensees, or Subcontractors), Sublicensees, or Subcontractors to abide by any Applicable Law, or (e) any claim or demand from any employee or contractor of Blueprint or its Affiliate who is an inventor of any Joint Collaboration Technology with respect to the ownership thereof, in each case of clauses (a) through (e) above, except to the extent such Third Party Claims arise out of any of a Zai Indemnitee's negligence or willful misconduct, breach of its representations, warranties, covenants, or obligations set forth in this Agreement or failure to abide by any Applicable Law.

**13.3** **Indemnification Procedure**. If either Party is seeking indemnification under Section 13.1 (By Zai) or Section 13.2 (By Blueprint) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations within [****] after receiving written notice of the Third Party Claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party that has been assumed by the Indemnifying Party. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. If the Parties cannot agree as to the application of Section 13.1 (By Zai) or Section 13.2 (By Blueprint) as to any Third Party Claim, pending resolution of the Dispute pursuant to Article 16 (Dispute Resolution), the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (By Zai) or Section 13.2 (By Blueprint), as applicable, upon resolution of the underlying Third Party Claim.

**13.4** **Insurance**. Each Party will procure and maintain during the Term of this Agreement [****], commercial general liability insurance from a minimum of "A-" AM Bests rated insurance company or insurer reasonably acceptable to Blueprint, including contractual liability and product liability or clinical trials, with coverage in an amount consistent with sound business practice and industry standards, and reasonable in light of the risks involved in its activities hereunder and its obligations under this Agreement. Such policies will name the other Party and its Affiliates as additional insureds and provide a waiver of subrogation in favor of the other Party and its Affiliates. Such insurance policies will be primary and non-contributing with respect to any other similar insurance policies available to the other Party or its Affiliates. Any deductibles for such insurance will be assumed by insured Party. Each Party will provide the other Party with evidence of such insurance upon the other Party's request and prior to expiration of any one coverage. Each Party will provide the other Party with written notice at least [****] prior to the cancellation or non-renewal of, or material adverse changes in, such insurance except for cancellation due to non-payment of premiums, in which case notice will be provided at least [****] prior to such cancellation. Such insurance will not be construed to create a limit of the insured Party's liability with respect to its indemnification obligations under this Article 13 (Indemnification).

## Article 14
## INTELLECTUAL PROPERTY

**14.1** **Inventions**.

14.1.1 **Ownership**. As between the Parties, (a) Blueprint will solely own all Blueprint Technology, including Assigned Collaboration Technology, and Blueprint Manufacturing Technology, (b) Zai will solely own all Zai Technology, and (c) the Parties will jointly own all Blueprint/Zai Combination Technology and other Joint Collaboration Technology.

14.1.2 **Disclosure**. Each Party will promptly disclose to the other Party all Inventions within the Collaboration Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such Inventions), including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto. Each Party will also promptly respond to reasonable requests from the other Party for additional information relating thereto.

14.1.3 **Inventorship**. For purposes of this Agreement, all determinations of inventorship will be in accordance with U.S. patent law.

14.1.4 **Assignment; Ownership of Joint Collaboration Technology**.

(a) **Assigned Collaboration Technology**. Zai will and hereby does assign to Blueprint all of its rights, title, and interests in and to all Assigned Collaboration Technology, and Blueprint hereby accepts such assignment. Zai will take (and cause its Affiliates, Sublicensees, Subcontractors, and their respective employees, agents, and contractors to take) such further actions reasonably requested by Blueprint to evidence such assignment and to assist Blueprint in obtaining patent and other intellectual property rights protection for Inventions within the Assigned Collaboration Know-How including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by Blueprint to establish, perfect, defend, or enforce its rights in any Assigned Collaboration Technology through prosecution of governmental filings, regulatory proceedings, litigation, and other means, including through the filing, prosecution, maintenance, and enforcement of the Assigned Collaboration Technology. Zai will obligate its Affiliates, Sublicensees, and Subcontractors to assign all Assigned Collaboration Technology to Zai (or directly to Blueprint) so that Zai can comply with its obligations under this Section 14.1 (Inventions), and Zai will promptly obtain such assignment. Without limitation, Zai will cooperate with Blueprint if Blueprint applies for U.S. or foreign patent protection for such Assigned Collaboration Technology and will obtain the cooperation of the individual inventors of any such Assigned Collaboration Technology. If Zai is unable to assign any Assigned Collaboration Technology, then Zai hereby grants and agrees to grant to Blueprint a royalty-free, fully paid-up, exclusive (even as to Zai, subject to the terms of this Agreement, including the licenses granted to Zai pursuant to Section 2.1 (License Grants to Zai)), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Assigned Collaboration Technology for any and all purposes.

(b) **Ownership of Joint Collaboration Technology**. The Parties will jointly own all Blueprint/Zai Combination Technology and all other Joint Collaboration Technology, [****] (subject to the terms of this Agreement, including the licenses granted under Article 2 (Licenses) and the rights retained under such licenses pursuant to Section 2.4 (Retained Rights)). For Blueprint/Zai Combination Technology solely invented by one Party, the inventing Party will and hereby does assign to the other Party a joint interest in and to all Blueprint/Zai Combination Technology, and the other Party hereby accepts such assignment. Each Party will take (and cause its Affiliates and Sublicensees, and their respective employees, agents, and contractors to take) such further actions reasonably requested by the other Party to evidence such assignment and to assist the Parties in obtaining jointly-owned Patent Rights and other intellectual property rights protection for Inventions within the Blueprint/Zai Combination Know-How including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by the Parties to establish, perfect, defend, or enforce their rights in any Blueprint/Zai Combination Technology through prosecution of governmental filings, regulatory proceedings, litigation, and other means, including through the filing, prosecution, maintenance, and enforcement of the Blueprint/Zai Combination Technology. Each Party will obligate its Affiliates, Sublicensees, and Third Party contractors (including all Subcontractors) to assign all Blueprint/Zai Combination Technology to such Party so that each Party can comply with its obligations under this Section 14.1 (Inventions), and each Party will promptly obtain such assignment. Without limitation, each Party will cooperate with the other Party if the Parties determine to apply for U.S. or foreign patent protection for such Blueprint/Zai Combination Technology in accordance with this Agreement and will obtain the cooperation of the individual inventors of any such Blueprint/Zai Combination Technology. If a solely inventing Party is unable to assign a joint interest in any Blueprint/Zai Combination Technology, then such Party hereby grants and agrees to grant to the other Party a royalty-free, fully paid-up, non-exclusive (subject to the terms of this Agreement, including the licenses granted to Zai pursuant to Section 2.1 (License Grants to Zai)), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Blueprint/Zai Combination Technology for any and all purposes.

(c) **Practice Under and other Use of Blueprint/Zai Combination Technology and other Joint Collaboration Technology**. Subject to the rights granted under and the restrictions set forth in this Agreement (including Section 2.8.1 (Exclusivity Covenant)), neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign, or otherwise exploit any Blueprint/Zai Combination Technology or other Joint Collaboration Technology by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Blueprint/Zai Combination Technology or other Joint Collaboration Technology, the other Party hereby grants such consent.

(d) **Employee Assignment**. Each Party and its respective Affiliates performing activities under this Agreement will enter into with each of their respective employees legally binding and sufficient agreements or employment policies providing for the payment by such Party or its Affiliate of any reward or remuneration required under Applicable Law in the applicable country or region in consideration for the development of Inventions by such employees. Without limiting the generality of the foregoing, each Party and its respective Affiliates will, and will cause its applicable licensees and Sublicensees, as applicable, to, enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to such Party (or its licensee or Sublicensee, as applicable) of all Collaboration Technology developed, invented, or filed by such employee during any performance under this Agreement; (b) automatically assigns to such Party (or its licensee or Sublicensee, as applicable) all rights, title, and interests in and to all Collaboration Technology, and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment; (c) includes an invention and patent reward and remuneration policy providing for the payment by such Party of any reward or remuneration required under Applicable Law in such region in consideration for the development of Inventions by such employees that is legally sufficient under Applicable Law; and (d) solely to the extent applicable, includes a waiver of pre-emption rights under any Applicable Law in such region, including in the case of an employee in the PRC, Article 326 of the Contract Law of the PRC to the effect that the employee will confirm that he/she will not have any right or claim with respect to any Collaboration Technology derived from his/her work, except for the reward and remuneration he/she is entitled to under the invention and patent reward and remuneration policy. [****]

(e) **Payments in Consideration of Assignments of Intellectual Property**.

(i) **Payment by Blueprint**. In consideration of the assignment by Zai to Blueprint of all Assigned Collaboration Technology and a joint ownership interest in all Blueprint/Zai Combination Technology, Blueprint will pay to Zai a one-time payment of [****], which payment will be payment in-full for the assignment of all Assigned Collaboration Technology and Blueprint/Zai Combination Technology hereunder regardless of how many patent applications are filed or patents are issued Covering the Assigned Collaboration Know-How or Blueprint/Zai Combination Know-How. Blueprint will notify Zai of Blueprint's filing of the first patent application claiming any Assigned Collaboration Know-How or Blueprint/Zai Combination Know-How with respect to which an employee of Zai is an inventor. Promptly thereafter, Zai will invoice Blueprint for the foregoing amount, and Blueprint will pay the undisputed invoiced amounts within [****] after the date of such invoice. The Parties expressly acknowledge that the foregoing amount is [****] and is [****].

(ii) **Reward and Remuneration Payments to Employees**. As between the Parties, Zai will be solely responsible for the payment of, and Zai will pay, any rewards and remuneration for inventions and technical achievements required by Applicable Law to be paid to its employees for the development or invention of any Collaboration Technology. As between the Parties, Blueprint will be solely responsible for the payment of, and Blueprint will pay, any rewards and remuneration for inventions and technical achievements required by Applicable Law to be paid to its employees for the development or invention of any Collaboration Technology.

**14.2 Patent Prosecution**.

14.2.1 **Blueprint Patent Rights**.

(a) **Right to Prosecute**. Subject to Section 14.2.3 (Joint Collaboration Technology), as between the Parties, Blueprint will have the right to control the Patent Prosecution of all Blueprint Patent Rights (including any Assigned Collaboration Patent Rights) and Blueprint Manufacturing Patent Rights throughout the world. Zai will obtain any necessary assignment documents for Blueprint with respect to the Patent Prosecution of such Patent Rights, to render all signatures that will be necessary for such patent filings, and to assist Blueprint in all other reasonably ways that are necessary for the issuance of such Patent Rights as well as for the Patent Prosecution of such Patent Rights. Zai will be responsible for [****] of the reasonable out-of-pocket costs incurred by or on behalf of Blueprint after the Effective Date with respect to the Patent Prosecution of such Patent Rights in the Territory, and will reimburse Blueprint for such costs [****] [****] after receiving an invoice with reasonable supporting documentation for such costs. Blueprint will be responsible for [****] of the out-of-pocket costs incurred by or on behalf of Blueprint with respect to the Patent Prosecution of such Patent Rights outside of the Territory.

(b) **Review and Consult**. Blueprint will consult with Zai and keep Zai reasonably informed of the Patent Prosecution of the Blueprint Patent Rights and Blueprint Manufacturing Patent Rights (following the applicable Manufacturing Technology Transfer) in the Territory and will provide Zai with all substantive correspondence received from any patent authority in the Territory in connection therewith. In addition, Blueprint will provide Zai with drafts of all proposed substantive filings in the Territory and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Blueprint Patent Rights and Blueprint Manufacturing Patent Rights (following the applicable Manufacturing Technology Transfer) in the Territory for Zai's review and comment prior to the submission of such proposed filings and correspondence. Further, Blueprint will notify Zai of any decision to cease Patent Prosecution of any Blueprint Patent Rights or Blueprint Manufacturing Patent Rights (following the applicable Manufacturing Technology Transfer) in the Territory. Blueprint will consider Zai's comments on Patent Prosecution [****] and will incorporate such comments [****].

(c) **Abandonment**. If Blueprint decides not to continue the Patent Prosecution of a particular Blueprint Patent Right or Blueprint Manufacturing Patent Right (following the applicable Manufacturing Technology Transfer) in any region in the Territory during the Term, then it will promptly [****] provide written notice to Zai of such decision. Zai may, upon written notice to Blueprint, assume the Patent Prosecution of such Patent Right in Blueprint's name [****]. In such event, (i) Blueprint will promptly deliver to Zai copies of all necessary files related to such Blueprint Patent Right or Blueprint Manufacturing Patent Right in such region(s) in the Territory and will take all actions and execute all documents reasonably necessary for Zai to assume such responsibility, (ii) Zai will continue to be responsible for [****] of the costs and expenses of the Patent Prosecution of such Patent Right, and (iii) Blueprint will have the rights to review and consult set forth in Section 14.2.1(b) (Review and Consult) *mutatis mutandis* (including that Zai will have final decision-making authority with respect to such Patent Prosecution activities).

14.2.2 **Zai Collaboration Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Zai will have the right to control the Patent Prosecution of all Zai Collaboration Patent Rights throughout the world. Zai will be responsible for [****] of the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights throughout the world.

(b) **Review and Consult**. Zai will consult with Blueprint and keep Blueprint reasonably informed of the Patent Prosecution of the Zai Collaboration Patent Rights inside and outside the Territory and will provide Blueprint with all substantive correspondence received from any patent authority in connection therewith. In addition, Zai will provide Blueprint with drafts of all proposed substantive filings and correspondence to any patent authority in connection with the Patent Prosecution of the Zai Collaboration Patent Rights for Blueprint's review and comment prior to the submission of such proposed filings and correspondence, [****]. Further, Zai will notify Blueprint of any decision to cease Patent Prosecution of any Zai Collaboration Patent Rights inside or outside the Territory. Zai will consider Blueprint's comments on Patent Prosecution [****] and will incorporate such comments [****].

(c) **Abandonment**. If Zai decides not to continue the Patent Prosecution of a particular Zai Collaboration Patent Right in any country or region inside or outside the Territory during the Term, then it will promptly [****] provide written notice to Blueprint of such decision. Blueprint may, upon written notice to Zai, assume such Patent Prosecution of such Zai Collaboration Patent Right in Zai's name [****]. In such event, (i) Zai will promptly deliver to Blueprint copies of all necessary files related to such Zai Collaboration Patent Right in such country(ies) or region(s) and will take all actions and execute all documents reasonably necessary for Blueprint to assume such responsibility, (ii) Blueprint will then be responsible for [****] of the future costs and expenses of the Patent Prosecution of such Patent Right, and (iii) Zai will have the rights to review and consult set forth in Section 14.2.2(b) (Review and Consult) *mutatis mutandis* (including that Blueprint will have final decision-making authority with respect to such Patent Prosecution activities).

14.2.3 **Joint Collaboration Technology**.

(a) **Joint Collaboration Technology and Blueprint/Zai Combination Technology**. Unless otherwise agreed upon by the Parties in connection with the JSC's approval of any Blueprint/Zai Combination, the provisions of this Section 14.2.3(a) (Joint Collaboration Technology and Blueprint/Zai Combination Technology) will apply with respect to the Patent Prosecution of the Blueprint/Zai Combination Patent Rights in addition to the other Joint Collaboration Patent Rights. Blueprint will control the Patent Prosecution of any Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Rights outside of the Territory, and Zai will control the Patent Prosecution of any Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Right inside of the Territory, *provided* that Blueprint will control [****]. The Parties will use [****] to agree on a mutually acceptable strategy for the Patent Prosecution of the Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Rights and will ensure that the external counsels engaged by each Party for the Patent Prosecution of such Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Rights coordinate with each other with respect to such Patent Prosecution of the Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Rights inside and outside of the Territory (including with respect to the timing of the filing of patent applications inside and outside of the Territory). The Party with the right to control the Patent Prosecution of any Blueprint/Zai Combination Patent Rights and any other Joint Collaboration Patent Right pursuant to this Section 14.2.3(a) (Joint Collaboration Technology and Blueprint/Zai Combination Technology) (the "**Prosecuting Party**") will be responsible for the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights in their respective territory[****].

(b) **Review and Consult**. The Prosecuting Party will consult with the other Party and keep the other Party reasonably informed of the Patent Prosecution of the Joint Collaboration Patent Rights in its respective territory and will provide the other Party with all substantive correspondence received from any patent authority in such territory in connection therewith. In addition, the Prosecuting Party will provide the other Party with drafts of all proposed substantive filings and correspondence to any patent authority in its respective territory in connection with the Patent Prosecution of the Joint Collaboration Patent Rights for the other Party's review and comment prior to the submission of such proposed filings and correspondence. Further, the Prosecuting Party will notify the other Party of any decision to cease Patent Prosecution of any of the Joint Collaboration Patent Rights in its respective territory. The Prosecuting Party will consider the other Party's comments on Patent Prosecution but will have final decision-making authority under this Section 14.2.3(b) (Review and Consult).

(c) **Abandonment**. If the Prosecuting Party decides not to continue the Patent Prosecution of a particular Joint Collaboration Patent Right in its respective territory during the Term, then it will promptly [****] provide written notice to the other Party of such decision. The other Party may, upon written notice to the Prosecuting Party, assume the Patent Prosecution of such Patent Right in the applicable territory. In such event, (i) such Party will [****] deliver to the other Party copies of all necessary files related to such Joint Collaboration Patent Right in such country(ies) or region(s) and will take all actions and execute all documents reasonably necessary for the other Party to assume such responsibility, (ii) the other Party will become the Prosecuting Party with respect to such Joint Collaboration Patent Rights in the applicable territory, (iii) the other Party will be responsible for [****] of the out-of-pocket costs incurred by the Prosecuting Party as set forth under Section 14.2.3(a) (Joint Collaboration Technology and Blueprint/Zai Combination Technology), and (iv) the other Party (that is no longer the Prosecuting Party) will retain the rights to review and consult set forth in Section 14.2.3(b) (Review and Consult).

14.2.4 **Cooperation**. Each Party will provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 14.2 (Patent Prosecution), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

**14.3 Patent Enforcement**.

14.3.1 **Notice**. Each Party will notify the other within [****] of becoming aware of any alleged or threatened infringement by a Third Party of any of the (a) Blueprint Patent Rights or Blueprint Manufacturing Patent Rights in the Territory, (b) Zai Collaboration Patent Rights in the Territory, or (c) Blueprint/Zai Combination Patent Rights or other Joint Collaboration Patent Rights in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "**Product Infringement**"). For clarity, Product Infringement excludes any adversarial Patent Prosecution proceedings.

14.3.2 **Enforcement Rights**.

(a) **First Right; Step-In**.

(i) **Blueprint First Right**. Unless otherwise agreed by the Parties in writing, Blueprint will have the first right to bring and control any legal action to enforce any Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Joint Collaboration Patent Rights other than the Blueprint/Zai Combination Patent Rights against any Product Infringement in the Territory as it reasonably determines appropriate, [****] and Blueprint will consider [****] the interests of Zai in such enforcement. [****]

(ii) **Zai First Right**. Zai will have the first right to bring and control any legal action to enforce the Blueprint/Zai Combination Patent Rights and Zai Collaboration Patent Rights against any Product Infringement in the Territory as it reasonably determines appropriate, [****] and Zai will consider [****] the interests of Blueprint in such enforcement. The Party with the first right to bring and control any legal action to enforce the Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, Zai Collaboration Patent Rights, Blueprint/Zai Combination Patent Rights, or other Joint Collaboration Patent Rights, as applicable, will be referred to herein as the "**Controlling Party**."

(iii) **Step-In Rights**. If the Controlling Party or its designee fails to abate such Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory related to Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, Zai Collaboration Patent Rights, or Joint Collaboration Patent Rights (including Blueprint/Zai Combination Patent Rights) within [****] after a written request from the other Party to do so, or if the Controlling Party discontinues the prosecution of any such action after filing without abating such infringement, then, in either case, the other Party will have the right, at such other Party's cost and expense, to enforce the applicable Patent Rights against such Product Infringement in the Territory as it reasonably determines appropriate *provided* that (A) the Controlling Party does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party), and (B) the other Party will not enter into any settlement admitting the invalidity of, or otherwise impairing, any such Patent Rights without the prior written consent of the Controlling Party.

(iv) **Zai's Rights**. Zai will have the sole right to bring and control any legal action to enforce Zai Patent Rights (other than Zai Collaboration Patent Rights) against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate. Zai will not have the right to enforce any Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, Zai Collaboration Patent Rights, Blueprint/Zai Combination Patent Rights, or other Joint Collaboration Patent Rights outside of the Territory.

14.3.3 **Cooperation**. At the request of the Party bringing an action related to a Product Infringement, the other Party will provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Law to pursue such action.

14.3.4 **Recoveries**. Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory will be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries relating to a claim of Product Infringement in the Territory in excess of such costs and expenses will be split as follows: [****].

**14.4 Infringement of Third Party Rights**.

14.4.1 **Notice**. If any Licensed Product used, sold, or manufactured (if applicable) by Zai or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then Zai will promptly notify Blueprint within [****] after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

14.4.2 **Defense**. Subject to any indemnification obligations under Section 13.2 (By Blueprint), Zai will be solely responsible for the defense of any such infringement claims brought against Zai[****]; *provided* that Zai will not agree to any settlement, consent to judgment, or other voluntary final disposition in connection with such defense action, in each case, without Blueprint's prior written consent (which consent will not be unreasonably delayed, withheld, or conditioned) if such settlement, consent to judgment, or other voluntary final disposition would (a) result in the admission of any liability or fault on behalf of Blueprint, (b) result in or impose any payment obligations upon Blueprint, or (c) subject Blueprint to an injunction or otherwise limit Blueprint's ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Blueprint Compound or Licensed Product. Zai will keep Blueprint informed on the status of such defense action, and Blueprint will have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense.

**14.5** **Patents Licensed from Third Parties**. Each Party's rights under this Article 14 (Intellectual Property) with respect to the Patent Prosecution and enforcement of any Patent Right that is in-licensed by Blueprint or Zai from a Third Party will be subject to the rights of such Third Party to prosecute, enforce, and defend such Patent Right.

**14.6** **Patent Listings**. With respect to patent listings in any patent listing system established by any applicable Regulatory Authority in a region in the Territory or under Applicable Law, including, (a) in the PRC, under Article 76 of the Patent Law of the PRC and its implementing measures and interpretations promulgated by relevant PRC Governmental Authorities, including the National Medical Products Administration (NMPA), the China National Intellectual Property Administration (CNIPA), and the Supreme People's Court, and (b) other equivalents thereof in the Territory, for Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Collaboration Patent Rights Covering any Licensed Product, the Parties will discuss and agree which Patent Rights to list in such patent listing in such region (the "**Listing Patents**") (i) prior to the submission of the first and any subsequent MAA for such Licensed Product in such region to such applicable Regulatory Authority, (ii) within [****], but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the receipt of the first and any subsequent Regulatory Approval in such region for such Licensed Product from such Regulatory Authority, including any additional Indication for such Licensed Product, (iii) within [****], but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the issuance in such region of a patent included in the Listing Patents, and (iv) within [****] following the submission of a new patent application in such region Covering any Licensed Product included in the Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Collaboration Patent Rights that has not been previously considered in any prior discussion and agreement of the Parties regarding Listing Patents; *provided* that, except as otherwise permitted under Applicable Laws, the Party holding the MAA for such Licensed Product in the Territory will not list, and will not be obligated to list, as of the date of listing, (A) any unissued patent, (B) any Patent Right that does not Cover the Licensed Product, (C) any patent that is of a type or that contains patent claims that are of a type not permitted to be listed under Applicable Law, or (D) any patent that such Party knows or has a reasonable basis to know is reasonably likely to be declared invalid by a competent Governmental Authority in such region. In furtherance of the foregoing clause (D), if either Party has such knowledge or reasonable basis, such Party will promptly notify and inform the Party of all facts and circumstances it is aware of underlying such knowledge or reasonable basis. In the event the Parties are unable to agree on which Patent Rights to list by the time required as provided under clause (i) to (iv) above, subject to the above proviso, Blueprint will have the final decision-making right over whether the Party holding the MAA for the applicable Licensed Product in the Territory will list any Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Joint Collaboration Patent Rights, and Zai will have the final decision-making right over whether the Party holding the MAA for the applicable Licensed Product in the Territory will list any issued patents included in the Zai Collaboration Patent Rights. The Party holding the MAA for the applicable Licensed Product in the Territory will promptly, and in any event at least [****] prior to the applicable deadline for listing under Applicable Laws, list the Listing Patents in the applicable patent listing system in the applicable regions in the Territory *provided*, that, without limiting the foregoing, if the Party holding the MAA for the applicable Licensed Product in the Territory has not listed the Listing Patents in the patent listing system of an applicable region before [****] prior to the deadline for listing in the applicable region, then the other Party may list the Listing Patents at anytime when permitted by Applicable Laws by providing prior written notice to the Party holding the MAA for the applicable Licensed Product in the Territory. The Party holding the MAA for the applicable Licensed Product in the Territory will provide copies of all documentation to be filed in connection with any such listing of Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Joint Collaboration Patent Rights to the other Party prior to filing thereof and will consider the other Party's comments with respect to such documentation in good faith. The Party holding the MAA for the applicable Licensed Product in the Territory will cooperate with the other Party to the extent reasonably requested by the other Party to effectuate the intent of this Section 14.6 (Patent Listings), including providing all documentation, certifications, and consents necessary to effectuate the foregoing and setting up an account to list patents on the applicable patent listing system, and granting the other Party access to and a right to use such account as reasonably necessary to effectuate the intent of this Section 14.6 (Patent Listings). Neither Party will list any patent in any patent listing system in a region in the Territory for the Licensed Product, except in accordance with this Section 14.6 (Patent Listings).

**14.7** **Patent Term Extensions**. With respect to any system for extending the term of Patent Rights in the Territory due to the time needed to obtain Regulatory Approval of a pharmaceutical product established by any applicable Regulatory Authority in any region in the Territory (a "**Patent Term Extension**"), adjusting the term of Patent Rights in the Territory due to the time needed to prosecute and obtain a grant of a Patent Right under Applicable Laws in any region in the Territory (a "**Patent Term Adjustment**"), or supplementary protection certificates and any other extensions that are now or become available in the future under Applicable Laws in any region in the Territory ("**Other Extensions**"), (a) Blueprint will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions, Patent Term Adjustments, or Other Extensions in the Territory that are applicable to Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Joint Collaboration Patent Rights and that become available directly as a result of the Regulatory Approval of a Licensed Product in the Territory or following issuance of a patent included in the Blueprint Patent Rights, Blueprint Manufacturing Patent Rights, or Joint Collaboration Patent Rights *provided* that Blueprint will consult with Zai with respect to such decisions and consider [****] the reasonable comments and concerns raised by Zai; and (b) Zai will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions, Patent Term Adjustments, and Other Extensions in the Territory that are applicable to Zai Collaboration Patent Rights and that become available directly as a result of the Regulatory Approval of a Licensed Product in the Territory or following issuance of a patent included in the Zai Collaboration Patent Rights; *provided* that Zai will consult with Blueprint with respect to such decisions and consider [****] the reasonable comments and concerns raised by Blueprint. The Party holding the MAA for the applicable Licensed Product in the Territory will make the appropriate filings and applications in the Territory in order to effectuate each Party's decisions regarding Patent Term Extensions, Patent Term Adjustments, or Other Extensions in the Territory in accordance with the foregoing sentence. The Party holding the MAA for the applicable Licensed Product in the Territory will cooperate with the other Party to the extent reasonably requested by the other Party to effectuate the intent of this Section 14.7 (Patent Term Extensions), including providing to the other Party all documentation, certifications, and consents necessary to make and prosecute such application and obtain such Patent Term Extension, Patent Term Adjustment, or Other Extension.

**14.8** **Filing of Agreement with CNIPA**. The Parties will file a redacted copy of this Agreement with the CNIPA as required by Applicable Law in the Territory no later than the date required under such Applicable Law.

**14.9** **Product Trademarks**.

14.9.1 **Global Brand Elements**. Zai acknowledges that Blueprint may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of each Licensed Product on a global basis (such trademarks, the "**Product Marks**" and such other branding elements together with the Product Marks, collectively, the "**Global Brand Elements**"). Blueprint will and hereby does grant Zai the exclusive right to use such Global Brand Elements in connection with the Commercialization of each Licensed Product in the Field in the Territory in accordance with the applicable Commercialization Plan.

14.9.2 **Product Marks in the Territory**. Zai will brand the Licensed Products in the Territory using Blueprint's Global Brand Elements; *provided*, *however*, a Product Mark may deviate from Blueprint's Global Brand Elements if (a) the JSC determines such Product Mark is not appropriate for the Territory due to linguistic reasons or market research showing that such Product Mark is not appropriate, (b) a Governmental Authority rejects or refuses such Product Mark for use in the Territory or such Product Mark is not registrable in the Territory, or (c) Zai reasonably desires alternative or additional trademarks in the applicable local language in the Territory. In the event of the foregoing (a), (b), or (c), Zai may select an alternative Licensed Product-specific trademark to use in connection with the Commercialization of Licensed Products in the Territory and will provide any such proposed Licensed Product-specific trademark to the JSC for review and comment prior to finally selecting and using any such proposed Licensed Product-specific trademark. Zai will not use any trademarks of Blueprint (including Blueprint's corporate name) or any trademark confusingly similar thereto without Blueprint's prior written consent. Following review thereof by the JSC, such Licensed Product-specific trademark will become a Product Mark for all purposes under this Agreement.

14.9.3 **Ownership**. Blueprint will be the sole and exclusive owner of all Product Marks and Global Brand Elements, including all trademark registrations and applications therefor and all goodwill associated therewith. To the extent Zai acquires any rights, title, or interests in or to any Product Mark or Global Brand Element (including any trademark registration or application therefore or goodwill associated with any Product Mark), Zai will, and hereby does, assign the same to Blueprint. Blueprint will and hereby does grant Zai the exclusive right to use such Product Marks in connection with the Commercialization of the applicable Licensed Product in the Territory. Upon Zai's request, Blueprint will register and maintain the Product Marks in the Territory using counsel of Blueprint's choice and [****].

14.9.4 **Use**. Zai agrees that it and its Affiliates and Sublicensees will Commercialize each of the Licensed Products in the Territory in a manner consistent with the Global Brand Elements and will: (a) ensure that all Licensed Products that are sold bearing the Product Marks and Global Brand Elements are of a high quality consistent with industry standards for global pharmaceutical and biologic therapeutic products; (b) ensure that each use of the Global Brand Elements and Product Marks by Zai and its Affiliates and Sublicensees is accompanied by an acknowledgement that such Global Brand Elements and Product Marks are owned by Blueprint; (c) not use such Global Brand Elements or Product Marks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Blueprint therein and includes the trademark registration symbol ® or ™ as appropriate; (d) not use any trademarks or trade names so resembling any of such Global Brand Elements or Product Marks as to be likely to cause confusion or deception; and (e) place and display the Global Brand Elements and the Product Marks on and in connection with the Licensed Products in a way that acknowledges Blueprint's role in discovering the Licensed Products and that such Licensed Product is under license from Blueprint. To the extent permitted by and consistent with Applicable Law, Zai will include the words (a) "*Discovered by Blueprint Medicines Corporation*" (or such other similar text provided by Blueprint and reasonably acceptable to Zai) on all packaging and labeling for any Licensed Product that is not a Blueprint/Zai Combination and in relevant scientific, medical, and other Licensed Product-related communications to the extent such communications address the Development or Commercialization of such a Licensed Product (that is not a Blueprint/Zai Combination), and (b) "*Discovered in Collaboration by Blueprint Medicines Corporation and Zai Pharmaceuticals*" (or such other similar text provided by Blueprint and reasonably acceptable to Zai) on all packaging and labeling for any Blueprint/Zai Combination (to the extent feasible, for example, if the Zai Product and the Blueprint Compound are co-packaged) and in relevant scientific, medical, and other Blueprint/Zai Combination-related communications to the extent such communications address the Development or Commercialization of a Blueprint/Zai Combination, in each case ((a) and (b)), in English unless required under Applicable Law to be in another language.

**14.10** **Patent Marking**. Zai will mark all Licensed Products in accordance with the applicable patent marking laws, and will require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Law, Zai will indicate on the product packaging, advertisement and promotional materials that such Licensed Product is in-licensed from Blueprint.

## Article 15
## TERM AND TERMINATION

**15.1** **Term**. This Agreement will be effective as of the Effective Date, and will continue, on a Licensed Product-by-Licensed Product and region-by-region basis, in effect until the expiration of all payment obligations set forth under this Agreement with respect to such Licensed Product in such region (the "**Term**"). On a Licensed Product-by-Licensed Product and region-by-region basis, upon the natural expiration of this Agreement as contemplated in this Section 15.1 (Term), so long as at such time Zai has paid to Blueprint all undisputed amounts due under this Agreement and accrued prior to such natural expiration of the Term in accordance with the terms hereof and is not at such time in material breach of any term of this Agreement, the licenses granted to Zai under Section 2.1 (License Grants to Zai) will become non-exclusive, perpetual, and irrevocable.

**15.2** **Termination**.

15.2.1 **Termination by Zai for Convenience**. Zai may terminate this Agreement in its entirety by providing a written notice of termination to Blueprint after the [****] anniversary of the Effective Date that includes an effective date of termination [****].

15.2.2 **Termination for Material Breach**.

(a) **Notice and Cure Period**. If either Party believes in good faith that the other is in material breach of any term of this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy ("**Breach Notification**"). For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have [****] from the receipt of the applicable Breach Notice to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, that breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement effective on written notice of termination to the other Party. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have [****] from the date of the Breach Notification to dispute or cure such breach, *provided* that if such breach (other than a payment breach) is not reasonably capable of cure within such [****] period, but is capable of cure within [****] from the date of such Breach Notification, then the breaching Party may submit, within [****] of such Breach Notification, a reasonable cure plan to remedy such breach as soon as possible and in any event prior to the end of such [****] period that is reasonably acceptable to the non-breaching Party, and, upon such submission, the [****] cure period will be automatically extended for so long as the breaching Party continues to use reasonable efforts to cure such breach in accordance with the cure plan, but for no more than [****]. Notwithstanding the foregoing, if the allegedly breaching Party disputes in good faith the existence or materiality of the alleged breach, then the other Party will not have the right to terminate this Agreement unless and until an arbitrator issues a final award pursuant to Section 16.3 (Arbitration) that the allegedly breaching Party has materially breached a term of this Agreement. During the pendency of such a dispute, all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder. The cure period will be tolled starting as of the date of such notice of a dispute from the allegedly breaching Party and for the remainder of the pendency of any such dispute and such breaching Party will have the time remaining of the applicable cure period to cure the applicable breach after such award finding such breach is issued.

15.2.3 **Termination for Patent Challenge**. Except to the extent unenforceable under the Applicable Law, Blueprint may terminate this Agreement by providing written notice of termination to Zai if Zai or its Affiliates or Sublicensees (individually or in association with any Person) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Blueprint Patent Right, Blueprint Manufacturing Patent Right, or Joint Collaboration Patent Right anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a "**Patent Challenge**") unless Zai or its applicable Affiliate withdraws, cancels, or otherwise terminates such Patent Challenge within [****] following the earlier of (a) Blueprint's notice or (b) the date on which Zai or its applicable Affiliate had written notice, or otherwise first became aware (as evidenced by written records), of such Patent Challenge[****] if: (i) [****] or (ii) [****] this Section 15.2.3 [****] As used herein, a Patent Challenge includes: (A) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (B) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any such Patent Right; (C) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (D) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country or region; or (E) any foreign equivalent of clauses (A), (B), (C), or (D) [****].

15.2.4 **Cessation of Development and Commercialization**. If Zai and its Affiliates do not conduct any material Development or Commercialization activities with respect to one or more Licensed Products [****], and such suspension of activity is not: [****] then Blueprint may, at its election, terminate this Agreement upon [****] prior written notice to Zai if Zai does not commence material Development or Commercialization activities with respect to one or more Licensed Products before the expiration of such [****] notice period. Notwithstanding the foregoing, if Blueprint gives a notice of termination to Zai pursuant to this Section 15.2.4 (Cessation of Development or Commercialization), and Zai provides notice during such [****] period that it disputes the basis for termination pursuant to this Section 15.2.4 (Cessation of Development or Commercialization), then this Agreement will not terminate unless and until an arbitrator issues a final award pursuant to Section 16.3 (Arbitration) upholding such basis for termination. During the pendency of such a dispute, all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder. The [****] notice period will be tolled starting as of the date of such notice of a dispute from Zai and for the remainder of the pendency of any such dispute and Zai will have the time remaining of the notice period to commence material Development or Commercialization activities with respect to one or more Licensed Products after the arbitrator has upheld the basis for termination.

15.2.5 **Termination for Insolvency**. Each Party will have the right to terminate this Agreement upon delivery of written notice to the other Party if (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [****] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

15.2.6 **Full Force and Effect During Notice Period**. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if Zai or any of its Affiliates or Sublicensees achieve any Milestone Event during the termination notice period, then the corresponding Milestone Payment is accrued and Zai will remain responsible for the payment of such Milestone Payment even if the due date of such Milestone Payment occurs after the effective date of the termination.

**15.3** **Effect of Termination**. Upon the termination of this Agreement (but not expiration of this Agreement):

15.3.1 **Licenses**. As of the effective date of termination of this Agreement (but not expiration of this Agreement), all licenses and all other rights granted by Blueprint to Zai under the Blueprint Technology and Blueprint Manufacturing Technology will terminate and all sublicenses granted by Zai pursuant to Section 2.2 (Sublicensing and Subcontractors) will also terminate. Each Party will retain its joint ownership interests in the Joint Collaboration Technology. In addition, upon the termination of this Agreement (but not expiration of this Agreement) Blueprint will have, and Zai hereby grants to Blueprint, effective upon such termination, a worldwide, exclusive, perpetual, royalty-bearing [****] and sublicenseable (through multiple tiers) license under the Zai Technology, Zai's interests in the Joint Collaboration Technology and any Zai Identified Rights, in each case, Controlled by Zai as of the effective date of such termination and solely to Exploit the Licensed Products (in the form that such Licensed Products exist as of the effective date of termination). In addition to [****], subject to Blueprint's right to decline a license or sublicense of Zai In-Licensed Rights in accordance with the terms of Section 2.6.6(b) (Right to Decline Zai In-Licensed Rights) or by providing written notice to Zai within [****] of the effective date of termination of this Agreement declining such rights, Blueprint will reimburse Zai for amounts owed under such Zai Third Party IP Agreement in accordance with Section 2.6.6(c) (Responsibility for Costs of Zai In-Licensed Rights). In addition, Zai will assign to Blueprint any Third Party IP Agreement pursuant to which Zai then Controls any Zai Identified Rights, if such Third Party IP Agreement is specific to the terminated Licensed Product and if permitted under such Third Party IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party IP Agreement cannot be assigned to Blueprint, then upon Blueprint's reasonable request, Zai will maintain such Third Party IP Agreement and Blueprint will pay to Zai [****] of all payments due to the applicable Third Party under any such Third Party IP Agreement in consideration of the sublicense to Blueprint and Blueprint's Exploitation of such Zai Identified Rights. If Zai is unable to sublicense any Zai Identified Rights to Blueprint pursuant to this Section 15.3.1 (Effect of Termination; Licenses) without the consent of the Third Party, then Zai undertakes, on request from Blueprint, to use reasonable efforts to procure such licenses with respect to the applicable Licensed Products on behalf of Blueprint to the extent that it is able to do so, and Blueprint will pay such fees and agree to be bound by the terms agreed between Zai and the Third Party licensor.

15.3.2 **Appointment as Exclusive Distributor**. If Zai is Commercializing any Licensed Product in any region in the Territory as of the effective date of termination of this Agreement (but not expiration of this Agreement), then, at Blueprint's election (in its sole discretion) in the event of termination of this Agreement by Blueprint pursuant to Section 15.2.2 (Termination for Material Breach), Section 15.2.5 (Termination for Insolvency), or Section 15.2.4 (Cessation of Development and Commercialization), by Zai pursuant to Section 15.2.1 (Termination by Zai for Convenience), or in all other cases, at Zai's election (in its sole discretion), on a region-by-region basis in the Territory, until such time as all Regulatory Approvals with respect to such Licensed Product in such region have been assigned and transferred to Blueprint, either (a) Zai will (with Blueprint's consent in the event such election is made by Zai) appoint Blueprint or its designee as its exclusive distributor of such Licensed Product in such region and grant Blueprint or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Zai or any of its Affiliates and a Third Party; *provided that* Blueprint will purchase any and all salable inventory of the Licensed Product held by Zai or its Affiliates as of the effective date of termination [****] or (b) Zai will have the continued right to sell the Licensed Product in such region from its inventory; *provided, however*, that Zai's obligations under this Agreement with respect to all such Licensed Product that Zai sells following termination, including the obligation to remit Royalty Payments to Blueprint hereunder, will continue in full force and effect during such period.

15.3.3 **Regulatory Submissions and Regulatory Approvals**. To the extent requested by Blueprint following the date that a Party provides notice of termination of this Agreement (but not expiration of this Agreement), Zai will and hereby does, and will cause its Affiliates and Sublicensees to, (a) [****] assign and transfer to Blueprint or its designee all of Zai's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals for Licensed Products then owned or Controlled by Zai or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Blueprint to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Zai with respect to a Licensed Product. Zai will take all steps necessary to transfer ownership of all such assigned Regulatory Submissions and Regulatory Approvals to Blueprint, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Blueprint) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and Regulatory Approval. In addition, upon Blueprint's written request, Zai will [****] provide to Blueprint copies of all material related documentation, including material non-clinical, preclinical, and clinical data that are held by or reasonably available to Zai or its Affiliates or Sublicensees. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, *provided* that Blueprint will assume all safety and safety database activities with respect to all Licensed Products no later than [****] after the effective date of termination of this Agreement.

15.3.4 **Assignment and Disclosure**. To the extent requested by Blueprint following the date that a Party provides notice of termination of this Agreement, Zai will promptly upon request (and in any event within [****]):

(a) assign and transfer to Blueprint or its designee all of Zai's rights, title, and interests in and to all clinical trial agreements, manufacturing and supply agreements, and distribution agreements (to the extent assignable and not cancelled), confidentiality and other agreements, data and other Know-How (including commercial information) in Zai's Control, in each case, relating solely to any Licensed Product and that are necessary or useful for the Exploitation of any Licensed Product;

(b) disclose to Blueprint or its designee all documents, records, and materials related to Licensed Products that are controlled by Zai or that Zai is able to obtain using reasonable efforts, and that embody the foregoing; and

(c) assign and transfer to Blueprint or its designee all of Zai's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information solely related to Licensed Products and copyrights and any registrations for the foregoing.

Unless this Agreement is terminated by Zai pursuant to Section 15.2.2 (Termination for Material Breach) or Section 15.2.5 (Termination for Insolvency), the costs and expenses associated with the assignments set forth in this Section 15.3.4 (Assignment and Disclosure) will be borne by Zai. To the extent that any agreement or other asset described in this Section 15.3.4 (Assignment and Disclosure) is not assignable by Zai, then such agreement or other asset will not be assigned, and upon the request of Blueprint, Zai will take such steps as may be necessary to allow Blueprint to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Zai has the right and ability to do so. For clarity, Blueprint will have the right to request that Zai take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in this Section 15.3.4 (Assignment and Disclosure).

15.3.5 **Regulatory Transfer Support**. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 15.3.3 (Regulatory Submissions and Regulatory Approvals) and Section 15.3.4 (Assignment and Disclosure), Zai will appoint Blueprint as Zai's or its Affiliate's agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Blueprint's or its Affiliate's name have been assigned to Blueprint or its designee. In the event of failure to obtain such assignment, Zai hereby consents and grants to Blueprint the right to access and reference (without any further action required on the part of Zai, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Products.

15.3.6 **Know-How Transfer Support**. In furtherance of the assignment of Know-How pursuant to Section 15.3.4 (Assignment and Disclosure) and in addition to the requirements in Section 15.3.9 (Supply Following Termination), Zai will for a period of [****] from the effective date of termination of this Agreement, provide such consultation or other assistance as Blueprint may reasonably request to assist Blueprint in becoming familiar with such Know-How in order for Blueprint to undertake further Exploitation of the Licensed Products following termination of this Agreement [****].

15.3.7 **Inventory**. At Blueprint's election and request, Zai will transfer to Blueprint or its designee some or all inventory of each Licensed Product (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Zai, its Affiliates or Sublicensees; *provided* that Blueprint will [****] and *provided further* that Zai may retain inventory to the extent retained to exercise its rights under Section 15.3.2 (Appointment of Exclusive Distributor).

15.3.8 **Wind Down and Transition**. Zai will be responsible, [****] for the wind-down of Zai's and its Affiliates' and its Sublicensees' Exploitation of all Licensed Products. Zai will, and will cause its Affiliates and Sublicensees to, reasonably cooperate with Blueprint to facilitate orderly transition of the Exploitation of each Licensed Product to Blueprint or its designee, including (a) assigning or amending as appropriate, upon request of Blueprint, any agreements or arrangements with Third Party vendors (including distributors) solely related to the Exploitation of each Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to Blueprint, reasonably cooperating with Blueprint to arrange to continue to provide such services for a reasonable time after termination of this Agreement; and (b) to the extent that Zai or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Blueprint to transfer such activities to Blueprint or its designee and continuing to perform such activities on Blueprint's behalf for a reasonable time after termination of this Agreement until such transfer is completed.

15.3.9 **Supply Following Termination**. If, as of the effective date of termination of this Agreement, Blueprint has completed the Manufacturing Technology Transfer for a one or more Licensed Products and Zai is Manufacturing one or more such Licensed Products, then at Blueprint's written request, Zai will supply to Blueprint such quantities of such Licensed Product (in bulk drug substance, bulk drug product, or finished drug product form, as requested by Blueprint, to the extent within Zai's then current capacity restrictions as of the effective date of termination) as Blueprint indicates in written forecasts and orders therefor from time to time [****] until [****] (a) [****] and (b) [****]. In addition, upon Blueprint's request, Zai will (i) provide a [****] technology transfer to Blueprint or its designee of information and materials [****] for Blueprint or its designee to Manufacture such Licensed Product in each formulation of such Licensed Product (as it exists at the time of termination of this Agreement and to the extent such information was not previously transferred by or on behalf of Blueprint to Zai or its Affiliate or designee), including providing reasonable assistance to Blueprint or its designee in connection therewith upon request, and (ii) assign to Blueprint any agreement that [****] relates to the Manufacture or supply of Licensed Products in the Territory, to the extent that such contract is assignable. If any such agreement is not assignable, then Zai will cooperate with Blueprint in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Blueprint on terms substantially similar to those granted to Zai. [****]

15.3.10 **Ongoing Clinical Trials**.

(a) **Transfer to Blueprint**. If, as of the effective date of termination of this Agreement, Zai or its Affiliates are conducting any Clinical Trials for Licensed Products, then, at Blueprint's election on a Clinical Trial-by-Clinical Trial basis, Zai will fully cooperate, and will ensure that its Affiliates fully cooperate, with Blueprint to transfer the conduct of such Clinical Trial to Blueprint or its designees. If Blueprint so elects, then Zai will continue to conduct such Clinical Trial [****] to enable such transfer to be completed without interruption of any such Clinical Trial (including the assignment of all related Regulatory Submissions and investigator and other agreements related to such Clinical Trials). [****] Zai will provide such knowledge transfer and other training to Blueprint or its designated Affiliate or Third Party as reasonably necessary for Blueprint or such designated Affiliate or Third Party to continue such Clinical Trial for the applicable Licensed Product.

(b) **Wind-Down**. If Blueprint does not elect to assume control over or have Zai continue to conduct any such Clinical Trials for a Licensed Product, then Zai will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Zai will be responsible for [****].

15.3.11 **Sublicense Survival**. Upon termination of this Agreement, upon the request of any Sublicensee of Zai that was granted a sublicense in accordance with the terms of Section 2.2.1 (Right to Sublicense) and that is not then in breach of its sublicense agreement or the terms of this Agreement applicable to such Sublicensee, Blueprint will negotiate [****] with such Sublicensee with respect to the grant of a direct license to such Sublicensee, which license will not be broader in license scope, territory, or duration than such sublicense agreement granted by Zai to such Sublicensee and not more burdensome on Blueprint [****] and no less favorable to Blueprint than the financial terms of Article 10 (Payments) for the scope, territory, and duration of such sublicense and *provided* that such Sublicensee agrees to comply with all applicable terms of this Agreement.

15.3.12 **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to any Licensed Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided that* the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

15.3.13 **Further Assistance**. Zai will provide any other assistance or take any other actions, in each case, reasonably requested by Blueprint as necessary to give effect to this Section 15.3 (Effect of Termination), and will execute all documents as may be reasonably requested by Blueprint in order to give effect to this Section 15.3 (Effect of Termination).

15.3.14 [****]

15.3.15 **Blueprint/Zai Combinations**. Notwithstanding any provision to the contrary set forth in this Agreement, the effects of termination as it relates to any Blueprint/Zai Combination will be subject to the applicable terms agreed upon by the Parties for such Blueprint/Zai Combination under Section 5.8 (Proposed Blueprint/Zai Combinations).

**15.4** **Termination Press Releases**. In the event of termination of this Agreement for any reason and subject to the terms of Section 11.7.1 (Press Release), the Parties will cooperate in good faith to coordinate public disclosure of such termination and the reasons therefor, and will not, except to the extent required by Applicable Law, disclose such information without the prior approval of the other Party. In any such disclosures, the Parties will observe the principles of accuracy, compliance with Applicable Law, and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news.

**15.5** **Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: Article 1 (Definitions), Section 2.3.2 (Outside of Territory), Section 5.15 (Development Records), Section 5.17 (Data Exchange and Use) (to the extent set forth therein), Section 10.3.4 (Royalty Reports and Payments) (with respect to payments becoming due during the Term), Section 10.5 (Other Amounts Payable) (with respect to amounts becoming due during the Term), Section 10.11 (Financial Records and Audits) (with respect to payments becoming due during the Term), Section 11.1 (Duty of Confidence), Section 11.2 (Confidential Information), Section 11.3 (Authorized Disclosures), Section 11.4 (Tax Treatment), Section 11.5 (Publications), Section 11.8 (Attorney-Client Privilege), Section 12.8 (Time for Claims), Article 13 (Indemnification), Section 14.1 (Inventions), Section 14.2.3 (Joint Collaboration Technology), Section 14.2.4 (Cooperation), Section 14.9.3 (Ownership), Section 15.1 (Term), Section 15.3 (Effect of Termination), Section 15.4 (Termination Press Releases), Section 15.5 (Survival), Section 15.6 (Termination Not Sole Remedy), Article 16 (Dispute Resolution), and Article 17 (Miscellaneous).

**15.6** **Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

## Article 16
## DISPUTE RESOLUTION

**16.1** **General**. The Parties recognize that a dispute may arise relating to this Agreement or to the breach, enforcement, interpretation, or validity of this Agreement (a "**Dispute**"). Except as otherwise expressly set forth in this Agreement, any Dispute, including Disputes that may involve the Affiliates of any Party, will be resolved in accordance with this Article 16 (Dispute Resolution).

**16.2** **Negotiation; Escalation**. The Parties will negotiate [****] to settle any Dispute under this Agreement, other than matters subject to resolution under Article 3 (Governance). Any Dispute relating to this Agreement or the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [****] after such Dispute is referred to them, then, upon the written request of either Party to the other Party, other than a Dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights (which will be submitted for resolution to a court of competent jurisdiction in the country or region in which such Patent Rights or trademark rights were granted or arose), the Dispute will be subject to arbitration in accordance with Section 16.3 (Arbitration).

**16.3** **Arbitration**.

16.3.1 **Rules**. In the event of a Dispute that cannot be resolved between the Parties or the Executive Officers as set forth in Section 16.2 (Negotiation; Escalation), either Party will be free to institute binding arbitration with respect to such dispute in accordance with this Section 16.3 (Arbitration) upon written notice to the other Party (an "**Arbitration Notice**") and seek remedies as may be available. Any dispute unresolved under this Section 16.3 (Arbitration) will be settled by binding arbitration administered by the International Chamber of Commerce ("**ICC**") (or any successor entity thereto) and in accordance with the ICC Rules of Arbitration then in effect, as modified in this Section 16.3 (Arbitration) (the "**Rules**"), except to the extent such rules are inconsistent with this Section 16.3 (Arbitration), in which case this Section 16.3 (Arbitration) will control.

16.3.2 **Selection of Arbitrators**. Upon receipt of an Arbitration Notice by a Party, the applicable dispute will be resolved by final and binding arbitration before a panel of three arbitrators (the "**Arbitrators**"), with each arbitrator having [****] of experience in the biotechnology or pharmaceutical industry and subject matter expertise with respect to the matter subject to arbitration [****]. Any Arbitrator chosen hereunder will have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical, and industry knowledge relevant to the particular dispute. Each Party will promptly select one Arbitrator, which selections will in no event be made later than [****] after receipt of the Arbitration Notice. The third Arbitrator will be chosen promptly by agreement of the Arbitrators chosen by each Party, but in no event later than [****] after the date on which the last of such Arbitrators was appointed. If the two Party-nominated Arbitrators cannot agree on the third Arbitrator, then the third Arbitrator will be appointed by ICC.

16.3.3 **Decisions**. The Arbitrators' decision and award will be made within [****]of the filing of the arbitration demand and the Arbitrators will agree to comply with this schedule before accepting appointment. However, this time limit may be extended by agreement of the Parties or by the Arbitrators. The Arbitrators will be authorized to award compensatory damages, but will not be authorized to reform, modify, or materially change this Agreement. The Arbitrators will, within [****] after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The proceedings and decisions of the arbitrator will be confidential, final, and binding on the Parties, and judgment upon the award of such arbitrator may be entered in any court having jurisdiction thereof.

16.3.4 **Responsibility for Costs**. Each Party will bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the Arbitrators and other related costs of the arbitration will be shared equally by the Parties, unless the Arbitrators determine that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the Arbitrators may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred.

16.3.5 **Limitations**. The Arbitrators will be required to apply the internal laws of the State of New York as the governing law for this Agreement and to render the decision in writing and to comply with, and the award will be limited by, any express provisions of this Agreement relating to damages or the limitation thereof. To the extent punitive or other indirect damages are expressly limited under this Agreement, no Arbitrator will have the power to award punitive damages under this Agreement, regardless of whether any such damages are contained in a proposal.

16.3.6 **Effectiveness of Agreement**. Unless the Parties otherwise agree in writing, during the period of time during which any arbitration proceeding is pending under this Agreement, (a) the Parties will continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding; and (b) in the event that the subject of the Dispute relates to the exercise by a Party of a termination right hereunder, including in the case of a material breach of this Agreement, the effectiveness of such termination will be stayed until the conclusion of the proceedings under this Section 16.3 (Arbitration).

16.3.7 **Confidential Proceedings**. All arbitration proceedings and decisions of the Arbitrators under this Section 16.3 (Arbitration) will be Confidential Information of both Parties and subject to the terms of Article 11 (Confidentiality; Publication). The arbitration proceedings will take place in New York, New York, in the English language.

16.3.8 **Equitable Relief**. Nothing in this Section 16.3 (Arbitration) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the *status quo* pending the arbitration proceeding.

## Article 17
## MISCELLANEOUS

**17.1** **Assignment**. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, Blueprint may assign its rights to receive payments under this Agreement to one or more Persons without consent of Zai [****], and either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder (a) in whole or in part to an Affiliate of such Party, or (b) in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions; *provided* that in the case of the foregoing clause (a) or (b), the assigning Party provides written notice of such assignment to the non-assigning Party within [****] after the effective date of such assignment. Any attempted assignment of this Agreement not in accordance with this Section 17.1 (Assignment) will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

**17.2** **Limitation of Liability**. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, OR DAMAGES FOR LOSS OF PROFIT IN CONNECTION WITH THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 17.2 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 (BY ZAI ) OR SECTION 13.2 (BY BLUEPRINT), OR DAMAGES AVAILABLE TO A PARTY FOR THE OTHER PARTY'S BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO Article 10 (CONFIDENTIALITY; PUBLICATION), MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY SUCH PARTY, OR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.8 (EXCLUSIVITY).

**17.3** **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the purposes of this Agreement.

**17.4** **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

*If to Blueprint:*

Blueprint Medicines Corporation
45 Sidney Street
Cambridge MA 02139 USA
Attention: Chief Executive Officer

with a copy to:

Blueprint Medicines Corporation
45 Sidney Street
Cambridge MA 02139 USA
Attention: Chief Legal Officer
Email: [****]

*If to Zai:*

Zai Lab Limited
4F, Bldg 1, Jinchuang Plaza
4560 Jinke Rd
Shanghai, China, 201210
Attention: [****]
With an electronic copy to [****]

with a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303
USA
Attention: [****]
with an electronic copy to [****]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) [****] after dispatch if sent by internationally-recognized overnight courier; or (b) [****] after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

**17.5** **Governing Law**. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations without giving effect to the conflicts of law provisions thereunder.

**17.6** **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will continue only so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the force majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, “force majeure” will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, failure of plant or machinery and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party’s failure to comply with Applicable Law). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a force majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making undisputed payments that have accrued and are owed hereunder because of a force majeure affecting such Party. The affected Party will notify the other Party in writing of any force majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such force majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. If the force majeure circumstance continues, then the affected Party will update such notice to the other Party on a bi-weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume.

**17.7** **Entire Agreement; Amendments**. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder, including the Confidentiality Agreement, are superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Agreement.

**17.8** **Headings**. The captions to the several Article**s**, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

**17.9** **Independent Contractors**. It is expressly agreed that Blueprint and Zai will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Blueprint nor Zai will have the authority to make any statements, representations, or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

**17.10** **Performance by Affiliates**. Notwithstanding anything to the contrary set forth in this Agreement, ether Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

**17.11** **Waiver**. Any waiver of any provision of this Agreement will be effective only if in writing and signed by Blueprint and Zai. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

**17.12** **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

**17.13** **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

**17.14** **Business Day Requirements**. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission will be deemed to be required to be taken on the next occurring Business Day.

**17.15** **Further Actions**. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**17.16** **Non-Solicitation of Employees**. [****] each Party agrees that neither it nor any of its Affiliates will recruit, solicit, or induce any employee of the other Party [****] to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit," "solicit," or "induce" will not be deemed to mean (a) circumstances where an employee of a Party (i) initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (ii) responds to general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements or postings, and (b) discussions, interviews, negotiations, offers, or acceptances of employment or similar activities that arise as a result of circumstances described in the foregoing clause (a).

**17.17** **Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

**17.18** **Language; Translations**. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All communications and notices to be made or given by one Party to the other pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, will be in the English language. If there is a discrepancy between this Agreement and any non-English translation of this Agreement, this Agreement will prevail. Upon Blueprint's request, Zai will provide to Blueprint any documentation in English already in Zai's possession. For other material data, information, documents or materials, Zai will provide to Blueprint [****] in English upon Blueprint's reasonable request. In addition, at Blueprint's request, Zai will provide a full English translation of such material data, information, or materials [****]. Zai will be responsible[****] for the translation to Chinese of any documentation provided by Blueprint. [****]

**17.19** **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

*{Signature Page Follows}*

**IN WITNESS WHEREOF**, the Parties intending to be bound have caused this License and Collaboration Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

**BLUEPRINT MEDICINES CORPORATION**

By: /s/ Jeff Albers

Name: Jeff Albers

Title: CEO

**ZAI LAB (SHANGHAI) CO., LTD**

By: /s/ Samantha Du

Name: Samantha Du

Title: CEO

*[Signature Page to License and Collaboration Agreement]*

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

# LICENSE AGREEMENT

This **License Agreement** (this "**Agreement**") is made as of November 8, 2021(the "**Effective Date**"), by and between **Karuna Therapeutics, Inc.**, a corporation organized and existing under the laws of Delaware, located at 99 High Street, 26th Floor, Boston, Massachusetts, 02110, United States of America ("**Karuna**"), and Zai Lab (Shanghai) Co., Ltd, an exempted company organized and existing under the laws of P.R. of China, having a place of business at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210 ("**Zai**"). Karuna and Zai are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

## RECITALS

**WHEREAS**, Karuna is a biopharmaceutical company specializing in transformative medicines for the treatment of psychiatric and neurological conditions;

**WHEREAS**, Zai is a pharmaceutical company having experience in the development and commercialization of pharmaceutical products in the Licensed Territory (as defined below); and

**WHEREAS**, Karuna wishes to grant to Zai, and Zai wishes to be granted, an exclusive license to develop, manufacture and commercialize the Compound (as defined below) and Licensed Product (as defined below) in the Field (as defined below) in the Licensed Territory in accordance with the terms and conditions set forth below.

## AGREEMENT

**NOW**, **THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

## ARTICLE 1

## DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

**1.1.** "**Adverse Event**" means any unwanted or harmful medical occurrence in a patient or subject who is administered the Licensed Product, whether or not considered related to the Licensed Product, including any undesirable sign (including abnormal laboratory findings of clinical concern).

**1.2.** "**Affiliate**" means, with respect to a specified Person, any entity that directly or indirectly controls, is controlled by or is under common control with such Person, in each case, for so long as such control exists. As used in this Section 1.2, "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means, in the case of a corporation, the ownership of more than fifty percent (50%) of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such entity or the power to appoint more than fifty percent (50%) of the members of the governing body of the entity or, where ownership of more than fifty percent (50%) of such securities or interest is prohibited by law, ownership of the maximum amount legally permitted.

**1.3.** "**Agreement**" has the meaning set forth in the preamble.

**1.4.** "**Alliance Manager**" has the meaning set forth in Section 3.2.

**1.5.** "**Anti-Corruption Laws**" has the meaning set forth in Section 10.4(a)(i).

**1.6.** **[***]**.

**1.7.** "**Applicable Laws**" means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the relevant activities contemplated by this Agreement.

**1.8.** "**Authorized Regulatory Agent**" means a local entity (a) authorized by Karuna or any of its Affiliates, where Karuna, its Affiliate or its Third Party contractor research organization is the license holder of imported drug product, to exclusively (even as to Karuna and its Affiliates, but in accordance with terms and conditions hereunder) manage the work associated with obtaining any Regulatory Approval or product registration in the Licensed Territory, and (b) which possesses and maintains valid licenses or permits in the Licensed Territory if such licenses or permits are required for such local entity to engage in the relevant activities in the Licensed Territory.

**1.9.** "**Bankruptcy Code**" has the meaning set forth in Section 12.7.

**1.10.** "**Business Day**" means a day other than Saturday, Sunday or any day on which banks located in the State of Massachusetts or Shanghai, the PRC are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

**1.11.** "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31st, June 30th, September 30th and December 31st.

**1.12.** "**Calendar Year**" means each twelve (12) month period commencing on January 1st.

**1.13.** "**cGMP**" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country or Region, each as may be amended and applicable from time to time.

**1.14.** "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty (50%) of the total voting power of all of the then outstanding voting securities of such Party, (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which results in shareholders or equity holders of such Party immediately prior to such transaction, no longer owning at least fifty (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction, or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

**1.15.** "**Claims**" has the meaning set forth in Section 11.1.

**1.16.** "**Clinical Trial**" means any clinical testing of the Licensed Product in human subjects.

**1.17.** "**CMOs**" means Third Party contractor manufacture organizations.

**1.18.** "**Commercialization**" or "**Commercialize**" means all activities directed to marketing, distribution, promoting or selling of pharmaceutical products (including importing and exporting activities in connection therewith and securing pricing and reimbursement approvals, as necessary).

**1.19.** "**Commercialization Plan**" means the written plan for the Commercialization of the Licensed Product in the Licensed Territory, as updated in accordance with this Agreement.

**1.20.** "**Commercially Reasonable Efforts**" means with respect to a Party, the use of diligent, good faith efforts and resources, in an active and ongoing program, as normally used by such Party for a product discovered or identified internally or in-licensed from a Third Party that is important to such Party's overall strategy or objectives, which product is at a similar stage in its development or product life and is of similar market potential and intellectual property protection; provided, however, that in no event shall such efforts and resources be less than [***].

**1.21.** "**Competing Product**" means: [***].

**1.22.** "**Competing Product Notice**" has the meaning set forth in Section 2.9(c).

**1.23.** "**Compound**" means Karuna's proprietary small molecule muscarinic modulator known as KarXT, which is a combination of xanomeline tartrate and trospium chloride, as developed by or on behalf of Karuna or its Affiliates as of the Effective Date and further described on Schedule 1.23, and [***].

**1.24.** "**Confidential Information**" means all confidential information of the Disclosing Party or its Affiliates, regardless of its form or medium as provided or made available to the Receiving Party or its Affiliates in connection with this Agreement; provided that, Confidential Information shall not include any information that the Receiving Party can show by competent written evidence: (a) was already known to the Receiving Party at the time it was disclosed to the Receiving Party by the Disclosing Party without an obligation of confidentiality and not through a prior disclosure by the Disclosing Party, (b) was or becomes generally known to the public through no act or omission of the Receiving Party in violation of the terms of this Agreement, (c) was lawfully received by the Receiving Party from a Third Party without restriction on its disclosure and without, to the reasonable knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party, or (d) was independently developed by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party (provided that such exception shall not apply to any Product Invention). All Product Inventions shall be the Confidential Information of Karuna, and Karuna shall be the Disclosing Party and Zai shall be the Receiving Party with respect thereto. All Zai Inventions shall be the Confidential Information of Zai, and Zai shall be the Disclosing Party and Karuna shall be the Receiving Party with respect thereto. The terms of this Agreement that are not publicly disclosed through a press release or by filings to financial regulatory authorities in accordance with the terms of this Agreement shall be the Confidential Information of both Parties. All confidential information disclosed by a Party pursuant to the Confidentiality Agreement shall be deemed to be such Party's Confidential Information.

**1.25.** "**Confidentiality Agreement**" means that Confidential Disclosure Agreement, dated as of [***], by and between Karuna and Zai.

**1.26.** "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise, after taking into account the provisions of this Agreement regarding ownership of Inventions, but without taking into account any license granted by one Party to the other Party pursuant to this Agreement) to grant a license, sublicense, access or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without (a) breaching the terms of any agreement with a Third Party or (b) incurring payments to a Third Party, except with respect to any Know-How and Patents in-licensed by Karuna pursuant to any Existing In-License Agreement or any New Karuna In-Licenses entered into in accordance with Section 2.12.

**1.27.** "**CRO**s" has the meaning set forth in Section 2.4.

**1.28.** "**CTA**" has the meaning set forth in Section 1.64.

**1.29.** "**Data**" means research, pharmacology, toxicological, preclinical, Clinical Trial, technical, chemical, formulation, Manufacturing, analytical and quality control, safety, and scientific data, including raw data, original records, investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases.

**1.30.** "**Develop**" or "**Development**" or "**Developing**" means preclinical and clinical drug development activities and other development activities with respect to a product, including test method development and stability testing, toxicology, formulation, process development, qualification and validation, quality assurance, quality control, clinical or preclinical trials, statistical analysis and report writing, the preparation and submission of INDs marketing authorization approvals or similar application, regulatory affairs with respect to the foregoing, and all other activities necessary or useful or otherwise requested or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining a Regulatory Approval.

**1.31.** "**Development Data**" has the meaning set forth in Section 4.10(a).

**1.32.** "**Development Milestone Event**" has the meaning set forth in Section 8.2(a).

**1.33.** "**Development Milestone Payment**" has the meaning set forth in Section 8.2(a).

**1.34.** "**Development Plan**" has the meaning set forth in Section 4.1.

**1.35.** "**Development Target**" has the meaning set forth in Section 4.2(c).

**1.36.** "**Development Target Deadline**" has the meaning set forth in Section 4.2(c).

**1.37.** "**Disclosing Party**" has the meaning set forth in Section 9.1(a).

**1.38.** "**Dispute**" has the meaning set forth in Section 14.1.

**1.39.** "**Effective Date**" has the meaning set forth in the preamble in this Agreement.

**1.40.** "**Exclusive Negotiation Period**" has the meaning set forth in Section 2.9(c).

**1.41.** "**Executive Officers**" means, with respect to Karuna, [***] and, with respect to Zai, [***].

**1.42.** "**Existing In-License Agreement**" means the agreement set forth on Schedule 1.42.

**1.43.** "**Existing Patent Application**" means [***].

**1.44.** "**Expiration Date**" has the meaning set forth in Section 13.1(a).

**1.45.** "**Exploit**" or "**Exploitation**" means to Develop, Commercialize, register, Manufacture, have manufactured, use, have used, import, have imported, market, have marketed, distribute, have distributed, offer for sale, sell or have sold.

**1.46.** "**FDA**" means the U.S. Food and Drug Administration or its successor.

**1.47.** "**Field**" means all uses in humans.

**1.48.** "**First Commercial Sale**" means, with respect to any particular country or Region, the first sale of the Licensed Product in such country or Region by any of Zai, an Affiliate, or a Sublicensee, or a distributor of any of them, after all Regulatory Approvals have been granted in such country or Region for the Licensed Product to be marketed and sold legally as a pharmaceutical in such country or Region.

**1.49.** "**Force Majeure Event**" has the meaning set forth in Section 15.2.

**1.50.** "**Fully Burdened Manufacturing Costs**" means the cost of Manufacturing the Licensed Product. Fully Burdened Manufacturing Costs shall be a "standard cost" per unit (calculated annually), comprised of the following elements calculated in accordance with GAAP or IFRS, as applicable: [***].

**1.51.** "**GAAP**" means the United States generally accepted accounting principles, consistently applied.

**1.52.** "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Licensed Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the Region in the Licensed Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.53.** "**Generic Launch Quarter**" has the meaning set forth in Section 8.4(c)(ii).

**1.54.** "**Global Development Plan**" has the meaning set forth in Section 4.4(a).

**1.55.** "**Global Study**" means a clinical study designed to obtain Regulatory Approvals for the Licensed Product in multiple jurisdictions through the conduct of a Clinical Trial in multiple medical institutions, countries, Regions, territories and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

**1.56.** "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the Region in the Licensed Territory, each as may be amended and applicable from time to time.

**1.57.** "**Governmental Authority**" means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, Region, state or local authority or any political subdivision thereof, or any association of countries.

**1.58.** [***].

**1.59.** [***].

**1.60.** "**GSP**" means all applicable Good Supply Practice standards, including, as applicable, as set forth in the then current good supply practice standards promulgated or endorsed by the FDA as defined in Good Supply Practice for Pharmaceutical Licensed Products or the equivalent Applicable Laws in the Region in the Licensed Territory, each as may be amended and applicable from time to time.

**1.61.** "**HGR Approval**" means any and all necessary record filings with, and approvals, licenses, and/or permits issued by, the Human Genetics Resources Administration of the PRC or any other Governmental Authorities in the PRC required for Development activities (including Clinical Trials) and data transfer and sharing under this Agreement with respect to the Exploitation of Licensed Product in the Field in the PRC.

**1.62.** "**ICC Rules**" has the meaning set forth in Section 14.4(a).

**1.63.** "**IFRS**" means international financial reporting standards, consistently applied.

**1.64.** "**IND**" means an investigational new drug application, or equivalent application such as a clinical trial applications filed with the applicable Regulatory Authority in a Region in the Licensed Territory (a "**CTA**"), which application is required to commence Clinical Trials in the Licensed Territory.

**1.65.** "**Indemnifying Party**" has the meaning set forth in Section 11.3.

**1.66.** "**Indemnitee**" has the meaning set forth in Section 11.3.

**1.67.** "**Indication**" means a separate and distinct disease or condition, or sign or symptom of a disease or medical condition in the Field. For clarity, different lines of treatment or the treatment of separate stages or forms or different population (e.g., adult vs pediatric) of the same disease or medical condition shall not constitute separate Indications.

**1.68.** "**Initial MAH**" has the meaning set forth in Section 5.1(e).

**1.69.** "**Invention**" means any and all inventions, discoveries and developments, whether or not patentable, which are created, conceived, developed or made in the course of performance of this Agreement, whether created, conceived, developed or made solely by, or on behalf of, Karuna, Zai, the Parties jointly or jointly with a Third Party, or any Affiliate of the same.

**1.70.** "**Joint Global Study**" has the meaning set forth in Section 4.4(b).

**1.71.** "**JSC**" has the meaning set forth in Section 3.1(a).

**1.72.** "**Karuna**" has the meaning set forth in the preamble of this Agreement.

**1.73.** "**Karuna Indemnitee(s)**" has the meaning set forth in Section 11.1.

**1.74.** "**Karuna Product Marks**" has the meaning set forth in Section 7.5.

**1.75.** "**Karuna Sponsored Regulatory and Commercial Activities**" has the meaning set forth in Section 5.1(e)(ii).

**1.76.** "**Karuna Sponsored Study**" has the meaning set forth in Section 5.1(d).

**1.77.** "**Know-How**" means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

**1.78.** "**Licensed Know-How**" means any and all Know-How Controlled by Karuna or its Affiliates as of the Effective Date or during the Term that is necessary for the Exploitation of the Compound or Licensed Product in the Field in the Licensed Territory, including all Product Inventions and all Development Data Controlled by Karuna and its Affiliates. Notwithstanding the foregoing, in the event a Change of Control of Karuna occurs after the Effective Date, Know-How Controlled by any Affiliate of Karuna that was not an Affiliate of Karuna immediately prior to such Change of Control transaction shall not be Licensed Know-How except to the extent such Know-How falls within the definition of Licensed Know-How in the immediately preceding sentence and (a) is also Controlled by Karuna or its Affiliate existing immediately prior to such transaction or (b) is generated or used by such Affiliate in the Exploitation of the Compound or Licensed Product after such transaction. Additionally, "Licensed Know-How" shall exclude (x) any Know-How relating to any other active ingredient or product in any combination regimen that includes the Licensed Product; or (y) any Know-How licensed to Karuna or its Affiliates pursuant to a Potential In-License entered into after the Effective Date unless such Potential In-License becomes a New Karuna In-License in accordance with Section 2.12.

**1.79.** "**Licensed Patents**" means the Patents in the Licensed Territory Controlled by Karuna or its Affiliates as of the Effective Date or during the Term that (a) claim or cover the Compound or the Licensed Product (including the composition of matter, method of use, formulation, manufacture, or method of packaging or labelling or use thereof), and (b) are necessary or reasonably useful for the Exploitation of the Compound or Licensed Product in the Field in the Licensed Territory, including all Patents that claim or cover Product Inventions. Schedule 1.79 contains a list of all Licensed Patents as of the Effective Date. Notwithstanding the foregoing, in the event a Change of Control of Karuna occurs after the Effective Date, Patents Controlled by any Affiliate of Karuna that was not an Affiliate of Karuna immediately prior to such Change of Control transaction shall not be Licensed Patents except to the extent any such Patent falls within the definition of Licensed Patents in the immediately preceding sentence and (i) is also Controlled by Karuna or its Affiliate existing immediately prior to such transaction or (ii) claims any Invention generated or used by such Affiliate in the Exploitation of the Licensed Product after such transaction. Additionally, "Licensed Patents" shall exclude (x) any Patent that claims or covers any other active ingredient or product in any combination regimen that includes the Licensed Product or (y) any Patents licensed to Karuna or its Affiliates pursuant to a Potential In-License entered into after the Effective Date unless such Potential In-License becomes a New Karuna In-License in accordance with Section 2.12.

**1.80.** "**Licensed Product**" means any product that contains the Compound in any forms, presentations, strengths, concentrations, delivery technology, dosages, formulation, package configuration and modalities.

**1.81.** "**Licensed Technology**" means the Licensed Know-How and Licensed Patents.

**1.82.** "**Licensed Territory**" means (a) Mainland China, (b) Macao Special Administration Region, (c) Taiwan and (d) subject to Section 2.5, Hong Kong Special Administration Region (each of (a)-(d), a "**Region**").

**1.83.** "**Local Study**" means any Clinical Trial for the Licensed Product in the Field and which (a) Zai determines to conduct and is conducted by or on behalf of Zai in the Licensed Territory, and (b) does not include clinical sites in any country or jurisdiction outside the Licensed Territory.

**1.84.** "**Losses**" has the meaning set forth in Section 11.1.

**1.85.** "**Mainland China**" or "**PRC**" means the People's Republic of China, excluding Macau, Hong Kong, and Taiwan.

**1.86.** "**Manufacture**" or "**Manufacturing**" or "**Manufactured**" means all operations involved in production, synthesis, manufacturing, processing, filling and finishing, quality assurance and quality control testing (including in-process, release and stability testing, if applicable), storage, releasing, packaging, labeling, shipping and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacturing and analytic development, product characterization, and stability testing.

**1.87.** "**Manufacturing Technology**" means any and all Licensed Know-How and other relevant information relating to the then-current process for the Manufacture of the Compound or Licensed Product.

**1.88.** "**Manufacturing Technology Transfer**" has the meaning set forth in Section 6.2.

**1.89.** "**Milestone Events**" means Development Milestone Events and Net Sales Milestone Events.

**1.90.** "**Milestone Payments**" means Development Milestone Payments and Net Sales Milestone Payments.

**1.91.** [***].

**1.92.** "**NDA**" has the meaning set forth in Section 1.115.

**1.93.** "**Net Sales**" means the gross amount invoiced by Zai, its Affiliates, or Sublicensees for sales or other transfers of Licensed Product to unrelated Third Parties in the Licensed Territory, in bona-fide arm's length transactions, in each case less the following deductions: [***].

Such amounts shall be determined from the books and records of Zai, its Affiliates, or Sublicensees, maintained in accordance with generally accepted accounting principles (in accordance with GAAP or IFRS, as applicable) as consistently applied across its pharmaceutical products generally.

Net Sales on Licensed Product provided as part of a non-cash exchange or other than through an arms-length transaction shall mean [***].

Notwithstanding the foregoing, Net Sales shall not include [***].

In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of deductions).

The above deductions shall be the only deductions made in Net Sales and only to the extent such deductions are actually taken and documented as attributable to Licensed Product, and in all cases in a manner consistent with generally accepted accounting principles (in accordance with GAAP or IFRS, as applicable) consistently employed with respect to external reporting.

**1.94.** "**Net Sales Milestone Event**" has the meaning set forth in Section 8.3(a).

**1.95.** "**Net Sales Milestone Payment**" has the meaning set forth in Section 8.3(a).

**1.96.** "**New Karuna In-License**" has the meaning set forth in Section 2.12(c).

**1.97.** "**NMPA**" means the National Medical Licensed Product Administration in the PRC, including its subdivisions (including Center for Drug Evaluation), and local or provincial, and any successor agency(ies) or authority thereto having substantially the same function.

**1.98.** "**Party**" or "**Parties**" has the meaning set forth in the preamble to this Agreement.

**1.99.** "**Patent Prosecution**" means the responsibility and authority for (a) preparing, filing and prosecuting applications (of all types) for any Patent (including any decision whether to file a further divisional application), (b) managing any interference, opposition, re-issue, reexamination, invalidation proceedings, revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding to abandon Patent(s), (d) listing in regulatory publications (as applicable), (e) patent term extension, and (f) settling any interference, opposition, revocation, nullification or cancellation proceeding.

**1.100.** "**Patents**" means (a) all national, regional and international patents and patent applications, including any provisional patent application, (b) any patent application claiming priority from such patent application or provisional patent applications, including divisions, continuations, continuations-in-part, additions, (c) any patent that has issued or in the future issues from any of the foregoing patent applications, including any utility or design patent or certificate of invention, and (d) re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

**1.101.** "**Person**" means any individual, sole proprietorship, corporation, joint venture, limited liability company, partnership, limited partnership, limited liability partnership, trust or any other private, public or governmental entity.

**1.102.** "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.8(a).

**1.103.** "**Post-Marketing Study**" means any study conducted by or for Zai in the Licensed Territory with respect to the Licensed Product after submission of a Regulatory Approval Application for the Licensed Product, whether initiated by a Party or at the request of an applicable Governmental Authority, to delineate additional information about a drug's risks, benefits, and optimal use, including safety surveillance studies, pharmacoeconomic studies, pharmacoepidemiology studies, studies relating to different dosing or schedules of administration, studies of the use of the drug in other patient populations or other stages of the disease, or studies of the use of the drug over a longer period of time, but, in any case, excluding any study that is necessary to be completed in order to obtain Regulatory Approval.

**1.104.** "**Potential In-License**" has the meaning set forth in Section 2.12(a).

**1.105.** "**Potential In-License Notice**" has the meaning set forth in Section 2.12(a).

**1.106.** "**Prime Rate**" means for any day a per annum rate of interest equal to the "prime rate," as published in the "Money Rates" column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least [***] of the ten largest U.S. banks.

**1.107.** "**Product Infringement**" has the meaning set forth in Section 12.4(a)(i).

**1.108.** "**Product Invention**" means all Inventions other than any Zai Invention.

**1.109.** "**Product Marks**" has the meaning set forth in Section 7.5.

**1.110.** "**Public Official**" has the meaning set forth in Section 10.4(d).

**1.111.** "**Receiving Party**" has the meaning set forth in Section 9.1(a).

**1.112.** "**Records**" has the meaning set forth in Section 4.9.

**1.113.** "**Region**" has the meaning set forth in Section 1.82.

**1.114.** "**Regulatory Approval**" means, with respect to the Licensed Product in a country, Region or jurisdiction, the approvals from the necessary Governmental Authority to import, market and sell the Licensed Product in such country, Region or jurisdiction (but excluding pricing approvals and reimbursement approvals).

**1.115.** "**Regulatory Approval Application**" means a New Drug Approval Application ( "**NDA**" as defined in the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time) in the U.S., or any corresponding application for approval to import, market or sell a product in any country, Region or jurisdiction in the Licensed Territory (but excluding any application for pricing and reimbursement approvals).

**1.116.** "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting Regulatory Approvals for Licensed Product, including the NMPA, and any corresponding national or regional regulatory authorities.

**1.117.** "**Regulatory Exclusivity**" means with respect to the Licensed Product in a country, Region or jurisdiction, any exclusive marketing rights or data exclusivity rights under Applicable Laws or conferred by any Regulatory Authority in accordance with Applicable Laws with respect to the Licensed Product in such country, Region or jurisdiction.

**1.118.** "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including INDs, Regulatory Approvals and Regulatory Approval Applications, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to the Licensed Product.

**1.119.** "**Remedial Action**" has the meaning set forth in Section 5.10.

**1.120.** "**Retained Rights**" has the meaning set forth in Section 2.6.

**1.121.** "**Royalty Payment**" has the meaning set forth in Section 8.4(a).

**1.122.** "**Royalty Term**" has the meaning set forth in Section 8.4(b).

**1.123.** "**Subcontractor**" has the meaning set forth in Section 2.4.

**1.124.** "**Sublicensee**" has the meaning set forth in Section 2.3(a)(iii). For clarity, a Third Party who was granted a sublicense by a Sublicensee under the right granted by Karuna hereunder, in whole or in part, shall also be deemed a Sublicensee.

**1.125.** "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon). For the avoidance of doubt, Taxes includes VAT.

**1.126.** "**Term**" has the meaning set forth in Section 13.1(a).

**1.127.** "**Third Party**" means an entity other than (a) Zai and its Affiliates or (b) Karuna and its Affiliates.

**1.128.** "**Third Party Product**" means any pharmaceutical product that (a) is sold or distributed in the Licensed Territory by a Third Party that is not an Affiliate or (sub)licensee (including a Sublicensee) of, or otherwise authorized by, Zai or its Affiliates under a marketing authorization granted by a Regulatory Authority in the Licensed Territory to such Third Party, and (b) contains [***].

**1.129.** "**U.S. Dollars**" or "**$**" means United States dollars, the lawful currency of the United States.

**1.130.** "**Upfront Payment**" has the meaning set forth in Section 8.1.

**1.131.** "**Valid Claim**" means (a) a claim of an issued and unexpired Patent included within the Licensed Patents (but excluding any Licensed Patent that claims Product Invention solely invented by Zai and assigned by Zai to Karuna pursuant to Section 12.2) that has not been (i) permanently revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, (ii) abandoned, disclaimed or rendered unenforceable through disclaimer or otherwise, or (iii) abandoned, or (b) a claim of any filed patent application included within the Licensed Patents (but excluding any Licensed Patent that claims Product Invention solely invented by Zai and assigned by Zai to Karuna pursuant to Section 12.2) which has not been held finally revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction and which (i) has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, (ii) has not been withdrawn or abandoned, or (iii) has not been lost through an interference proceeding, or (iv) has not been pending for more than [***] from its earliest priority date (after which time, such claim shall cease to be considered a Valid Claim until it subsequently issues and falls within the description in subclause (a)).

**1.132.** "**VAT**" means value-added taxes or other similar taxes.

**1.133.** "**Withholding VAT Taxes**" has the meaning set forth in Section 8.8(b).

**1.134.** "**Zai**" has the meaning set forth in the preamble of this Agreement.

**1.135.** "**Zai Implemented Patents**" has the meaning set forth in Section 12.3(b).

**1.136.** "**Zai Indemnitee(s)**" has the meaning set forth in Section 11.2.

**1.137.** "**Zai Inventions**" means all Inventions created, conceived, developed or made solely by or on behalf of Zai or its Affiliates under this Agreement other than those that relate specifically to [***]. For clarity, Zai Inventions do not include any Inventions that [***].

**1.138.** "**Zai Invention Patents**" means any Patents that claim or cover Zai Inventions.

**1.139.** "**Zai IP**" means all Zai Know-How and Zai Patents.

**1.140.** "**Zai Know-How**" all Know-How that is Controlled by Zai or its Affiliates as of the Effective Date or during the Term and is actually used by Zai or any of its Affiliates in its Exploitation of the Compound or Licensed Product in the Licensed Territory or in connection with the performance of Zai's activities under this Agreement, including all Zai Inventions, but excluding any Know-How relating to any other active ingredient or product in any combination regimen that includes the Licensed Product.

**1.141.** "**Zai Patents**" means any Patents that are Controlled by Zai or its Affiliates as of the Effective Date or during the Term and claim or cover Zai Know-How, including Zai Invention Patents.

## ARTICLE 2

## LICENSES

**2.1. License Grant and Right of Reference to Zai**.

(a) Subject to the terms and conditions of this Agreement, Karuna hereby grants to Zai an exclusive (subject to Section 2.6), royalty-bearing license, with the right to grant sublicenses through multiple tiers (solely in accordance with Section 2.3), under the Licensed Technology, to Exploit the Compound and Licensed Product in the Field in the Licensed Territory.

(b) Subject to the terms and conditions of this Agreement, Karuna hereby grants to Zai the right of reference to all Regulatory Submissions related to the Licensed Product in the Field submitted by or on behalf of Karuna or its Affiliates or (sub)licensees (and all data contained or referenced therein), with the right to grant further rights of reference to Sublicensees to the extent permitted pursuant to Section 2.3. Subject to the terms and conditions of this Agreement (including Section 4.4(b)), Zai and its Affiliates (and any Sublicensee to whom it may grant a further right of reference) may use such right of reference to Karuna's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Licensed Product in the Field in the Licensed Territory. Karuna shall provide to Zai, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the right of reference as contemplated under this Section 2.1(b).

**2.2. License Grant and Right of Reference to Karuna**.

(a) Subject to the terms and conditions of this Agreement, Zai hereby grants to Karuna an exclusive, fully paid-up and royalty free, and sublicenseable license under Zai IP to (i) exercise its Retained Rights and (ii) perform Karuna's obligations under this Agreement, provided that, in each case ((i)-(ii)), such license shall be non-exclusive in the Licensed Territory.

(b) Subject to the terms and conditions of this Agreement, Zai hereby grants to Karuna the right of reference to all Regulatory Submissions related to the Licensed Product in the Field submitted by or on behalf of Zai or its Affiliates or Sublicensees (and all data contained or referenced therein), with the right to grant further rights of reference to Karuna's Affiliates and (sub)licensees with respect to Licensed Product. Subject to the terms and conditions of this Agreement, Karuna and its Affiliates (and any licensee to whom it may grant a further right of reference) may use the right of reference to Zai's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Licensed Product outside the Licensed Territory. Zai shall provide to Karuna, as necessary, a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate the right of reference as contemplated under this Section 2.2(b).

**2.3. Right to Sublicense**.

(a) **General**. Subject to the remainder of this Section 2.3, Zai shall have the right to grant sublicenses under the license and rights granted in Section 2.1 to:

(i) its Affiliates without Karuna's consent,

(ii) any Third Party Subcontractors engaged under Section 2.4, without Karuna's consent, and

(iii) any Third Party (other than those described in subclause (ii)) as proposed in writing by Zai, upon Karuna's prior written consent, not to be unreasonably withheld, conditioned, or delayed (each such permitted Third Party sublicensee in (ii) and (iii), a "**Sublicensee**").

(b) Zai shall ensure that each sublicense agreement between Zai and its Affiliate or Sublicensee is consistent with the terms of this Agreement, and specifically contains terms and conditions that: (i) require each such Affiliate or Sublicensee to protect and keep confidential any Confidential Information of the Parties, including in accordance with ARTICLE 9; (ii) provide Karuna with the right to audit (either by itself or through Zai or Zai's designee) the books and records of each such Sublicensee in accordance with this Agreement (including pursuant to Sections 4.7, 5.9, 7.7, 8.6(b), 8.6(c), and 10.4(a)(iv)); (iii) do not impose any payment obligations or liability on Karuna; (iv) contain appropriate intellectual property assignment and license provisions to give effect of the IP ownership and license provisions in this Agreement. Zai shall, (A) with respect to any sublicense agreement with a Sublicensee other than those described in Section 2.3(a)(ii), prior to entering into any sublicense agreement, provide Karuna a copy of the draft sublicense agreement that is substantially final, [***], in order for Karuna to confirm compliance with the foregoing requirements and approve such sublicense agreement; and (B) within [***] after execution of each sublicense agreement, provide a copy of the complete executed agreement with each Affiliate or Sublicensee to Karuna, [***], provided that, Zai shall be permitted to redact commercially sensitive terms of any such agreement which terms are not necessary for Karuna to confirm Zai's compliance with its obligations hereunder.

(c) **Restrictions**. Zai shall not grant a sublicense to any Affiliate or Third Party that has been debarred or disqualified by any Governmental Authority or is subject to any proceedings, sanctions or fines under any Anti-Corruption Law. Zai shall remain primarily responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any Affiliate or Sublicensee, and Karuna shall have the right to proceed directly against Zai without any obligation to first proceed against such Affiliate or Sublicensee. Karuna may require that Zai enforce any provisions of any sublicense agreement between Zai (or its Affiliate) and a Sublicensee against the applicable Sublicensee. Without limiting the foregoing, Zai shall be liable for (i) its Affiliate's Sublicensee's conduct under this Agreement, and (ii) its Affiliates' or Sublicensees' breach of this Agreement which shall be deemed a breach of this Agreement as if Zai had itself conducted the action or inaction that contributed to the breach of this Agreement.

**2.4. Subcontracting**. Subject to the terms and conditions of this Agreement, Zai may engage Third Party contract research organizations ("**CRO**s"), contract manufacturing organization, logistic service providers, sales contract sales, marketing providers or similar independent contractors (each, a "**Subcontractor**") solely for purposes of, as applicable, conducting Development activities in accordance with the Development Plan, Manufacturing or Commercialization activities for the Licensed Product in the Field in the Licensed Territory, in each case, for or on behalf of Zai under this Agreement without Karuna's prior written consent, provided that (a) any Subcontractor shall be bound by a written agreement that is consistent with the terms and conditions of this Agreement and shall include confidentiality and non-use of confidential information, and intellectual property assignment and license provisions, in each case, that are consistent with the applicable provisions of this Agreement, (b) Zai shall promptly notify Karuna identity of any such Subcontractor, including any audits Zai performs on such Subcontractor and provide Zai with a copy of any audit responses or audit reports [***]. Notwithstanding the foregoing, Zai shall remain primarily responsible for all of its obligations under this Agreement that have been delegated to or performed by a Subcontractor, and Karuna shall have the right to proceed directly against Zai without any obligation to first proceed against such Subcontractor. Karuna may require that Zai enforce any provisions of any agreement between Zai (or its Affiliate) and a Subcontractor against the applicable Subcontractor. Without limiting the foregoing, Zai shall be liable for (i) its Subcontractors' conduct under this Agreement, and (ii) its Subcontractors' breach of this Agreement which shall be deemed a breach of this Agreement as if Zai had itself conducted the action or inaction that contributed to the breach of this Agreement.

**2.5. Hong Kong License**. The Parties agree that the licenses and rights granted to Zai under Section 2.1 shall be extended to Hong Kong on the additional terms and conditions set forth on Schedule 2.5. Unless specifically stated otherwise on Schedule 2.5, all terms and conditions of this Agreement shall apply with respect to the Parties' rights and obligations in connection with Exploitation of the Compound and Licensed Product in Hong Kong (*mutatis mutandis*).

**2.6. Karuna Retained Rights**. Notwithstanding anything to the contrary in this Agreement, Karuna hereby expressly retains, on behalf of itself (and its Affiliates, other (sub)licensees, and designees) (a) all rights under the Licensed Technology to fulfill, either itself, its Affiliates or through subcontractors, Karuna's obligations under this Agreement, (b) the exclusive rights to Exploit the Compound and Licensed Product outside the Licensed Territory or outside the Field anywhere in the world (but without the right to Commercialize the Compound or the Licensed Product in the Licensed Territory during the Term, except with respect to any right or obligation of Karuna as the Initial MAH in accordance with the terms of this Agreement or otherwise required by Applicable Laws), (c) subject to and in accordance with Section 4.4, the non-exclusive rights under the Licensed Technology to conduct the Global Studies, (d) the non-exclusive rights to Manufacture or have Manufactured the Compound or Licensed Product in the Licensed Territory, solely to support (i) the Exploitation of the Compound and Licensed Product outside of the Licensed Territory, and (ii) the Exploitation of the Licensed Product in the Licensed Territory (including through the conduct of Global Studies by Karuna pursuant to Section 4.4), and (e) the right to exercise its rights and perform obligations as the CTA holder for the Karuna Sponsored Studies and the Initial MAH, as set forth in this Agreement or otherwise required by Applicable Laws (collectively (a)-(e), the "**Retained Rights**"). Zai acknowledges and agrees that the Retained Rights include the right for Karuna to grant licenses under clauses (a) through (e) of the Retained Rights to its Affiliates and Third Parties.

**2.7. No Other Rights**. Except for the licenses and rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by a Party to the other Party. All rights with respect to Know-How, Patents or other intellectual property rights that are not specifically granted herein are reserved to the owner thereof. Further, the licenses and other rights granted to Zai herein are subject to the rights retained by the counterparty to each Existing In-License Agreement and New Karuna In-License, as applicable.

**2.8. Covenant Not to Exceed the Scope of the License**. Each Party shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Patent or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

**2.9. Exclusivity**.

(a) Subject to the remainder of this Section 2.9, unless otherwise agreed by the Parties in writing:

(i) During the period commencing on the Effective Date and ending on [***], neither Party shall, for itself, or with, through or for its Affiliates or any Third Party (including the grant of any license, option or other right to any Third Party), directly or indirectly, seek Regulatory Approval of, or Commercialize any [***] anywhere in the Licensed Territory, other than the Compound or Licensed Product as expressly permitted under this Agreement.

(ii) During the Term, Zai shall not, for itself, or with, through or for its Affiliates or any Third Party (including the grant of any license, option or other right to any Third Party), directly or indirectly, engage in or conduct any clinical Development, seek Regulatory Approval of, or Commercialize any [***] anywhere in the Licensed Territory, other than the Compound or Licensed Product as expressly permitted under this Agreement.

(b) Notwithstanding Section 2.9(a), in the event that a Third Party becomes an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged in the Exploitation of [***] in the Licensed Territory in a manner that is not permitted under Section 2.9(a), then:

(i) if such transaction results in a Change of Control of such Party, then such new Affiliate shall have the right to continue the Exploitation of [***] in the Licensed Territory and such continuation shall not constitute a breach of such Party's exclusivity obligations set forth above; provided that such Party and its new Affiliate, for the duration of the applicable exclusivity obligation, [***]; and

(ii) if such transaction does not result in a Change of Control of such Party, then such Party and its new Affiliate shall have [***] from the closing date of such transaction to wind down or divest (including exclusively out-license with no further active Exploitation) such [***], and its new Affiliate's Exploitation of such [***] during such [***] period shall not deemed a breach of such Party's exclusivity obligations set forth above; provided that, during such [***], such Party and its new Affiliate [***].

(c) During the Term, if Karuna or any of its Affiliates directly or indirectly, engages in or conducts clinical Development of [***] and desires to, either by itself, or through its Affiliates or any Third Party (including the grant of any license, option or other right to any Third Party), engage in any Commercialization of [***] anywhere in the Licensed Territory, it shall promptly notify Zai in writing of such intention, together with a reasonably detailed summary of any material Development results of [***] (the "**Competing Product Notice**"). Zai may, within [***] following receipt of the Competing Product Notice, provide a written notice to Karuna and elect to exclusively negotiate with Karuna a license for the Exploitation of [***] in the Licensed Territory. Thereafter, the Parties shall negotiate in good faith for a period of [***] (the "**Exclusive Negotiation Period**"). If Zai fails to provide such notice, or, despite exercising good faith efforts, the Parties cannot reach an agreement with respect to such license for [***] in the Licensed Territory within the Exclusive Negotiation Period, then Karuna shall, have the right, either by itself or with, through or for its Affiliates or any Third Party, to Exploit [***] in the Licensed Territory, without any obligation to Zai, provided that, (i) if despite good faith negotiations, the Parties cannot agree with respect to such license for [***], Karuna agrees not to [***]; and (ii) if Karuna does not enter an agreement with any Third Party with respect to the grant of such rights [***], then Zai's first right of negotiation under this Section 2.9(c) with respect to [***] shall again become effective and applicable;

(d) The obligations of Karuna set forth in Section 2.9(c) (x) shall terminate if Karuna undergoes a Change of Control after the Effective Date; except that, upon Change of Control of Karuna during the Term, such obligations set forth in Section 2.9(c) shall continue to apply to [***] prior to such Change of Control by Karuna or any of its Affiliates existing prior to such Change of Control; and (y) shall not apply if a Third Party becomes an Affiliate of Karuna after the Effective Date through merger, acquisition, consolidation or other similar transaction, and such transaction does not result in a Change of Control of Karuna, with respect to [***] Exploited by such new Affiliate or any of its Affiliates with a Third Party as of the closing date of such transaction.

**2.10. Access to Licensed Know-How**. Within [***] following the Effective Date, Karuna shall provide Zai access to all Licensed Know-How as of the Effective Date, which access shall occur in a manner and following a reasonable schedule mutually agreed by the Parties. During the Term, Karuna shall provide or make available to Zai additional Licensed Know-How, to the extent that such Licensed Know-How comes to Karuna's attention (or is reasonably requested by Zai) and has not previously been provided or made available to Zai, to the extent necessary or reasonably useful for Zai to exercise its rights or perform its obligations under this Agreement. In connection with transfer of the Licensed Know-How, Karuna shall also provide Zai with reasonable technical assistance in order for Zai to use and apply the Licensed Know-How in the Exploitation of the Compound and Licensed Product, including reasonable access to its technical personnel involved in the Exploitation of the Compound and Licensed Product. Zai shall reimburse Karuna for the cost incurred by Karuna to provide such technical assistance, [***].

**2.11. Existing In-License Agreements**. All licenses and other rights granted to Zai under this Agreement (including any sublicense rights) are subject to the rights and obligations of Karuna under the Existing In-License Agreements. Zai acknowledges and agrees that it will comply with all of the obligations under the Existing In-License Agreements to the extent applicable to Zai as a sublicensee thereunder that are set forth on Schedule 2.11 (the "**Existing In-License Agreement Terms**"), which shall be incorporated in this Agreement by reference. Karuna shall be solely responsible for the payment of any royalty, milestone and other payments due to Third Parties under any Existing In-License Agreement on account of Zai's, its Affiliates' and Sublicensees' Exploitation of the Compound and Licensed Product in the Field in the Licensed Territory in accordance with this Agreement and the Existing In-License Agreement Terms.

**2.12. New Karuna In-Licenses**.

(a) If, during the Term, Karuna enters into any agreement with a Third Party pursuant to which it obtains a licensable or sublicensable (in accordance with the terms of this Agreement) right or license from such Third Party to any Patents or Know-How that would, but for the provisions of this Section 2.12 constitute Licensed Technology (such agreement, a "**Potential In-License**"), then Karuna shall promptly notify Zai thereof in writing, including by providing a summary description of: (i) such Patents or Know-How under such Potential In-License; (ii) all payments that Karuna would be obligated to pay to such Third Party in connection with the grant, maintenance, or exercise of a license or sublicense to or by Zai under such Patents or Know-How; and (iii) all obligations with which Zai would be required to comply as a licensee or sublicensee under such Potential In-License (such notice, a "**Potential In-License Notice**").

(b) If, within [***] after the receipt of a Potential In-License Notice, Zai provides Karuna with written notice indicating interest in obtaining a license or sublicense under such Patents or Know-How, then Karuna shall promptly provide Zai with a copy of such Potential In-License, which copy may be redacted to exclude terms not relevant to the rights or obligations that Zai would receive or assume if it were to exercise its rights under this Section 2.12 to include such Patents or Know-How as Licensed Technology.

(c) If, within [***] after receipt of such copy referenced in Section 2.12(b), Zai provides Karuna with written notice in which: (i) Zai consents to including the applicable Patents or Know-How in the Licensed Technology; and (ii) Zai agrees to (A) make all payments when due under such Potential In-License to the extent arising out of the grant, maintenance, or exercise of a license or sublicense to or by Zai under such Patents or Know-How and (B) comply with all obligations under such Potential In-License as required to comply as a licensee or sublicensee under such Potential In-License, then (x) such Potential In-License shall be deemed a "**New Karuna In-License**" thereafter, (y) any such Patents or Know-How, to the extent otherwise falling within the definition of Licensed Technology, shall be added to Licensed Technology and licensed or sublicensed to Zai under this Agreement, and (z) Zai shall be obligated to make any payments referenced in the foregoing sub-clause (ii)(A). If Zai does not provide such notices required by this Section 2.12, such Patents and Know-How will be excluded from the Licensed Technology pursuant to this Agreement and such Potential In-License will not become a New Karuna In-License.

## ARTICLE 3

## GOVERNANCE

**3.1. Joint Steering Committee**.

(a) **Formation**. Within [***] after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") to cooperate, coordinate, integrate and monitor the Development and Commercialization of the Compound and Licensed Product in the Field in the Licensed Territory under this Agreement. Each Party shall appoint [***] (or such other equal number of representatives as agreed by the Parties in writing) to the JSC, each of whom shall be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its JSC representatives upon written notice to the other Party. Upon the JSC's establishment, a representative from Zai shall act as the chairperson of the JSC. Once a year, the role of chairperson shall rotate between the Parties. The chairperson shall not have any greater authority than any other representative of the JSC.

(b) **Role**. The JSC shall [***].

(c) **Limitation of Authority**. The JSC shall only have the powers expressly assigned to it in this ARTICLE 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) make any decisions related to, or determine, approve or oversee the initiation, suspension, cessation, conduct, strategy, implementation of or other matters related to, any Global Study; or (v) impose any other obligations on either Party without the prior written consent of such Party.

(d) **Meetings**. The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [***]. Each Party may call additional ad hoc JSC meetings as the needs arise with reasonable advance notice to the other Party. Meetings of the JSC may be held in person, or by audio or video teleconference, unless otherwise agreed by the Parties. In-person JSC meetings shall be held at locations mutually agreed by the Parties. Each Party shall be responsible for such Party's expenses of participating in the JSC meetings. No action taken at any JSC meeting shall be effective unless at least [***] of each Party are participating in such JSC meeting. The Alliance Manager appointed by Zai as set forth in Section 3.2 herein shall prepare the minutes for all JSC meetings, which such minutes shall be approved by the JSC at the subsequent meeting.

(e) **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants relevant to items on the issued agenda, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party, and such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making**. [***]. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within [***] after such matter was brought to the JSC for resolution, such matter shall be referred by a notice sent pursuant to Section 15.5 by the JSC to the Executive Officers of both Parties for resolution. If the Executive Officers cannot resolve such matter within [***] after such matter has been referred to them, then such matter shall be resolved as follows:

(i) Except as otherwise provided in Section 3.1(f)(iii), Zai shall have final decision making authority over such matter to the extent such matter primarily relates to [***]. Notwithstanding the foregoing, if Karuna reasonably believes that any decision made by Zai pursuant to this Section 3.1(f)(i) would be reasonably expected to [***], Karuna shall have the final decision-making authority over such matter. Notwithstanding the foregoing, Zai shall have the final decision-making authority regarding [***].

(ii) Karuna shall have the final decision-making authority over all matters relating to [***], provided that Karuna shall not use its final decision-making authority in a manner that would [***].

(iii) Notwithstanding anything to the contrary, the following matters shall require the Parties' mutual agreement, with neither Party having the final decision-making authority with respect thereto: [***].

(g) **Exchange of Information**. The Parties shall cooperate to exchange information through the JSC and otherwise as reasonably requested by the other Party with respect to Development, Manufacture, Commercialization and medical affairs activities conducted by each Party and their Affiliates, in the case of Zai its Sublicensees, and in the case of Karuna, its (sub)licensees of rights to the Compound or Licensed Product outside the Licensed Territory. Such exchange shall include summaries of information relating to material Development activities of each Party, including all Clinical Trials of the Licensed Product, IND and Regulatory Approval Application filings for all Indications for the Licensed Product. For Clinical Trials of the Licensed Product that may be used to support Regulatory Approval for the Licensed Product in the other Party's territory (including Global Studies), such exchange shall also include all data, results and analyses as reasonably requested by a Party, and the other Party shall have the right to use such data and results for the purpose of obtaining and maintaining Regulatory Approval for the Licensed Product in its territory, subject to Section 4.4(d).

**3.2. Alliance Managers**. Within [***] following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) to act as its alliance manager with respect to this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as the primary contact points between the Parties regarding the activities in the Licensed Territory contemplated under this Agreement. The Alliance Managers shall (a) facilitate the flow of information; (b) otherwise promote communication, coordination and collaboration between the Parties by providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party or cross-functional disputes in a timely manner; and (c) manage the JSC meetings by (i) calling meetings of the JSC; (ii) preparing and issuing minutes of each such meeting within [***] thereafter; and (iii) preparing and circulating an agenda for the upcoming meeting, in each case at the direction of and in consultation with the then-current chairperson, provided that the Alliance Manager of each Party shall not have the authority to vote on behalf of such Party with respect to any matters within the authority of the JSC. Each Party may replace its Alliance Manager by written notice to the other Party.

## ARTICLE 4

## DEVELOPMENT

**4.1. Development Plan**. The Parties shall undertake the Development of the Licensed Product in a collaborative and efficient manner in accordance with this ARTICLE 4. The Development and Manufacturing of the Compound and Licensed Product relating to the Licensed Territory under this Agreement shall be governed by a written development plan (the "**Development Plan**"), as revised from time to time in accordance with this Section 4.1. The Development Plan shall include [***]. The Development Plan shall contain in reasonable detail the major Development activities and the projected timelines for conducting such activities, including activities designed to achieve Regulatory Approvals for the Licensed Product in the Licensed Territory. An initial Development Plan is attached hereto as Schedule 4.1. From time to time, and subject to Zai's diligence obligations set forth in Section 4.2(c) (as may be modified by Section 4.2(d)), Zai may propose certain necessary updates or amendments to the Development Plan in consultation with Karuna and submit such proposed updated or amended plan to the JSC for review, discussion and approval. In accordance with Section 3.1(b), the JSC shall review, discuss and approve any updates or amendments to the Development Plan. For clarity, the Parties acknowledge and agree that Zai will not undertake any activities relating to [***].

**4.2. Responsibilities; Diligence**.

(a) **General**. During the Term, subject to the JSC's oversight, and rights of Karuna as the CTA holder for the Karuna Sponsored Studies and the Initial MAH, as set forth in this Agreement or otherwise required by Applicable Laws, Zai shall have the primary responsibility for the Development of the Licensed Product in the Field in the Licensed Territory, in accordance with the Development Plan, at Zai's sole cost and expense subject to Section 4.4(b). Zai shall perform such obligations under the Development Plan in a professional and scientific manner, and in compliance with the requirements of Applicable Laws, GCP and cGMP. Changes in the scope or direction of the Development work under this Agreement that would be a material deviation from the Development Plan must be approved by the JSC as set forth in Section 3.1(b); provided that any change with respect to Joint Global Studies shall be consistent with the Joint Global Studies as set forth in the Global Development Plan.

(b) **Diligence**. During the Term, Zai, by itself or through its Affiliates and Sublicensees, shall use Commercially Reasonable Efforts to Develop the Licensed Product in the Field in each Region in the Licensed Territory in accordance with the Development Plan.

(c) **Development Targets**. Without limiting the foregoing, Zai shall achieve the following Development milestones with respect to the Development of the Licensed Product in the PRC (each, a "**Development Target**" and the associated deadline, "**Development Target Deadline**"). [***].

(d) **Extension for Delay.** Upon the JSC's approval (not to be unreasonably withheld, conditioned or delayed), the Development Target Deadline for each Development Target above may be extended by the duration of any delays that are encountered during the course of Development and caused by [***]. Notwithstanding the foregoing, if Zai fails to meet any Development Target Deadline that is due, the JSC shall be deemed to have approved an extension to the extent Zai has presented reasonable written documentary evidence demonstrating that, at the time such Development Target Deadline is due: [***].

(e) **Failure to Meet Development Target Deadlines.** and [***] Karuna shall have the right to terminate this Agreement as provided in Section 13.3, [***] subject to Zai's right to dispute the applicability of.

**4.3. Local Study**.

(a) Subject to rights of Karuna as the CTA holder of the Karuna Sponsored Studies and Initial MAH, as set forth in this Agreement or otherwise required by Applicable Laws, Zai shall be solely responsible for performing any Local Study at its sole cost (including handling relevant Regulatory Submissions for any Local Studies in the Licensed Territory at its own cost, as applicable, in accordance with ARTICLE 5), as set forth in the Development Plan; provided that [***]. Each Local Study conducted in the Licensed Territory shall be conducted in accordance with the Development Plan, including the study protocol set forth therein and approved by any relevant Regulatory Authority, and Applicable Laws in the Licensed Territory.

(b) Without limiting the foregoing, for each Karuna Sponsored Study, [***].

(c) [***].

**4.4. Global Study**.

(a) **General**. Karuna may initiate, suspend, or cease a Global Study for the Licensed Product for any Indication. As between the Parties, Karuna shall be responsible for any Global Study of the Licensed Product, subject to this Section 4.4, with respect to participation by Zai in Joint Global Studies. Karuna shall present to the JSC a global development plan for any Global Study that includes clinical sites for Clinical Trials for the Licensed Product in the Licensed Territory (the "**Global Development Plan**"). The JSC shall discuss such Global Development Plan for Zai's potential participation in such Global Study in the Licensed Territory.

(b) Zai may participate in a Global Study presented by Karuna in a Global Development Plan based upon mutual agreement of the Parties (such agreed Global Study, a "**Joint Global Study**"). Unless otherwise agreed between the Parties, Zai shall be responsible for all activities associated with conducting each Joint Global Study in the Licensed Territory set forth in the applicable Global Development Plan, and any additional or modified activities for such Joint Global Study in the Licensed Territory so agreed between the Parties shall be included in an amendment to the Global Development Plan. Zai shall recruit, enroll, treat, and provide follow-up in a timely manner with respect to an agreed number or percentage of the total number of patients to be treated under the protocol set forth in the Regulatory Submission to the FDA and NMPA for the Joint Global Study and in accordance with the Global Development Plan (as may be amended pursuant to the preceding sentence), provided that if the percentage of the total number of patients enrolled in the Licensed Territory exceeds [***] of the total number of patients enrolled in a Joint Global Study, Karuna will be responsible for the costs of such patients enrolled in the Licensed Territory above such [***].

(c) Zai, itself or with or through any other of its Affiliates or Sublicensees, shall, in accordance with Section 5.1, be the Authorized Regulatory Agent of each Joint Global Study in the Licensed Territory. For any Joint Global Study, Zai shall be responsible for [***], and Karuna shall be responsible for [***].

(d) If Zai elects not to participate in any Global Study presented by Karuna by notifying Karuna in writing of such election not to participate (or by failing to notify Karuna in writing of its election to participate) within [***] after the date of Karuna's presentation of such Global Study to the JSC, Karuna may conduct such Global Study in the Licensed Territory [***] but in conducting such Global Study, the Parties shall coordinate the Parties' Development activities for the Licensed Product in the Licensed Territory, provided that Zai shall not have access, or any right of reference to, any data (except for safety data) generated from such Global Study, and any Know-How (except for safety data) or Patents resulting from such Global Study shall be excluded from Licensed Technology unless Zai notifies Karuna in writing of Zai's intent to have access and right of reference to such data, and to include any such Know-How or Patents in Licensed Technology, in which case, Zai shall pay to Karuna [***].

**4.5. Post-Marketing Studies**. If the Regulatory Authority requires that a Post-Marketing Study for the Licensed Product be conducted in the Licensed Territory, or if the Parties mutually agree that a Post-Marketing Study for the Licensed Product in the Licensed Territory is necessary (such agreement not to be unreasonably withheld, conditioned, or delayed), Zai shall be responsible for conducting such Post-Marketing Study for the Licensed Product in the Licensed Territory, including [***].

**4.6. Development Reports**. The status, progress and results of Zai's Development activities under this Agreement shall be discussed at meetings of the JSC. At least [***] before each regularly scheduled JSC meeting, Zai shall provide the JSC with a written report in English summarizing its Licensed Product Development activities and the results thereof, covering subject matter at a level of detail reasonably requested by Karuna and sufficient to enable Karuna to determine such Zai's compliance with its obligations pursuant to Section 4.1 to Section 4.4. In addition, Zai shall make available to Karuna such additional information about its Development activities with Licensed Product as may be reasonably requested by Karuna from time to time. All updates and reports provided by Zai pursuant to this Section 4.6 shall be the Confidential Information of Zai.

**4.7. Clinical Trials Compliance and Registration**. Each Party shall conduct all Clinical Trials of the Licensed Product in the Licensed Territory in compliance with all Applicable Laws, including GCP and regulations promulgated by the NMPA. Zai shall be responsible for registering in the appropriate clinical trial registry and posting the results of all studies for the Licensed Product conducted under an IND filed by or on behalf of Zai for the Licensed Product in the Licensed Territory as required by Applicable Law. Zai further agrees to allow Karuna to post the clinical trial results of Zai's Clinical Trials for the Licensed Product as required by Applicable Law.

**4.8. Conduct of Audits**. Upon [***] prior written notification by Karuna but no more frequent than [***] (except in the event that Karuna has reasonable cause), and based on an audit scope agreed upon by the Parties, Karuna or its representatives may conduct an audit of Zai, its Affiliates, or any Sublicensees or Subcontractors, and all Clinical Trial sites engaged by Zai or its Affiliates, Sublicensees or Subcontractors to perform Zai's obligations under any Development Plan, in each case, to ensure that the applicable Clinical Trials are conducted in compliance with the Development Plan, GCP, and Applicable Laws; provided that in the event any such audit of Zai's Subcontractors or Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees, in each case, requires Zai's assistance, Zai shall provide Karuna or its representatives with such assistance [***], to the extent reasonable, including providing personnel of Zai to be present for such audit and producing any documents or authorizations allowing Karuna or its representatives to conduct such audit, to the extent reasonable. No later than [***] after the completion of such audit, Karuna shall provide Zai with a written summary of Karuna's findings of any deficiencies or other areas of remediation that Karuna identifies during any such audit. Zai shall use Commercially Reasonable Efforts to respond or remediate any such deficiencies within [***] following Karuna's receipt of such report. Without limiting the foregoing, Zai shall have the right to be present at any such audit conducted by Karuna pursuant to this Section 4.8 of any Sublicensees, Subcontractors, or Clinical Trial sites.

**4.9. Records**. In conformity with Applicable Law, standard pharmaceutical industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data (including Development Data) with respect to activities conducted concerning the Licensed Product ("**Records**") in the Licensed Territory; provided, that in no instance shall such Records be maintained for less than the latest of (a) [***] following the end of the Calendar Year to which the records pertain, (b) requirements under Applicable Law or (c) such Party's standard operating practice. Upon a Party's written request and to the extent required by Applicable Law or applicable Regulatory Authorities in the Licensed Territory, the other Party shall make available to the requesting Party electronic copies (unless otherwise required by Applicable Law) of the aforesaid required Records to the requesting Party throughout the Term and thereafter as long as such other Party Controls such Records, which shall be at minimum for the time period set forth above.

**4.10. Ownership, Disclosure and Use of Development Data**.

(a) Except as otherwise provided by Section 12.1 with respect to Inventions, during the Term, any and all Data and other results generated by a Party, its Affiliate or its respective licensees, sublicensees, collaboration partners, contractors, subcontractors (including Subcontractors) concerning the Licensed Product, including relevant laboratory notebook information, screening data, regulatory data (including all data and results created for or provided to any Regulatory Authority) and data from all pre-clinical studies (including toxicology studies) and Clinical Trials of the Licensed Product (including all data and results created for or provided to any Investigator Review Board or principal investigator of any pre-clinical study or Clinical Trial) (collectively, the "**Development Data**"), shall, as between Zai and Karuna, (i) be owned solely and exclusively by Karuna if [***], (ii) be jointly owned by Karuna and Zai if [***]. Each Party shall require that all of its Affiliates, Sublicensees and subcontractors (including Subcontractors) assign any of such Affiliates', Sublicensees' and subcontractors'(including Subcontractors') right, title and interest in and to such Development Data to such Party in order to comply with this provision.

(b) All material Development Data in Control of Karuna or its Affiliates and existing as of the Effective Date that is necessary for the Development and Commercialization of the Licensed Product in the Licensed Territory shall be made available to Zai (or its designee) as promptly as practicable, in any event within [***] after the Effective Date. Any additional material Development Data generated by or on behalf of a Party or its Affiliates and in its Control after the Effective Date and during the Term of this Agreement that is necessary for the Development and Commercialization of the Licensed Product in the Licensed Territory shall be made available to the other Party (or its designee) within [***] after such Party or its Affiliate distributes copies or summaries of such Development Data internally.

(c) During the Term, each Party shall promptly provide to the JSC (in the case of Zai, together with the Development reports submitted to the JSC pursuant to Section 4.6), or to the other Party upon the other Party's request, any Development Data generated pursuant to the Development Plan by or on behalf of such Party, its Affiliates, licensees or Sublicensees, to the extent not previously provided to the JSC or the other Party.

(d) Each Party and its Affiliates may only use and disclose the Development Data during the Term for the purposes of exercising its rights and performing its obligations with respect to the Licensed Product in its territory (and with respect to Karuna, for purposes of exercising the Retained Rights) pursuant to this Agreement, including Development and regulatory activities with respect to the Licensed Product under this Agreement or its or their ongoing compliance with record retention requirements with respect to the Licensed Product by any Regulatory Authority in its territory; provided, for clarity, that neither Party nor its Affiliates will have any right to use or disclose any Development Data of the other Party as a comparator with, or in comparison to, any other compound or product without such other Party's prior written consent.

## ARTICLE 5

## REGULATORY

**5.1. Zai's Responsibilities**.

(a) The regulatory strategy for the Licensed Territory will be consistent with the overall objectives of obtaining and maintaining Regulatory Approval of the Licensed Product in the Licensed Territory in accordance with the Development Plan. During the Term, subject to the oversight of the JSC, Zai shall, at its sole cost and expense, (i) be responsible for all regulatory activities leading up to and including the obtaining of the Regulatory Approval for the Licensed Product from the Regulatory Authority on a Region-by-Region basis in the Field in the Licensed Territory, at its sole cost and expense, except as set forth in the Global Development Plan and Development Plan; and (ii) to the extent permitted by Applicable Law, hold and maintain all Regulatory Approvals, Regulatory Submissions and all pricing and reimbursement approvals, in each case, for the Licensed Product in the Field in the Licensed Territory, in the name of Zai or its Affiliates, provided that, if Applicable Laws in a Region in the Licensed Territory do not allow Zai (or an Affiliate of Zai) to hold Regulatory Approvals or Regulatory Submissions for the Licensed Product in the Field in the Licensed Territory, then during the Term, Karuna will, at Zai's costs, (A) hold such Regulatory Approval, Regulatory Submissions and pricing and reimbursement approvals for the Licensed Product in the Field in such Region solely for Zai's benefit, (B) appoint Zai (or an Affiliate of Zai) as sole Authorized Regulatory Agent to handle all regulatory activities for the Licensed Product in the Field in such Region, and (C) shall promptly transfer such Regulatory Approval, Regulatory Submissions and pricing and reimbursement approvals to Zai or its designee when allowed by Applicable Laws.

(b) Zai shall use Commercially Reasonable Efforts to obtain and maintain, in its own name (or in the name of its Affiliates, but subject to Section 5.1(a)(ii)), Regulatory Approvals, Regulatory Submissions and pricing and reimbursement approvals (if applicable) for Licensed Product in the Field in each Region in the Licensed Territory in accordance with the Development Plan and Zai shall be [***]. During any period when Karuna holds any Regulatory Approval, Regulatory Submissions or pricing and reimbursement approvals for the Licensed Product in the Field in a Region for Zai's benefit pursuant to Section 5.1(a)(ii), (i) Karuna shall not be obligated to [***]; (ii) Karuna shall not assume any liability [***]; (iii) should Karuna or its Affiliates incur any costs or expenses related to holding or transferring any such Regulatory Approval, Regulatory Submissions or pricing and reimbursement approvals, Zai shall [***]; and (iv) Zai shall [***].

(c) Zai shall keep Karuna promptly informed (and in any event within [***] for any significant matter) of regulatory developments related to the Licensed Product in each Region in the Licensed Territory and shall promptly notify Karuna in writing of any decision by any Regulatory Authority in such Region in the Licensed Territory regarding the Licensed Product. Zai shall share with Karuna copies of correspondences or a summary of phone calls received from and sent to any Regulatory Authority in each Region in the Licensed Territory relating to the Licensed Product promptly after (and in any event within [***] for any significant matter) Zai or its Affiliate distributes such copies or summaries internally.

(d) [***].

(e) [***].

**5.2. Review of Regulatory Submissions**. Zai shall provide to Karuna for review and comment drafts of all material Regulatory Submissions (including application for HGR Approvals) in Field in the Licensed Territory for the Licensed Product no later than [***] prior to the planned submission, provided that, [***]. Zai shall incorporate any comments received from Karuna on such Regulatory Submissions where required under any Applicable Laws and shall use good faith efforts to incorporate any other comments received from Karuna on such Regulatory Submissions; provided that in the event of any disagreement regarding incorporation of comments made by Karuna with respect to the contents of any substantive proposals or Regulatory Submission for the Licensed Product in the Licensed Territory or any written correspondence with any Regulatory Authority for the Licensed Product in the Licensed Territory, the Parties shall discuss, through the JSC, such disagreements in good faith. In addition, Zai shall notify Karuna of any material Regulatory Submissions for the Licensed Product and any other material documents, comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Licensed Territory and shall provide Karuna with copies thereof as soon as reasonably practicable, but in all events within [***] after submission or receipt thereof [***].

**5.3. Notice of Meetings**. Zai shall provide Karuna with notice of any material meeting or discussion with any Regulatory Authority in the Licensed Territory related to the Licensed Product no later than [***] after receiving notice thereof. Zai shall lead any such meeting or discussion and Karuna or its designee shall have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Laws or Regulatory Authority. At Zai's request, Karuna shall reasonably cooperate with Zai in preparing for any such meeting or discussion. If Karuna elects not to attend such meeting or discussion, then Zai shall provide to Karuna a written summary thereof in English promptly following the issuance or approval of the corresponding official minutes by the applicable Regulatory Authority.

**5.4. Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Zai, its Affiliates, Sublicensees or Subcontractors, in each case, relating to the Licensed Product, then Zai shall notify Karuna of such contact, inspection, or notice or action within [***] after receipt of such notice (or, if action is taken without notice, within [***] of Zai becoming aware of such action). Karuna shall have the right to review and comment on any responses to any Regulatory Authority that pertain to the Licensed Product in the Licensed Territory.

**5.5. Karuna's Responsibilities**. Subject to Section 4.4(d), Karuna shall reasonably cooperate with Zai in obtaining any Regulatory Approvals for the Licensed Product in the Licensed Territory by providing, to the extent reasonably requested by Zai, access to Regulatory Approvals, Regulatory Submissions, Development Data, and other information and documentation for the Licensed Product outside of the Licensed Territory if such information is required by Applicable Laws in the Licensed Territory or requested by a Regulatory Authority in the Licensed Territory in furtherance of such Regulatory Approvals for the Licensed Product in the Licensed Territory. In addition, upon Zai's reasonable request, Karuna shall, and shall cause its Affiliates and sublicensees to provide to Zai copies of such records of Development, Manufacturing, and Commercialization activities to the extent required to obtain Regulatory Approval of the Licensed Product in the Licensed Territory. [***].

**5.6. No Harmful Actions**. If Karuna believes that Zai is taking or intends to take any action with respect to the Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product outside the Licensed Territory, Karuna shall have the right to bring the matter to the attention of the JSC and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Zai shall not communicate with any Regulatory Authority having jurisdiction outside the Licensed Territory, unless so ordered by such Regulatory Authority, in which case Zai shall immediately notify Karuna of such order; and (b) Zai shall not submit any Regulatory Submissions or seek Regulatory Approvals for the Licensed Product outside the Licensed Territory.

**5.7. Regulatory Authority Communications Received by a Party**. Each Party shall keep the other Party informed in a timely manner, and compliant with the reporting requirements of the applicable Regulatory Authorities, of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority (inside or outside of the Licensed Territory as applicable) which: (a) raises any material concerns regarding the safety or efficacy of the Licensed Product; (b) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Licensed Product in the Field in the Licensed Territory; (c) is reasonably likely to lead to a recall or market withdrawal of the Licensed Product; (d) relates to expedited and periodic reports of Adverse Events with respect to the Licensed Product and which may have a material impact on obtaining or maintaining Marketing Approval or the continued commercialization of the Licensed Product in the Licensed Territory, as then conducted; or (e) relates to any dissatisfaction regarding the Licensed Product in the Licensed Territory of such a nature and magnitude that it is required under the Applicable Law to be collected, maintained and reported to a Regulatory Authority, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients. Each Party shall provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above. Karuna shall reasonably cooperate with and assist Zai in complying with regulatory obligations and communications, including by providing to Zai, in a timely manner upon request, such information and documentation in Karuna's possession or Control as may be necessary for Zai to prepare a response to an inquiry from any Regulatory Authority regarding the Licensed Product in the Licensed Territory. To the extent there are any inconsistencies or conflicts between this Section 5.7 and the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control, unless otherwise agreed to in writing by the Parties.

**5.8. Adverse Events Reporting**.

(a) Promptly following the Effective Date, but in no event later than [***] thereafter, Zai and Karuna shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the "**Pharmacovigilance Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The Pharmacovigilance Agreement shall be promptly updated if required by changes in Applicable Law. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 5.8, Section 5.9, or any related definitions and the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control with respect to safety matters and this Agreement shall control with respect to all other matters.

(b) Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Licensed Territory for all Clinical Trials performed by or on behalf of Zai, its Affiliates, Subcontractors and Sublicensees, including the Local Studies and Joint Global Studies, and Karuna shall be responsible for complying with all Applicable Laws covering Adverse Events (i) in the Licensed Territory for all Clinical Trials performed by or on behalf of Karuna, its Affiliates, Subcontractors and licensees for the Global Studies that Zai does not participate in, and (ii) outside the Licensed Territory for all Clinical Trials.

(c) Karuna shall hold and control the global safety database for all Licensed Product and for the exchange by the Parties in English of any information which a Party becomes aware of concerning any Adverse Event experienced by a subject or patient being administered the Licensed Product, including any such information received by either Party from any Third Party (subject to receipt of any required consents from such Third Party). It is understood that each Party and its Affiliates, licensees and sublicensees shall have the right to disclose such information if such disclosure is reasonably necessary to comply with Applicable Laws or requirements of any applicable Regulatory Authority.

**5.9. Safety and Regulatory Audits**. Upon reasonable notification, Karuna shall be entitled to conduct an audit of safety and regulatory systems, procedures and practices of Zai, its Affiliates, and Sublicensees (including Clinical Trial sites), in each case, relating to the Development of the Licensed Product in the Field in the Licensed Territory, including on-site evaluations. Karuna may conduct such audit no more than [***] (unless an additional audit is warranted for cause) upon [***] prior written notice to Zai. With respect to any inspection of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to the Licensed Product, Zai shall notify Karuna of such inspection (a) no later than [***] after Zai receives notice of such inspection or (b) within [***] after the completion of any such inspection of which Zai did not receive prior notice. Zai shall promptly provide Karuna with all information related to any such inspection. Zai shall also permit Governmental Authorities outside of the Licensed Territory to conduct inspections of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product, and shall ensure that all such Affiliates or Sublicensees permit such inspections. [***]. Following any such regulatory inspection related to the Licensed Product, Zai shall provide Karuna with (i) an unredacted copy of any finding, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Product) within [***] of Zai receiving the same, and (ii) [***]. Zai shall provide Karuna with a copy of any proposed response to such communications and shall consider in good faith Karuna's reasonable comments with respect to such proposed response. Further details including notification, timing, response and scope of such audits shall be included in the Pharmacovigilance Agreement.

**5.10. Remedial Actions**. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Licensed Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (as to Karuna's notification obligation, only to the extent it would reasonably be expected to affect the Licensed Territory) (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action with respect to the Licensed Territory. Zai shall have sole discretion with respect to any matters relating to any Remedial Action in the Field in the Licensed Territory (including decision to commence such Remedial Action), provided that, unless required by Regulatory Authorities or Applicable Law, Zai shall not commence such Remedial Action in the Field in the Licensed Territory without prior notice to Karuna, provided further that, Karuna shall have sole discretion with respect to any matters relating to any Remedial Action in the Licensed Territory to the extent related to any Global Study. The reasonable cost and expenses of any Remedial Action in the Licensed Territory shall be borne [***]. Zai shall, and shall ensure that its Affiliates and Sublicensees shall, maintain adequate records to permit the Parties to trace the distribution and use of the Licensed Product in the Licensed Territory.

## ARTICLE 6

## MANUFACTURING

**6.1. Supply**. During the Term, subject to the terms and conditions of this Agreement (including Karuna's Retained Rights and Karuna's obligations under Section 6.3), Zai shall have the sole right (and shall solely control, at its discretion) itself or with or through its Affiliates, Sublicensees, or other Third Parties, to Manufacture or have Manufactured the Compound and Licensed Product for use in Development (including Clinical Trials) in the Licensed Territory and for Commercialization in the Field in the Licensed Territory. Zai shall ensure that all Licensed Products Manufactured by or on behalf of Zai, its Affiliates, Sublicensees or Subcontractors shall comply with this Agreement, the specifications for the Licensed Product, other quality standards as mutually agreed by the Parties for the Licensed Product, and Applicable Laws in the applicable Region in the Licensed Territory (including applicable cGMP).

**6.2. Manufacturing Technology Transfer**. At Zai's request, the Parties shall (a) cooperate in good faith through the JSC to identify the Manufacturing Technology, and (b) Karuna shall use Commercially Reasonable Efforts to (i) transfer all Know-How within the Manufacturing Technology to Zai or its permitted designee (which designee may be an Affiliate or a Third Party manufacturer, and subject to Section 2.4), and (ii) provide reasonable assistance to Zai or such permitted designee, [***], in order to enable Zai and its designees to obtain the regulatory or governmental approvals necessary to authorize Zai and its designees to Manufacture the Compound or Licensed Product for clinical and commercial supply in the Licensed Territory (clauses (i) and (ii) together, the "**Manufacturing Technology Transfer**"). The Parties shall conduct the Manufacturing Technology Transfer in accordance with a mutually agreed transfer plan, including the timelines set forth therein, and Zai shall be fully responsible, at its own costs, for obtaining all licenses, permits and other certifications required by the applicable Regulatory Authorities in order to complete such Manufacturing Technology Transfer.

**6.3. Supply by Karuna.** Zai shall make a written request to Karuna to commence the Manufacturing Technology Transfer before [***]. Promptly after such request by Zai, and subject to Zai exercising Commercially Reasonable Efforts to conduct and complete the Manufacturing Technology Transfer set forth in Section 6.2, Karuna shall (either by itself or through an Affiliate or CMO) Manufacture and supply the Compound and Licensed Product to Zai for Development and Commercialization use in the Field in the Licensed Territory, until Zai is approved by applicable Regulatory Authorities to manufacture the Compound and Licensed Product (by itself or through an Affiliate or CMO) to support its Development and Commercialization of the Product in the Territory after the completion of the Manufacturing Technology Transfer set forth in Section 6.2. Karuna shall supply the Compound and Licensed Product to Zai at the Fully Burdened Manufacturing Cost plus [***] for Development use or, as the case may be, [***] for Commercialization use. Subject to further agreement by the Parties with respect to compliance with applicable cGMP and additional standards required by Regulatory Authorities or Applicable Laws in any particular Region in the Licensed Territory, all Compound and Licensed Product supplied by Karuna shall comply with applicable specifications, shall be manufactured in compliance with all Applicable Laws (including cGMP) of the country where such Compound and Licensed Product are manufactured, and shall be accompanied by a certificate of analysis and certificate of conformity as required under Applicable Laws. The Parties shall negotiate in good faith and agree on other detailed terms for such supply, including forecast, ordering, delivery, inspection, acceptance and other customary terms, which shall be set forth in one or more separate supply agreement and quality agreement.

## ARTICLE 7

## COMMERCIALIZATION

**7.1. General**; **Commercialization**. During the Term, and subject to the rights of Karuna as the Initial MAH, as set forth in this Agreement or otherwise required by Applicable Laws, Zai shall be solely responsible to Commercialize and obtain pricing and reimbursement approvals for the Licensed Product in the Field in the Licensed Territory in accordance with the Commercialization Plan, at its sole cost and expense. Without limiting the foregoing, for each Region in the Licensed Territory in which the Licensed Product receives Regulatory Approval, Zai shall use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Field in such Region.

**7.2. Commercialization Plan**. The Commercialization Plan shall contain in reasonable detail the significant Commercialization activities and the projected timelines for achieving such activities. Zai shall provide an initial Commercialization Plan to the JSC for review and discussion [***] of the first Regulatory Approval Application for the Licensed Product in the Licensed Territory, which shall include general information regarding marketing plans and budget estimates. Thereafter, Zai may propose updates or amendments to the Commercialization Plan to reflect necessary or material changes in such plans, including those in response to changes in the marketplace, relative success of the Licensed Product, and other relevant factors influencing such plan and activities, and submit such proposed updated or amended Commercialization Plan to the JSC. In preparing the initial Commercialization Plan and any updates or amendments thereto, Zai shall provide Karuna with an opportunity to comment and Zai shall consider any Karuna's comments in good faith in finalizing the initial Commercialization Plan and any updates or amendments thereto.

**7.3. Commercialization Reports**. Zai shall update the JSC at each regularly scheduled JSC meeting regarding Commercialization activities conducted by Zai, its Affiliates and Sublicensees, in each case, with respect to the Licensed Product in Field the Licensed Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Zai's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Licensed Product in the Field in the Licensed Territory, covering subject matter at a level of detail reasonably required by Karuna and sufficient to enable Karuna to determine Zai's compliance with its diligence obligations pursuant to this Agreement. In addition, Zai shall make available to Karuna such additional information about its Commercialization activities as may be reasonably requested by Karuna from time to time. All updates and reports generated pursuant to this Section 7.3 shall be the Confidential Information of Zai.

**7.4. Pricing**. Zai shall advise the JSC of its proposed pricing for the Licensed Product in each Region in the Licensed Territory prior to the anticipated filing of Regulatory Approval Application in such Region for the Licensed Product. Zai shall consider in good faith any comments provided by Karuna with respect to pricing of the Licensed Product sold in each Region. Zai shall keep Karuna informed on the status of any application for pricing and reimbursement approval for the Licensed Product in each Region in the Field and in the Licensed Territory, including any discussion with Regulatory Authority with respect thereto. Notwithstanding anything to the contrary in this Agreement (including Section 3.1(f)), Zai shall have the final decision-making authority on [***].

**7.5. Product Trademarks**. As soon as reasonably practicable following the Effective Date, but no later than [***] prior to the filing of any Regulatory Approval Application for the Licensed Product in each Region in the Licensed Territory, the Parties shall discuss in good faith a branding strategy for Commercialization of the Licensed Product in the Licensed Territory, including selection of any trademarks, logos and trademarks for use in connection with Commercialization of the Licensed Product in each Region in the Licensed Territory, which strategy shall be consistent with and subject to Karuna's global branding strategy for the Licensed Product. Zai may use (pursuant to this Section 7.5) the trademarks Controlled by Karuna in the Licensed Territory as Karuna may provide to Zai in writing from time to time (the "**Karuna Product Marks**") and may use the English mark thereof with Chinese phonetic translation below. Karuna hereby grants to Zai, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, exclusive license under Karuna's rights to use such Karuna Product Marks in connection with the Commercialization of the Licensed Product in the Field in the Licensed Territory in compliance with Applicable Laws and this Agreement. Zai shall comply with Karuna's brand usage guidelines provided to Zai in its use of the Karuna Product Marks. Zai may also (in addition to or in lieu of the Karuna Product Marks) brand the Licensed Product in the Field in the Licensed Territory using its (and its Affiliates' and Sublicensees') own corporate name or logo, and other trademarks, logos, and trade names specific for the Licensed Product that differ from the Karuna Product Marks and do not contain the name of Karuna; provided, however, that (a) such trademarks, logos and trade names shall not be confusingly similar to any of the trademarks Controlled by Karuna or any of its Affiliates, (b) prior to such use, Zai shall submit such trademarks, logos and trade names for Karuna's prior written approval (not to be unreasonably withheld, delayed or conditioned), and (c) such trademarks, logos and trademarks shall be deemed owned by Zai (the "**Product Marks**"). Zai shall own all rights in the Product Marks in the Licensed Territory and shall register and maintain the Product Marks in the Licensed Territory that it determines reasonably necessary.

**7.6. No Diversion**. To the extent permitted by Applicable Law, each Party hereby covenants and agrees that, with respect to Commercialization of the Licensed Product in the Field, (a) it shall not, and shall cause its Affiliates and contractually obligate its sublicensees not to, directly or indirectly, including via the Internet or mail order, engage in marketing to any Third Party or to any address or Internet Protocol address or the like, in the other Party's territory for the purposes of Commercializing the Licensed Product in the other Party's territory, (b) neither Party shall engage, nor permit its Affiliates, sublicensees to engage, in any advertising or promotional activities relating to the Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, Region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, Region or jurisdiction in the other Party's territory, and (c) if it receives any order or inquiry with respect to the Licensed Product from customers or any Third Party outside its territory, it shall direct such order or inquiry to the other Party. For clarity, Karuna's territory means anywhere in the world other than the Licensed Territory.

**7.7. Transfer of Compound; Audits**. Zai shall not, and shall ensure that its Affiliates and Sublicensees do not, directly or indirectly, sell, resell, donate, assign, hypothecate, export, distribute, transfer or divert the Compound or Licensed Product to an entity other than Zai, or an entity approved by Zai, in each case outside the Licensed Territory or otherwise in a manner that would cause the sale of such Compound or Licensed Product in the chain of distribution (from Zai or its Affiliates or Sublicensees to the end user) to be excluded (except as an exception provided in the Net Sales definition) in the calculation of Net Sales, provided that for each unit of the Compound or Licensed Product, the inclusion of such sales in the calculation of Net Sales shall occur only once. Subject to Applicable Laws, upon Karuna's reasonable request and [***], but no more often than once in every [***], Zai (either directly or indirectly through its sublicenses or designees) shall allow Karuna to perform an audit, site visit or similar inspection of any site or facility where Development or Commercialization activities for the Licensed Product are being conducted to ensure (i) compliance with applicable cGMP, GCP, GLP, and GSP standards, and (ii) compliance with this Section 7.7.

**7.8. Medical Affairs**. Zai shall be solely responsible, at its sole cost and expense, for conducting medical affairs activities with respect to the Licensed Product in the Field in the Licensed Territory, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), publications, congress presentations and posters, published manuscripts, activities performed in connection with patient registries and post-approval trials, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product, all of which shall be conducted in accordance with Applicable Law. Zai shall update the JSC at each regularly scheduled JSC meeting regarding Zai's medical affairs activities. All updates and reports generated pursuant to this Section 7.8 shall be the Confidential Information of Zai.

## ARTICLE 8

## PAYMENTS AND MILESTONES

**8.1. Upfront Payment**. Zai shall pay to Karuna an one-time, irrevocable, non-refundable, non-creditable amount of thirty-five million U.S. Dollars ($35,000,000) (the "**Upfront Payment**") within [***] after the Effective Date.

**8.2. Development Milestones Payments to Karuna**.

(a) Subject to the remainder of this Section 8.2, within [***] after the Licensed Product first achieves each of the Milestone Events set forth below (each such event, a "**Development Milestone Event**"), the Party that achieves such Milestone Event shall notify the other Party. Zai shall pay to Karuna the corresponding one-time, irrevocable, non-refundable, non-creditable Development Milestone Payments (each such payment, a "**Development Milestone Payment**") within [***] after the receipt of an invoice for such payment issued pursuant to Section 8.5(c) after the receipt of such notice.

| Development Milestone Event | Development Milestone Payment |
|---|---|
| 1) [***] | $ [***] |
| 2) [***] | $ [***] |
| 3) [***] | $ [***] |
| 4) [***] | $ [***] |
| 5) [***] | $ [***] |
| 6) [***] | $ [***] |
| 7) [***] | $ [***] |
| **Total:** | **$** [***] |

(b) For the avoidance of doubt, (i) each Development Milestone Payment shall be payable on the first occurrence of the corresponding Development Milestone Event for the Licensed Product, and (ii) none of the Development Milestone Payments shall be payable more than once.

(c) [***].

(d) [***].

(e) [***].

(f) [***].

(g) [***].

**8.3. Sales Milestones**.

(a) Zai shall pay to Karuna the following one-time, irrevocable, non-refundable, non-creditable Milestone Payments (each such payment, a "**Net Sales Milestone Payment**") for the achievement of the corresponding Net Sales Milestone Events set forth below (each such event, a "**Net Sales Milestone Event**") within [***] after the receipt of an invoice for such payment issued pursuant to Section 8.5(c) after the end of the Calendar Year in which the Net Sales Milestone Event is achieved.

| Net Sales Milestone Event First time annual Net Sales of the Licensed Product in the Licensed Territory (other than Hong Kong) exceed: | Net Sales Milestone Payment |
|---|---|
| 1) $[***] | $ [***] |
| 2) $[***] | $ [***] |
| 3) $[***] | $ [***] |
| **Total:** | **$** [***] |

(b) For the avoidance of doubt each Net Sales Milestone Payment shall be payable on the first occurrence of the corresponding Net Sales Milestone Event, and if annual Net Sales in a given Calendar Year exceed more than one (1) applicable threshold, then all corresponding Net Sales Milestone Payments shall be payable. Licensed Products sold after the expiration of the Royalty Term shall not be included in the calculation of annual Net Sales to determine whether any Net Sales threshold has been achieved.

**8.4. Royalties**.

(a) **Royalty Payment**. During the Royalty Term, Zai shall pay to Karuna tiered royalties as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated Net Sales of all Licensed Products in the Licensed Territory (other than Hong Kong) in a Calendar Year (a "**Royalty Payment**"). Each Royalty Payment shall be non-creditable, irrevocable, and non-refundable. The tiered royalty rates on Net Sales shall be as set forth below:

| For that portion of annual aggregated Net Sales of all Licensed Products in the Licensed Territory (other than Hong Kong) in a Calendar Year | Royalty Rate |
|---|---|
| 1) [***] | [***]% |
| 2) [***] | [***]% |
| 3) [***] | [***]% |
| 4) [***] | [***]% |

(b) **Royalty Term**. The Royalty Payments payable under this Section 8.4 shall be payable on the Licensed Product-by-Licensed Product and Region-by-Region basis from the First Commercial Sale of the applicable Licensed Product in such Region until the latest 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 twelve (12) years after the date of the First Commercial Sale of the Licensed Product in such Region; and (iii) the expiration date of any Regulatory Exclusivity for the Licensed Product in such Region (the "**Royalty Term**"). Licensed Products sold after the expiration of the Royalty Term shall not be included in the calculation of annual Net Sales to determine the applicable royalty tiers.

(c) **Royalty Reductions**.

(i) During the Royalty Term, on the Licensed Product-by-Licensed Product and Region-by-Region basis, subject to Section 8.4(c)(vi), the royalty rate applicable to Net Sales of the Licensed Product in such Region shall be reduced by [***] after the expiration of the last-to-expire Valid Claim in such Region.

(ii) During the Royalty Term, on the Licensed Product-by-Licensed Product and Region-by-Region basis, subject to Section 8.4(c)(vi), if at any time during a Calendar Quarter following receipt of all necessary Regulatory Approvals from the applicable Regulatory Authorities in such Region to market and sell such Third Party Product as a pharmaceutical product for one or more Indications for the corresponding Licensed Product in such Region (the "**Generic Launch Quarter**"), the applicable royalty rate for Net Sales, in such Region for such Licensed Product shall be reduced as follows: (A) if for any Calendar Quarter after the Generic Launch Quarter the comparable unit sales of the Third Party Product(s) in such Region is greater than [***] but equal to or less than [***] of the comparable unit sales of such Licensed Product, then the royalty payments owed by the Zai for such Licensed Product in such Region for such Calendar Quarter shall be reduced by [***], and (B) if for any Calendar Quarter after the Generic Launch Quarter the comparable unit sales of the Third Party Product(s) in such Region is greater than [***] of the comparable unit sales of such Licensed Product, then the royalty payments owed by Zai for such Licensed Product in such Region for the remainder of the Royalty Term shall be reduced by [***].

(iii) [***].

(iv) [***].

(v) If Zai reasonably determines in good faith after advice of counsel that it is [***] and enters into such a license, subject to Section 8.4(c)(vi), on the Licensed Product-by-Licensed Product and Region-by-Region basis, Zai shall have the right to deduct, from the Royalty Payment that would otherwise have been due pursuant to this Section 8.4, an amount equal to [***] of the royalties paid by Zai to such Third Party pursuant to such license on account of the sale of the Licensed Product in such Region the Licensed Territory; provided that (A) prior to entering into such license, Zai shall [***]; and (B) in the event [***]. Within [***] following the execution of any such Third Party license, Zai shall provide Karuna with a true and complete copy of such Third Party license.

(vi) Notwithstanding the foregoing, in no event shall the operation of Section 8.4(c)(i) through 8.4(c)(v), individually or in combination, reduce the royalties payable by Zai to Karuna with respect to the Net Sales of the Licensed Product in any Region in the Licensed Territory in any Calendar Quarter to an amount less than [***] of the amount that would otherwise have been due pursuant to Section 8.4(a) with respect to such Net Sales.

(d) **Royalty Reports**. Following the First Commercial Sale of the Licensed Product for which royalties are due pursuant to this Section 8.4, and continuing for so long as royalties are due hereunder:

(i) Zai shall, within [***] after the end of each Calendar Quarter, provide Karuna with a royalty report (in a template agreed to by the Parties) showing, on a Region-by-Region basis:

(1) [***];

(2) [***];

(3) [***];

(4) [***];

(5) [***];

(6) [***];

(7) [***].

(e) **Royalty Payment**. Concurrently with each royalty report provided by Zai under Section 8.4(d) above, Zai shall pay to Karuna applicable royalties for each Calendar Quarter within [***] after the end of such Calendar Quarter. If no royalty is due for any Calendar Quarter following commencement of the reporting obligation, Zai shall so report.

**8.5. Payment**.

(a) **Mode of Payment**. All payments to be made under this Agreement shall be made in U.S. Dollars and shall be paid by electronic transfer in immediately available funds to such bank account in the United States as is designated in writing by Karuna. All payments shall be free and clear of any transfer fees or charges.

(b) **Currency Exchange Rate**. All payments under this Agreement shall be payable in U.S. Dollars. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars for calculating Net Sales in a Calendar Quarter (for purposes of both the royalty calculation and whether a Net Sales milestone has been achieved) shall be made at the average exchange rate as published by the Wall Street Journal for such Calendar Quarter, or such other source as the Parties may agree in writing.

(c) **Payment Timeline**. Except as otherwise provided herein, all payments to be made by one Party to the other Party under this Agreement require a corresponding invoice and shall be due within [***] (or such other time period set forth herein) following such Party's receipt of an invoice from the other Party.

**8.6. Audits**.

(a) Zai shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the GAAP or IFRS), for a period not less than [***] from the end of the Calendar Year to which they pertain, complete and accurate records in sufficient detail to properly reflect Net Sales and to enable any Milestone Payment payable hereunder to be determined.

(b) Upon the written request of Karuna, Zai shall permit, and shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Karuna and reasonably acceptable to Zai, at Karuna's expense, to have access during normal business hours to such records of Zai or its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any Calendar Year ending not more than [***]. These rights with respect to any Calendar Year shall [***] the end of any such Calendar Year and shall be limited to once each Calendar Year (provided that the foregoing frequency limit shall not apply if Karuna has reasonable cause). The accounting firm shall provide Karuna and Zai with a written report [***]. If such accounting firm concludes that an underpayment was made, then Zai shall pay the amount due within [***] after receipt of such accounting firm's written report so concluding. If such accounting firm concludes that an overpayment was made, then such overpayment shall be credited against any future payment due to Karuna hereunder (if there is no future payment due, then Karuna shall promptly refund such overpayment to Zai). Karuna shall bear the full cost of such audit unless such audit discloses that the additional payment payable by Zai for the audited period is more than [***] of the amount otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

(c) Zai shall include in each relevant sublicense granted by it a provision requiring any Sublicensee to maintain records of sales of Licensed Product made pursuant to such sublicense, and to grant access to such records by an accounting firm to the same extent and under the same obligations as required of Zai under this Agreement. Karuna shall advise Zai in advance of each audit of any such Sublicensee with respect to the Net Sales of the Licensed Product either by Karuna or its designated auditor under the terms of such Sublicensee agreement. The accounting firm shall provide Karuna and Zai with a copy of the audit report at the same time. Karuna shall pay the full costs charged by the accounting firm, unless the audit discloses that the additional payments payable to Karuna for the audited period is more than [***] from the amounts otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

**8.7. Interest**. Each Party shall pay interest on any amounts overdue under this Agreement [***] from the day payment was initially due; provided, however, that in no case shall such interest rate exceed the highest rate permitted by Applicable Laws. The payment of such interest shall not foreclose a Party from exercising any other rights it may have because any payment is overdue.

**8.8. Taxes**.

(a) Each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of Applicable Law (other VAT and Withholding VAT Taxes described in 9.8(c)). The Party that is required to make such withholding shall: (i) timely remit the taxes to the proper taxing authority; and (ii) send evidence of the obligation, together with proof of tax payment, to the other Party on a timely basis following such tax payment. Each Party shall reasonably cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect to ensure that any amounts required to be withheld pursuant to this Section 8.8 are reduced in amount to the fullest extent permitted by Applicable Law. In addition, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as VAT, sales tax, consumption tax, and other similar taxes) in connection with this Agreement. In the event of any such any withholding is required to be withheld and deducted from payments by Zai (or its Affiliate paying on behalf of Zai) pursuant to this Agreement under Applicable Laws, notwithstanding anything to the contrary herein, [***].

(b) [***]. If Zai is required to deduct or withhold any VAT on any payments payable by Zai under this Agreement (the "**Withholding VAT Taxes**"), Zai will (i) pay such Withholding VAT Tax on behalf of Karuna to the appropriate Governmental Authority, (ii) furnish Karuna with proof of payment of such Withholding VAT Tax within [***] following such payment, and (iii) [***]. Zai will promptly provide to Karuna applicable receipts evidencing payment of such Withholding VAT Taxes and other documentation reasonably requested by Karuna. Upon Zai's request, Karuna shall provide reasonable assistance to Zai for Zai to recover any such Withholding VAT Taxes. For clarity, [***].

**8.9. Blocked Currency**. If by Applicable Laws in a Region in the Licensed Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Zai shall promptly notify Karuna and, thereafter, amounts accrued in such country or region under this ARTICLE 8 shall be paid to Karuna (or its designee) in such country or Region in local currency by deposit to an escrow account in a local bank designated by Karuna and to the credit of Karuna, unless the Parties otherwise agree.

## ARTICLE 9

## CONFIDENTIALITY; PUBLICATION

**9.1. Nondisclosure Obligation**.

(a) For the Term and [***] thereafter, the Party receiving (the "**Receiving Party**") the Confidential Information of the other Party (the "**Disclosing Party**") shall keep confidential and not publish, make available or otherwise disclose any Confidential Information to any Third Party, without the express prior written consent of the Disclosing Party; provided, however, the Receiving Party may disclose certain Confidential Information to those of its Affiliates, officers, directors, employees, agents, consultants or independent contractors, existing and potential licensees, sublicensees, upstream licensors, and bona-fide purchasers of such Receiving Party who need to know such Confidential Information in connection with exercising rights or performing obligations as contemplated by this Agreement or any other written agreement between the Parties and are bound by confidentiality and non-use obligations with respect to such Confidential Information consistent with those set forth herein; the Receiving Party shall remain responsible for the compliance by its Affiliates, officers, directors, employees, agents, consultants or independent contractors (including licensees and sublicensees) with such confidentiality and non-use obligations. Either Party may disclose the terms and existence of this Agreement to any bona fide existing or potential investors, lenders and acquirers and the accountants and advisors of any of the foregoing who are bound by a written agreement (or in the case of attorneys or other professional advisors, formal ethical duties) requiring such recipients to treat, hold and maintain the terms of this Agreement as confidential information in a manner that is consistent with the terms and conditions of this Agreement. The Receiving Party shall exercise at a minimum the same degree of care it would exercise to protect its own Confidential Information (and in no event less than a reasonable standard of care) to keep confidential the Confidential Information. The Receiving Party shall use the Confidential Information solely in connection with exercising rights or performing obligations as contemplated by this Agreement or any other written agreement between the Parties.

(b) It shall not be considered a breach of this Agreement if the Receiving Party discloses Confidential Information or either Party discloses the terms and conditions of this Agreement in order to comply with a lawfully issued court or governmental order or with a requirement of Applicable Laws or the rules of any internationally recognized stock exchange; provided that: (i) the Receiving Party gives prompt written notice of such disclosure requirement to the Disclosing Party and cooperates with the Disclosing Party's efforts to oppose such disclosure or obtain a protective order for such Confidential Information, and (ii) if such disclosure requirement is not quashed or a protective order is not obtained, the Receiving Party shall only disclose those portions of the Confidential Information that it is legally required to disclose and shall make a reasonable effort to obtain confidential treatment for the disclosed Confidential Information. To the extent there is any conflict between this ARTICLE 9 and any other agreement related to Confidential Information entered into between the Parties, including the Confidentiality Agreement, the terms of this ARTICLE 9 shall control to the extent of such conflict.

(c) **Scientific Publication**. The JSC shall discuss the publication strategy for the publication of scientific papers, abstracts, meeting presentations and other disclosure of the results of the Clinical Trials carried out under this Agreement, taking into consideration the Parties' interest in publishing the results of the Licensed Product Development work in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, and the need to protect Confidential Information, intellectual property rights and other business interests of the Parties; provided that Zai's publication outside the Licensed Territory (including in any form or media that may be distributed outside the Territory) shall require Karuna's prior written consent, not to be unreasonably withheld. Zai shall provide Karuna with the opportunity to review and comment on any proposed publication [***] that pertains to the Licensed Product at least [***] prior to its intended submission for publication, which shall be limited to data, results and the like with respect to patients or subjects located in the Licensed Territory. Karuna shall provide Zai with its comments, if any, within [***] after the receipt of such proposed publication. Zai shall consider in good faith the comments provided by Karuna and shall comply with Karuna's request to: (a) remove any and all Confidential Information of Karuna from such proposed publication; and (b) if Karuna determines that such publication would entail the disclosure of patentable Inventions upon which patent applications should be filed prior to such publication, delay the submission for a period as may be reasonably necessary for the drafting and filing of a patent application covering such Inventions; provided that such additional period shall not exceed [***] from the proposed date of the intended submission for publication. Zai agrees to acknowledge the contribution of Karuna and its employees in all publications as scientifically appropriate.

**9.2. Publication and Listing of Clinical Trials**. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Product and to the extent applicable to a Party's activities conducted under this Agreement, each Party shall comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 9.2 shall be considered a publication for purposes of this Agreement and shall be subject to Section 9.1.

**9.3. Publicity; Use of Names**.

(a) Subject to permitted disclosures under Section 9.1, each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to (i) advisors (including consultants, financial advisors, attorneys and accountants), (ii) bona fide potential and existing investors, acquirers, merger partners or other financial or commercial partners on a need to know basis for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship, in each case under circumstances that reasonably protect the confidentiality thereof, or (iii) to the extent required by Applicable Laws, including securities laws and regulations. Notwithstanding the foregoing, the Parties agree to issue the initial press release(s) to announce the execution of this Agreement as contained in Schedule 9.3(a); thereafter, Karuna and Zai may each disclose to Third Parties the information contained in such press release(s) or in any other press releases or disclosures made in accordance with this Section 9.3, without the need for further approval by the other.

(b) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Product for use in the Field in the Licensed Territory and other activities in connection with this Agreement, beyond what may be strictly required by Applicable Laws and the rules of a recognized stock exchange, and each Party may make such disclosures from time to time with respect to the Licensed Product in each case with the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed. Such disclosures may include achievement of significant events in the Development (including regulatory process) or Commercialization of the Licensed Product for use in the Field in the Licensed Territory. Unless otherwise requested by the applicable Party, Zai shall indicate that Karuna is the licensor of the Licensed Product and Licensed Technology in each public disclosure issued by Zai regarding the Licensed Product. When Zai elects to make any public disclosure under this Section 9.3(b) or Karuna elects to make any public disclosure regarding results and significant developments regarding the Licensed Product for use in the Field in the Licensed Territory under this Section 9.3(b), the disclosing Party shall give the other Party at least [***]prior to its intended disclosure to review and comment on such statement, it being understood that (i) if the other Party does not notify such Party in writing within [***] or such shorter period if required by Applicable Laws of any reasonable objections, as contemplated in this Section 9.3(b), such disclosure shall be deemed approved, and (ii) if the other Party does notify such Party in writing within the time period set forth in clause (i) above, and reasonably determines that such public disclosure would entail the public disclosure of the other Party's Confidential Information or of patentable Inventions upon which patent applications should be filed prior to such public disclosure, such public disclosure shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party, or the drafting and filing of a patent application covering such Inventions; provided that such additional period shall not exceed [***] from the proposed date of the public disclosure, and, in any event, the other Party shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative reactions of applicable Regulatory Authorities.

(c) The Parties acknowledge the need to keep investors and others informed regarding such Party's business under this Agreement, including as required by Applicable Laws or the rules of a recognized stock exchange. To the extent a Party is publicly listed or becomes publicly listed, and subject to Section 9.3(b) as applicable, such Party may issue press releases or make disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with Applicable Laws; provided that each Party shall provide the other Party with reasonable advance notice of such legally required disclosures. The Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

(d) The Parties agree and acknowledge that, upon reasonable request by Zai and subject to mutual agreement by the Parties, Zai may record or file this Agreement (or a summary or translation of this Agreement as is necessary to effect such recordation or filing) with any patent and trademark office or similar authority in the Licensed Territory, if Zai reasonably determines that such recordation or filing is beneficial or required to give effect to or protect its rights under this Agreement. Upon Zai's reasonable request, Karuna shall provide such cooperation and reasonable assistance in connection with such recordation or filing.

**9.4. Prior Confidentiality Agreement**. As of the Effective Date, the terms of this ARTICLE 9 shall supersede any prior non-disclosure, secrecy or confidentiality provisions in any agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including such provisions in the Confidentiality Agreement.

## ARTICLE 10

## REPRESENTATIONS, WARRANTIES, AND COVENANTS

**10.1. Representations and Warranties of Each Party**. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar laws affecting the enforcement of creditors' rights generally;

(c) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement, including any Existing In-License Agreement; and

(d) all consents, approvals and authorization from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with execution of this Agreement have been obtained.

**10.2. Additional Representations, Warranties and Covenants of Karuna**. Karuna represents, warrants and covenants to Zai that as the Effective Date with respect to itself and its Affiliates:

(a) Karuna and its Affiliates are the sole owners or exclusive licensees of the Licensed Patents and material Licensed Know-How, and Karuna has the right under the Licensed Technology to grant the licenses to Zai as purported to be granted pursuant to this Agreement;

(b) Schedule 1.79 sets forth a complete and accurate list all Licensed Patents as of the Effective Date;

(c) neither Karuna nor any of its Affiliates is a party to any license or similar agreement under which it has granted or agreed to grant a license to any Third Party to any Licensed Technology that would conflict with the rights or licenses granted to Zai under this Agreement;

(d) neither Karuna nor any of its Affiliates will grant any license, sublicense or other rights in or to the Licensed Technology which is inconsistent with the terms and conditions of this Agreement;

(e) Karuna and its Affiliates and their employees, consultants and contractors involved in the Development of the Compound and Licensed Product are not, and have not been, debarred or disqualified by any Regulatory Authority as of the Effective Date, and have complied in all material respects with all Applicable Laws in connection with the Development of the Compound and Licensed Product;

(f) no claim or action has been brought against Karuna or, to Karuna's knowledge, threatened in writing to Karuna, by any Third Party alleging that (i) the Licensed Patents are invalid or unenforceable, or (ii) the Exploitation of the Compound or Licensed Product infringes the Patents or misappropriates the Know-How of any Third Party;

(g) to its knowledge, the Exploitation of the Compound and Licensed Product does not infringe or misappropriate any Patent or Know-How of any Third Party;

(h) it is not aware of any infringement or misappropriation of any Licensed Technology by any Third Party;

(i) except for the Existing In-License Agreements listed on Schedule 1.42, there is no material in-license agreement between Karuna or its Affiliates with any Third Party pursuant to which Karuna or its Affiliates has obtained Control to any Licensed Technology;

(j) it has provided Zai with true and complete copy of each Existing In-License Agreement, and each Existing In-License Agreement is in full force and effect; no notice of default or termination has been received or given under any Existing In-License Agreement and, to its knowledge, there is no act or omission by Karuna or its Affiliates that would provide a right to terminate any Existing In-License Agreement;

(k) it will not knowingly breach any Existing In-License Agreement (and New Karuna In-License, if any); it will not terminate, modify or amend the Existing In-License Agreement (and New Karuna In-License, if any), or exercise, waive, release, or assign any rights thereunder, in any manner that would limit, restrict or otherwise materially adversely affect the rights of Zai hereunder without obtaining Zai's prior written consent;

(l) in the event of any notice of breach of any Existing In-License Agreement (and New Karuna In-License, if any) by Karuna or its Affiliate, Karuna will as promptly as practicable notify Zai in writing, and will use Commercially Reasonable Efforts to cure such breach, or, if Karuna reasonably determines that it has not committed such breach, use Commercially Reasonable Efforts to resolve such dispute;

(m) in the event of any notice of breach of any Existing In-License Agreement (and New Karuna In-License, if any) by the applicable counter party in a manner that will or is likely to materially adversely affect Zai's rights or obligations under this Agreement, Karuna will as promptly as practicable notify Zai in writing, and will use Commercially Reasonable Efforts to enforce such Existing In-License Agreement (and New Karuna In-License, if any) or resolve such dispute; and

(n) all information provided by Karuna to Zai for due diligence purposes in relation to this Agreement is complete and accurate in all material respects. Without limiting the foregoing, it has disclosed or made available to Zai for review all material non-clinical and clinical data for the Compound and Licensed Product, and all other material information (including relevant correspondence with Regulatory Authorities) relating to the Compound and Licensed Product, in each case that would be material for Zai to assess the safety and efficacy of the Compound and Licensed Product.

**10.3. Additional Representations**, **Warranties and Covenants of Zai**. Zai represents, warrants and covenants to Karuna that as of the Effective Date with respect to itself and its Affiliates:

(a) there are no legal claims, judgments or settlements against or owed by Zai or its Affiliates (nor any of their respective directors, officers, employees, Affiliates, nor any Person authorized to act on behalf of Zai or its Affiliates), or pending or, to Zai's or its Affiliates' actual knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations, including under any Anti-Corruption Laws; and

(b) Zai and its Affiliates are not, and have not been, debarred or disqualified by any Regulatory Authority;

(c) Zai has sufficient financial wherewithal (at the time when such financial resources are required) to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business;

(d) Zai shall, in the course of performing its obligations or exercising its rights under this Agreement, and shall cause its Affiliates, Sublicensees and Subcontractors to, in all material aspects comply with the Development Plan, all agreements referenced herein, all Applicable Laws, including as applicable, cGMP, GCP, GLP, and GSP standards, and shall not employ or engage any party who has been debarred by any Regulatory Authority, or, to its knowledge, is the subject of debarment proceedings by a Regulatory Authority;

(e) Zai shall perform, and shall cause its Affiliate and Sublicensees and their respective Subcontractors to perform, all necessary or required record filings with and obtain all necessary or required licenses, approvals and permits from, all applicable Governmental Authorities in the Licensed Territory (including the HGR Approvals) for the conduct of Development activities and sharing of any data or information under this Agreement, and shall provide Karuna with copies of such record filings, licenses, approvals, and permits, [***].

**10.4. Compliance with Anti-Corruption Laws**.

(a) Notwithstanding anything to the contrary in this Agreement, each Party hereby covenants to each other that:

(i) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (collectively "**Anti-Corruption Laws**", including the provisions of the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Law, and the PRC Anti-Unfair Competition Law and the PRC Criminal Law, in each case, as amended) that may be applicable to either or both Parties to this Agreement;

(ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it shall, on request by the other Party, conduct reasonable investigation to verify that there has not been any violation of Anti-Corruption Laws by such Party or persons employed by or subcontractors (including, in the case of Zai, any Sublicensees or Subcontractors) used by such Party in the performance of this Agreement;

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement in order to document or verify compliance with the provisions of this Section 10.4, and upon request of the other Party, upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 10.4. Acceptance of a proposed Third Party auditor may not be unreasonably withheld or delayed by either Party. It is expressly agreed that the costs related to the Third Party auditor shall be fully paid by the Party requesting the audit (unless such audit identifies any violation of the obligations under this Section 10.4, in which case the audited Party shall bear all the costs), and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

(b) To its knowledge as of the Effective Date and during the Term, neither Zai nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its subsidiaries or any of their Affiliates:

(i) has taken or shall take any action in violation of any applicable anticorruption law, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78 dd-1 et seq.); or

(ii) has corruptly, offered, paid, given, promised to pay or give, or authorized or shall corruptly, offer, pay give, promise to pay or give or authorize, the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 10.4(d) below), for the purposes of:

(iii) has influenced or shall influence any act or decision of any Public Official in his or her official capacity;

(iv) has induced or shall induce such Public Official to do or omit to do any act in violation of his lawful duty;

(v) has secured or shall secure any improper advantage; or

(vi) has induced or shall induce such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.

(c) As of the Effective Date, none of the officers, directors, employees of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case that are employed or reside outside the United States, are themselves Public Officials.

(d) For purposes of this Section 10.4, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility; (iii) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank or similar organizations in each Region in the Licensed Territory; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

**10.5. NO OTHER REPRESENTATIONS OR WARRANTIES**. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## ARTICLE 11

## INDEMNIFICATION

**11.1. By Zai**. Zai shall indemnify and hold harmless Karuna, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Karuna Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (individually and collectively, "**Losses**") incurred by them in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Claims**") arising after the Effective Date to the extent arising from (a) the Exploitation of the Licensed Product in the Licensed Territory, including promotion of the Licensed Product and any actions (or omissions) in the performance of its regulatory activities, in each case by Zai or any of its Affiliates, Sublicensees, or Subcontractors, (b) the gross negligence, illegal conduct or willful misconduct of Zai or any of its Affiliates or Sublicensees, (c) Zai's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, or (d) Karuna holding any Regulatory Approval, Regulatory Submission or pricing and reimbursement approval for the Licensed Product for Zai's benefit in accordance with Section 5.1, in each case of clauses (a) through (d) above except to the extent such Losses arise from, are based on, or result from any activity or occurrence for which Karuna is obligated to indemnify the Zai Indemnitees under Section 11.2.

**11.2. By Karuna**. Karuna shall indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Zai Indemnitee(s)**") from and against all Losses incurred by them in connection with any Claims to the extent arising from (a) Exploitation of the Compound and Licensed Product outside the Licensed Territory, including the promotion of the Licensed Product and any actions (or omissions) in the performance of its regulatory activities, in each case by Karuna or any of its Affiliates or licensees (other than Zai or its Affiliates or Sublicensees), or in the Licensed Territory with respect to Global Studies or any Manufacturing activities in the Licensed Territory of the Licensed Product for use outside of the Licensed Territory pursuant to Karuna's Retained Rights, in each such case by Karuna or any of its Affiliates or licensees (other than Zai or its Affiliates, Sublicensees or Subcontractors); (b) the gross negligence, illegal conduct or willful misconduct of Karuna or any of its Affiliates or licensees (other than Zai), or (c) Karuna's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement; in each case of clauses (a) through (c) above, except to the extent Losses arise from, are based on, or result from any activity or occurrence for which Zai is obligated to indemnify the Karuna Indemnitees under Section 11.1.

**11.3. Defined Indemnification Terms**. Either of the Zai Indemnitee or the Karuna Indemnitee shall be an "**Indemnitee**" for the purpose of this ARTICLE 11, and the Party that is obligated to indemnify the Indemnitee under Section 11.1 or Section 11.2 shall be the "**Indemnifying Party**."

**11.4. Defense**. If any such Claims are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee; provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such Claim, subject to the terms of this ARTICLE 11.

**11.5. Settlement**. The Indemnifying Party may settle any such Claim or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, without admission of any wrongdoing or fault of the Indemnitee, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld or delayed.

**11.6. Notice**. The Indemnitee shall notify the Indemnifying Party promptly of any Claim with respect to which it seeks indemnification under Sections 11.1 or 11.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

**11.7. Permission by Indemnifying Party**. The Indemnitee may not settle any such Claim or otherwise consent to an adverse judgment in any such Claim or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

**11.8. Insurance**. Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide the other Party with written notice at least [***] prior to such Party's decision or receipt of notice from the insurance company, as applicable, with respect to the cancellation, non-renewal or material decrease in the coverage level of such insurance. It is understood that such insurance shall not be construed to create a limit of either Party's liability. Zai shall impose substantially identical obligations on its Affiliates (to the extent not named insureds under Zai's coverages) and Sublicensees.

**11.9. LIMITATION OF LIABILITY**. SUBJECT TO AND WITHOUT LIMITING (A) THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTIONS 11.1 OR 11.2, (B) LIABILITY AS A RESULT OF A BREACH OF ARTICLE 9 OR (C) LIABILITY FOR BREACH OF COVENANTS UNDER SECTION 2.9, NEITHER PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

**11.10. No Third Party Beneficiary Rights**. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights to any Third Party (including any Third Party beneficiary rights).

## ARTICLE 12

## INTELLECTUAL PROPERTY

**12.1. Ownership**. Subject to the license grants under this Agreement, as between the Parties, Karuna shall own and retain all right, title and interest in and to all Product Inventions (and any intellectual property associated therewith), and Zai shall own and retain all right, title and interest in and to all Zai Inventions (and any intellectual property associated therewith). Inventorship shall be determined in accordance with U.S. patent laws.

**12.2. Disclosure of Inventions**. Zai shall promptly disclose to Karuna in writing all Inventions created, conceived, developed or reduced to practice under this Agreement by or on behalf of Zai or its Affiliates. Zai, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign) to Karuna all its right, title and interest in and to any Product Inventions. Zai will cooperate, and will cause the foregoing persons and entities to cooperate, with Karuna to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership. For clarity, all Product Inventions assigned by Zai to Karuna shall be included in the Licensed Technology and licensed back to Zai under the terms and conditions of this Agreement, but Licensed Patents claiming such Product Inventions shall not be included in Valid Claim to determine Royalty Term.

**12.3. Patent Prosecution**.

(a) **Licensed Patents in the Licensed Territory**. Karuna shall have the first right, but not the obligation, to conduct Patent Prosecution of the Licensed Patents in the Licensed Territory at its sole cost and expense. Karuna shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution of the Licensed Patents in the Licensed Territory and shall provide Zai with all material correspondence received from any patent authority in the Licensed Territory in connection therewith. In addition, Karuna shall provide Zai with drafts of all proposed material filings and correspondence to any patent authority in the Licensed Territory in connection with the Patent Prosecution of the Licensed Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence. Karuna shall consider in good faith Zai's comments on such Patent Prosecution but shall have final decision-making authority under this Section 12.3(a). Further, Karuna shall notify Zai of any decision to cease Patent Prosecution of any Licensed Patent in the Licensed Territory at least [***] before any due date for filing, payment or other action to avoid loss of rights, in which case Zai shall have the right to continue the Patent Prosecution of such Licensed Patent at Zai's discretion and expense. If Zai decides to take over Patent Prosecution of a Licensed Patent in such Region(s) in the Licensed Territory, then Karuna shall promptly deliver to Zai copies of all necessary files related to such Licensed Patent in such Region(s) in the Licensed Territory and shall take all actions and execute all documents reasonably necessary for Zai to assume such responsibility. For the avoidance of doubt, Zai's assumption of responsibility for Patent Prosecution of any Licensed Patent in any Region(s) in the Licensed Territory pursuant to this Section 12.3(a) shall not change the Parties' respective ownership rights with respect to such Licensed Patent.

(b) **Zai Patents**. Zai shall, at its sole cost and expense, (i) have the sole right, but not the obligation, in the Licensed Territory to conduct the Patent Prosecution and maintenance of any Zai Patents; and (ii) have the first right, but not the obligation, outside the Licensed Territory, to conduct the Patent Prosecution and maintenance of any Zai Patents that are used by a Party or its Affiliates in the Exploitation of the Licensed Product, if any ("**Zai Implemented Patents**"). Zai shall keep Karuna reasonably informed of the status of all actions taken, including its plans to enter into national phase for PCT applications of Zai Implemented Patent in any country outside the Licensed Territory, and shall consider in good faith Karuna's recommendations with respect to the Zai Implemented Patents prosecuted by Zai in the PCT stage or outside the Territory. Further, Zai shall notify Karuna of any decision to cease Patent Prosecution or maintenance of any Zai Implemented Patent outside the Licensed Territory (including any decision of not entering into national phase in any country outside the Licensed Territory) at least [***] before any due date for filing, payment or other action to avoid loss of rights, in which case Karuna shall have the right, but not the obligation, to continue the Patent Prosecution or maintenance of such Zai Implemented Patent outside the Licensed Territory (including entering into national phase in any country outside the Licensed Territory that Zai has decided not to enter) at Karuna's discretion and expense. If Karuna decides to take over Patent Prosecution or maintenance of a Zai Implemented Patent outside the Licensed Territory, then Zai shall promptly deliver to Karuna copies of all necessary files related to such Zai Implemented Patent outside the Licensed Territory and shall take all actions and execute all documents reasonably necessary for Karuna to assume such responsibility. For the avoidance of doubt, Karuna's assumption of responsibility for Patent Prosecution or maintenance of any Zai Implemented Patent outside the Territory pursuant to this Section 12.3(b) shall not change the Parties' respective ownership rights with respect to such Zai Implemented Patent.

**12.4. Enforcement**.

(a) **Product Infringement**.

(i) Each Party shall notify the other within [***] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Licensed Patents in the Licensed Territory, by commercializing (or seeking Regulatory Approval to commercialize) the Licensed Product or any other product containing the Compound in the Field in the Licensed Territory, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any Licensed Patent in the Licensed Territory, in each case, within the scope of the license grants in Section 2.1 (collectively "**Product Infringement**").

(ii) Zai shall have the first right to bring and control any legal action in connection with such Product Infringement in the Licensed Territory at its own expense as it reasonably determines appropriate, provided that Karuna may, [***], elect to be represented by its own counsel and participate in such legal action. Notwithstanding the foregoing, Zai shall not settle or consent to entry of any judgment that would have a material adverse effect on the Licensed Product or any Licensed Patent without Karuna's prior written consent. If Zai does not bring such legal action prior to the earlier of: (A) [***] following the receipt or delivery of the notice under Section 12.4(a)(i), or (B) [***] before the deadline, if any, set forth in the Applicable Laws for the filing of such actions, or discontinues the prosecution of any such action after filing without abating such infringement, Karuna shall have the right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate.

(b) **Non-Product Infringement**. Karuna shall have the exclusive right, but not the obligation, to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any Licensed Patent that is not a Product Infringement, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of such Licensed Patent, at its own expense as it reasonably determines appropriate.

(c) **Enforcement of Zai Patents**. Karuna shall have the first right, but not the obligation, to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any of the Zai Implemented Patents, which infringement takes place outside the Licensed Territory by commercializing (or seeking Regulatory Approval to commercialize) the Licensed Product or any other product containing the Compound in the Field outside the Licensed Territory, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Zai Implemented Patents outside the Licensed Territory, at its own expense as it reasonably determines appropriate, in each case within the scope of the license grants in Section 2.2. Notwithstanding the foregoing, Karuna shall not settle or consent to entry of any judgment that would have a material adverse effect on any Zai Implemented Patent without Zai's prior written consent. If Karuna does not bring such legal action prior to the earlier of: (i) [***] following receipt or delivery of notice between the Parties regarding such alleged infringement, or (ii) [***] before the deadline, if any, set forth in the Applicable Laws for the filing of such actions, or discontinues the prosecution of any such action after filing without abating such infringement, Zai shall have the right to bring and control any legal action in connection with infringement at its own expense as it reasonably determines appropriate. Except as otherwise provided under this Section 12.4(c), Zai shall have the exclusive right, but not the obligation, to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any of the Zai Patents, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Zai Patents anywhere in the world, at its own expense as it reasonably determines appropriate.

(d) **Coordination**. At the request of the Party bringing an action related to Product Infringement or otherwise as described in this Section 12.4, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Laws to pursue such action, at each such Party's sole cost and expense. In connection with an action related to Product Infringement or otherwise as described in this Section 12.4, the Party bringing the action shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the Licensed Patents or Zai Patents, as applicable, without the prior written consent of the other Party (which consent shall not be unreasonably delayed, withheld or conditioned). The enforcing Party shall keep the non-enforcing Party reasonably informed of the status of any action it brought in connection with such Product Infringement or otherwise as described in this Section 12.4. The non-enforcing Party shall be entitled to attend any substantive meetings, hearings, or other proceedings related to any such action pursued by the enforcing Party. The enforcing Party shall provide the non-enforcing Party with copies of all pleadings and other documents to be filed with the court reasonably in advance and shall consider in good faith reasonable and timely input from the non-enforcing Party during the course of the action.

(e) **Recoveries**. Any recoveries resulting from enforcement action relating to a claim of Product Infringement or otherwise as described in this Section 12.4 shall be first applied against payment of the enforcing Party's costs and expenses in connection therewith and then the non-enforcing Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall [***].

**12.5. Defense**.

(a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the Exploitation of the Compound or Licensed Product in the Field in the Licensed Territory or any embodiment of any technology or intellectual property licensed by the other Party under this Agreement infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than [***] following receipt of such allegations. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties.

(b) As between the Parties, Zai shall have the first right, but not the obligation to control and be solely responsible for the defense of any such suit against Zai, at Zai's sole cost and expense; provided, however, Zai shall not enter into any compromise or settlement relating to such suit that (i) admits the invalidity or unenforceability of any Licensed Patents; or (ii) requires abandonment of any Licensed Patents; or (iii) contemplates payment or other action by Karuna or has a material adverse effect on Karuna's business, in all cases ((i) through (iii)), without obtaining the prior written consent of Karuna (which consent shall not be unreasonably delayed, withheld or conditioned).

(c) If Zai decides not to bring such legal action subject to its first right, it shall so inform Karuna promptly and Karuna shall have the right, but not the obligation, to bring and control any such legal action in connection with such infringement in the Licensed Territory at its own expense as it reasonably determines appropriate; provided, however, Karuna shall not enter into any compromise or settlement relating to such suit that (i) admits the invalidity or unenforceability of any Licensed Patents; or (ii) requires abandonment of any Licensed Patents; or (iii) contemplates payment or other action by Zai or has a material adverse effect on Zai's business, in all cases ((i) through (iii)), without obtaining the prior written consent of Zai (which consent shall not be unreasonably delayed, withheld or conditioned).

(d) Upon the defending Party's request and at the defending Party's expense, the non-defending Party shall provide reasonable assistance to the defending Party for such defense and shall join such suit if deemed a necessary party. If the non-defending Party does not join such suit, the defending Party shall keep the non-defending Party reasonably informed of the status of such suit. The non-defending Party shall be entitled to attend any substantive meetings, hearings, or other proceedings related to such suit. The defending Party shall provide the non-defending Party with copies of all pleadings and other documents to be filed with the court reasonably in advance and shall consider in good faith reasonable and timely input from the non-defending Party during the course of the suit.

**12.6. Patent Marking**. Zai agrees to mark, and have its Affiliates and Sublicensees mark, all patented Licensed Product they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the Regions of sale thereof.

**12.7. Bankruptcy Protection.** All licenses granted by one Party to the other Party under this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code or any applicable foreign equivalent laws (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101 of the Bankruptcy Code. Each Party, as the licensee, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. To the extent permitted under Applicable Law, upon the bankruptcy of a Party, the other Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered to such other Party, unless the bankruptcy Party elects to continue, and continues, to perform all of its obligations under this Agreement.

## ARTICLE 13

## TERMS AND TERMINATION

**13.1. Term and Expiration**.

(a) **Term**. The term of this Agreement shall be effective as of the Effective Date, and shall continue in effect until the expiration of the last Royalty Term with respect to for all Licensed Product in each Region in the Licensed Territory (the "**Term**", and the date of such expiration with respect to such Region, the "**Expiration Date**"). Following the Expiration Date, [***].

(b) **Expiration of Royalty Term**. On a Region-by-Region and Licensed Product-by-Licensed Product basis, upon the expiration of the Royalty Term for a given Licensed Product in a given Region, the licenses granted by Karuna to Zai under Section 2.1 of this Agreement in such Region with respect to the Licensed Product in the Field shall become fully paid-up, non-exclusive, perpetual, irrevocable and sublicenseable in multiple tiers.

**13.2. Termination for Convenience**. This Agreement may be terminated by Zai at any time for convenience upon [***] advance written notice to Karuna.

**13.3. Termination for Material Breach**. This Agreement may be terminated in its entirety, at any time during the Term upon [***] (or [***] with respect to any payment breach) written notice by either Party if the other Party is in material breach of this Agreement and, if such breach is curable, such breach has not been cured within [***] (or [***] with respect to any payment breach) of such written notice. Notwithstanding the foregoing, if the alleged breaching Party disputes the existence or materiality of the alleged breach, the other Party shall not have the right to terminate this Agreement unless and until it is determined in accordance with ARTICLE 14 that the alleged breaching Party has materially breached this Agreement and such breaching Party fails to cure such breach within [***] (or [***] with respect to any payment breach) after such determination.

**13.4. Termination for Insolvency**. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization under the Chapter 7 of the United States of Bankruptcy Code or other similar Applicable Law or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

**13.5. Termination for Patent Challenge**. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, Karuna may terminate this Agreement in its entirety upon [***] written notice to Zai if Zai or its Affiliates or Sublicensees commences a legal, administrative or other action challenging the validity, enforceability or scope of any Licensed Patent anywhere in the world, unless (a) such action is withdrawn during such [***] period or, (b) if such action is commenced by a Sublicensee, Zai terminates its sublicense during such [***] period; provided however that Karuna shall not have the right to terminate this Agreement under this Section 13.5 if such action (i) is made as a defense against any claim, action or proceeding with respect to infringement of a Licensed Patent asserted against Zai or its Affiliate or Sublicensee; or (ii) is a legal or administrative proceeding derived from a bona fide inventorship dispute or an argument to distinguish the Product Invention from other inventions in the ordinary course of patent prosecution.

**13.6. Termination by Mutual Agreement**. This Agreement may be terminated by the Parties' mutual written agreement.

**13.7. Election to Terminate**. If either Party has the right to terminate under Sections 13.3 through 13.5, it may at its sole option, elect either to (a) terminate this Agreement and pursue any legal or equitable remedy available to it, or (b) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

**13.8. Effects of Termination**.

(a) Upon the termination of this Agreement for any reason, unless otherwise provided in this Section 13.8, all rights and licenses granted to each Party herein shall immediately terminate, and all sublicenses of such rights and licenses shall also terminate. Upon termination of this Agreement, [***].

(b) Upon termination of this Agreement for any reason, the following additional provisions shall apply:

(i) **Reversion of Rights to Karuna.** Any rights and licenses with respect to the Licensed Product granted to Zai under this Agreement shall immediately terminate, and all such rights shall revert back to Karuna. In addition, the licenses granted by Zai to Karuna pursuant to Section 2.2 shall continue and become exclusive with respect to the Licensed Territory, and shall automatically be extended to include Exploitation of the Licensed Product in the Field in the Licensed Territory, provided that, if this Agreement is terminated by Zai pursuant to Section 13.3, such license shall only be granted by Zai upon agreement by the Parties on a reasonable reversion royalty payment to Zai, in which case, Clauses (ii) through (v) below shall apply only after the Parties' agreement on such reversion royalty.

(ii) **Regulatory Materials; Data**. Zai shall, and shall cause its Affiliates and Sublicensees to, [***], to the maximum extent permitted by Applicable Laws at the time of any such termination to promptly (A) assign all Regulatory Submissions and Regulatory Approvals and pricing and reimbursement approvals of Licensed Product to Karuna, and (B) assign all data generated by or on behalf of Zai or its designee while conducting Development or Commercialization activities under this Agreement to Karuna or its designee, including non-clinical and clinical studies conducted by or on behalf of Zai on Licensed Product and all pharmacovigilance data (including all Adverse Event database information) on Licensed Product.

(iii) **Trademarks**. Zai shall, and shall cause its Affiliates and Sublicensees, to promptly transfer and assign to Karuna or its designee, [***], all Product Marks (excluding the corporate name and logo of Zai, its Affiliates and Sublicensees).

(iv) **Transition Assistance**. Zai shall, and shall cause its Affiliates and Sublicensees, to provide reasonable administrative assistance, [***], as may be reasonably necessary or useful for Karuna or its designee to commence or continue Developing or Commercializing Licensed Product in the Licensed Territory, including transferring or amending as appropriate, upon request of Karuna, any agreements or arrangements with Third Party to Develop, Manufacture and Commercialize the Licensed Product in the Licensed Territory. To the extent that any such contract between Zai and a Third Party is not assignable to Karuna or its designee, then Zai shall reasonably cooperate with Karuna to arrange to continue to and provide such services from such entity (for clarity, Karuna shall be responsible for paying the cost of such services), including, where applicable, continue to supply the Licensed Product in the Field in the Licensed Territory to Karuna or its designee for a reasonable period of time (which period shall not exceed [***]) to ensure a smooth transitioning and continuous operation of any Development, Manufacture and Commercialization activities for the Licensed Product in the Field in the Licensed Territory.

(v) **Ongoing Clinical Trial**. If at the time of such termination, any Clinical Trials for the Licensed Product are being conducted by or on behalf of Zai, then, at Karuna's election on a Clinical Trial-by-Clinical Trial basis: (1) Zai shall, and shall cause its Affiliates and Sublicensees to, (A) fully cooperate with Karuna to transfer the conduct of all such Clinical Trial to Karuna or its designee, or (B) continue to conduct such Clinical Trials for so long as necessary to enable such transfer to be completed without interruption of any such Clinical Trials but no more than [***], and in each case of (A) and (B), [***], unless this Agreement is terminated by Zai pursuant to Section 13.3, in which case Karuna shall be responsible for all such costs; and (2) Zai shall, and shall cause its Affiliates and Sublicensees to, [***], orderly wind down the conduct of any such Clinical Trial which is not assumed by Karuna under clause (1).

(vi) **Preclinical Studies**. In the event that as of the date a notice of termination has been issued Zai is conducting any ongoing preclinical work with respect to the Licensed Product in support of a current Regulatory Approval or future regulatory filings for an Indication that is the subject of ongoing clinical development, including without limitation ongoing stability or toxicology studies of the Licensed Product, Zai agrees to promptly inform Karuna of the status of each preclinical activity and at Karuna's election either: (A) terminate such preclinical activity, (B) continue to conduct any such preclinical studies for a period of no more than [***] after the effective date of such termination, or (C) promptly transition to Karuna or its designee such preclinical studies, in each case, [***], unless this Agreement is terminated by Zai pursuant to Section 13.3, in which case Karuna shall be responsible for all such costs.

(vii) **Inventory**. At Karuna's election and request, Zai shall (A) upon Karuna's request, transfer to Karuna or its designee all inventory of the Licensed Product provided by Karuna [***] then in possession or control of Zai, its Affiliates or Sublicensees; provided that Karuna shall pay Zai a price equal to [***] or (B) (x) continue to use Commercially Reasonable Efforts to Commercialize all inventory of the Licensed Product then in possession or control of Zai for a period [***] after the effective date of such termination and make the corresponding payments, including any Milestone Payments or royalties to Karuna under this Agreement as though this Agreement had not been terminated and (y) after such for a period [***] after the effective date of such termination, transfer to Karuna or its designee any remaining inventory of the Licensed Product to Karuna or its designee at a price equal to [***].

(viii) **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party shall return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); provided that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic.

(c) **Other Remedies**. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

(d) **Termination by Zai Due to Material Breach**. Upon the termination of this Agreement by Zai pursuant to Section 13.3, all of the provisions of Section 13.8(b) shall apply, except that [***].

**13.9. Survival**. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. The following provisions shall survive the termination or expiration of this Agreement for any reason: [***].

## ARTICLE 14

## DISPUTE RESOLUTION

**14.1. General**. The Parties recognize that a claim, dispute or controversy may arise relating to this Agreement or to the breach, enforcement, interpretation or validity of this Agreement (a "**Dispute**"). Any Dispute, including Disputes that may involve the Affiliates of any Party, shall be resolved in accordance with this ARTICLE 14.

**14.2. Continuance of Rights and Obligations during Pendency of Dispute Resolution**. If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under ARTICLE 13, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this ARTICLE 14.

**14.3. Escalation**. Any Dispute shall be referred to the Executive Officers for attempted resolution by notice served pursuant to Section 15.5. In the event the Executive Officers are unable to resolve such Dispute within [***] of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 14.4.

**14.4. Arbitration**.

(a) If the Parties fail to resolve the Dispute through escalation to the Executive Officers under Section 14.3, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for final resolution by arbitration under the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"), excepted as modified herein. Any disputes concerning the propriety of the commencement of the arbitration or the scope or applicability of this agreement to arbitrate shall be finally settled by the arbitral tribunal. The arbitration shall be conducted by a tribunal of [***] arbitrators, each with at least [***] of pharmaceutical industry experience and independent of both Parties. An arbitrator shall be deemed to meet this qualification unless a Party objects within [***] after the arbitrator is nominated. Within [***] after initiation of arbitration, each Party shall nominate one (1) arbitrator and the two (2) Party-nominated arbitrators shall nominate a third arbitrator, who shall serve as the chairperson of the tribunal, [***] of the second arbitrator's appointment (if the two Party-nominated arbitrators cannot agree on the third arbitrator, the third arbitrator shall be appointed by ICC). The seat of arbitration shall be [***] and the language of the proceedings, including all communications, shall be English.

(b) The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction, and the Parties undertake to carry out any award without delay. The arbitral tribunal shall render its final award or decision within [***] from the date on which the request for arbitration by one of the Parties wishing to have recourse to arbitration is received by the ICC Secretariat. The arbitral tribunal shall resolve the Dispute by applying the provisions of this Agreement and the governing law set forth in Section 15.1.

(c) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the Dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(d) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

(e) Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the administrator and the arbitrators.

(f) Notwithstanding anything in this Section 14.4, in the event of a Dispute with respect to (i) the validity, scope, enforceability or ownership of any Patent or other intellectual property rights, (ii) a matter for which this Agreement assigns decision-making to the Parties or to the JSC or requires the consent of one or both of the Parties, or (iii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, and such Dispute is not resolved in accordance with Section 14.3, such Dispute shall not be submitted to an arbitration proceeding in accordance with this Section 14.4, and instead shall be resolved, (A) in the case of subsections (ii), in accordance with the respective terms of the relevant provisions, or, (B) in the case of subsection (i) and (iii), unless otherwise agreed by the Parties in writing, via litigation initiated by either Party in a court of competent jurisdiction in any country in which such rights apply.

## ARTICLE 15

## MISCELLANEOUS

**15.1. Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without reference to any rules of conflict of laws. The United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement and is expressly and entirely excluded.

**15.2. Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, pandemics, epidemics or other acts of God or any other deity (or orders of any Governmental Authority related to any of the foregoing), or acts, omissions or delays in acting by any Governmental Authority (each, a "**Force Majeure Event**"). The affected Party shall notify the other Party of any Force Majeure Event as soon as reasonably practical, the JSC shall review and discuss any such matter to the extent related to any Clinical Trials in the Licensed Territory, including adjustment to any Development Target and the associated Development Target Deadlines affected by such Force Majeure Event, and the affected Party shall promptly undertake all reasonable efforts necessary to mitigate the impact of such Force Majeure Event.

**15.3. Assignment**. Neither Party may assign this Agreement to a Third Party without the other Party's prior written consent (such consent not to be unreasonably withheld); except that (a) subject to Section 2.9, either Party may make such an assignment without the other Party's prior written consent to a successor to substantially all of the business of such Party to which this Agreement relates (whether by merger, spinoff, sale of stock, sale of assets, exclusive license or other transaction), provided that such successor shall agree in writing to comply with the terms of this Agreement, including, in the case of Zai, its obligations under Sections 2.9, 4.2, 5.1(b) and 7.1, and (b) either Party may assign this Agreement to an Affiliate without the other Party's prior written consent for so long as such Affiliate remains an Affiliate of the Party making the assignment. For clarity, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assignees. Any assignment or transfer in violation of this Section 15.3 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

**15.4. Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**15.5. Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Karuna:

Karuna Therapeutics, Inc.
Attention: [***]
99 High Street, 26th Floor
Boston, MA 02110, USA

with a copy to (which shall not constitute notice):

Goodwin Procter LLP
Attention: [***]
100 Northern Avenue
Boston, MA 02210

If to Zai:

Zai Lab
Attention: [***]
314 Main Street, Suite 04-100
Cambridge, MA 02142, USA

with a copy to (which shall not constitute notice):

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303-1130
USA
Attention: [***] with an electronic copy to [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) if sent by email, upon electronic confirmation of receipt; (c) on [***] after dispatch if sent by internationally-recognized overnight courier; or (d) on [***] following the date of mailing if sent by mail.

**15.6. Entire Agreement; Amendments**. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

**15.7. Export Control Regulations**. The rights and obligations of the Parties under this Agreement shall be subject in all respects to United States laws and regulations as shall from time to time govern the license and delivery of technology and products abroad, including the United States Foreign Assets Control Regulations, Transaction Control Regulations and Export Control Regulations, as amended, and any successor legislation issued by the applicable Governmental Authorities in the United States. Without limiting the provisions of this Agreement, Zai agrees that, unless prior authorization is obtained from the Office of Export Licensing or other applicable Governmental Authority of the United States, it will not export, re-export, or transship, directly or indirectly, via an Affiliate or a Third Party, to any country, any technical data, information or materials provided to it by Karuna hereto if such export would violate the laws of the United States or the regulations of any Governmental Authority of the United States.

**15.8. Headings**. The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Sections of this Agreement.

**15.9. Independent Contractors**. It is expressly agreed that Karuna and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Karuna nor Zai shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

**15.10. Waiver**. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

**15.11. Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**15.12. Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits as described in this Agreement, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or" where applicable.

**15.13. Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

**15.14. Language**. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

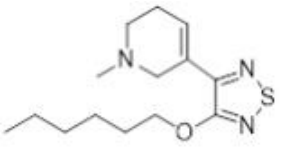
*[Signature Page Follows]*

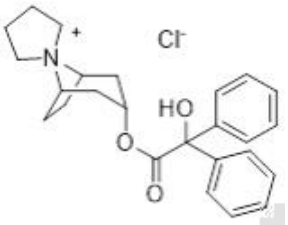
**IN WITNESS WHEREOF**, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

| **Karuna Therapeutics, Inc.** | | **Zai Lab (Shanghai) Co., Ltd** | |
|---|---|---|---|
| By: | /s/ Steven M. Paul, M.D. | By: | /s/ Samantha Du |
| Name: | Steven M. Paul, M.D. | Name: | Samantha Du |
| Title: | CEO, President & Chairman | Title: | CEO and Chairperson |

**Schedule 1.23**

**Compound**

KarXT is combination of xanomeline tartrate, a muscarinic agonist developed by Lilly, and trospium chloride, a muscarinic agonist, indicated for treating overactive bladder. Xanomeline has the IUPAC name of 3-(hexyloxy)-4-(1-methyl-1,2,5,6-tetrahydropyridin-3-yl)-1,2,5-thiadiazole tartrate and the structure 

.. Trospium chloride has the IUPAC name of [(1*R*,5*S*)-spiro[8-azoniabicyclo[3.2.1]octane-8,1'-azolidin-1-ium]-3-yl] 2-hydroxy-2,2-diphenylacetate chloride and the structure of 

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**Schedule 1.42**

**Existing In-License Agreement**

[***]

**Schedule 1.43**

**Claims in the Existing Patent Application**

[***]

**Schedule 1.58**

[***]

**Schedule 1.59**

[***]

**Schedule 1.79**

**Licensed Patents**

**[***]**

**Schedule 2.5**

**Hong Kong License Terms**

[***]

**Schedule 2.11**

**Existing In-License Agreement Terms**

[***]

**Schedule 4.1**

**Initial Development Plan**

[***]

**Schedule 9.3(a)**

**Initial Press Release**

**Karuna Therapeutics and Zai Lab Announce Strategic Collaboration for Development, Manufacturing, and Commercialization of KarXT in Greater China**

*Zai Lab obtains exclusive rights to develop and commercialize KarXT in Greater China*

*Karuna to receive upfront cash payment of $35 million, up to $152 million in potential near- and long-term development and commercial milestones and other payments, and low-double-digit to high-teens tiered royalties*

**BOSTON, SHANGHAI and SAN FRANCISCO – Nov. 9, 2021 —** Karuna Therapeutics, Inc. (NASDAQ: KRTX), a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions, and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced their entry into an exclusive license agreement for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including mainland China, Hong Kong, Macau, and Taiwan.

KarXT is an oral, investigational M1/M4-preferring muscarinic agonist that stimulates receptors in the central nervous system implicated in various psychiatric conditions. KarXT was designed to unlock the therapeutic potential of xanomeline, which demonstrated significant benefits in reducing symptoms of psychosis in Phase 2 studies in schizophrenia and Alzheimer's disease, while ameliorating side effects seen in earlier studies. In the Phase 2 EMERGENT-1 trial, KarXT demonstrated clinically meaningful and statistically significant improvements in the primary endpoint of Positive and Negative Syndrome Scale (PANSS) total score, and in key secondary endpoints, including PANSS-positive subscore and PANSS-negative subscore, at week 5, and was generally well-tolerated.

Karuna is evaluating KarXT in late-stage clinical trials for the treatment of schizophrenia and psychosis in Alzheimer's disease. The EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia, is underway. The EMERGENT program is comprised of the previously completed Phase 2 EMERGENT-1 trial and four ongoing Phase 3 trials, with data from EMERGENT-2 and EMERGENT-3, the two Phase 3 acute efficacy and safety trials, expected in mid-2022 and in the second half of 2022, respectively. Karuna plans to initiate the Phase 3 ARISE trial evaluating KarXT as an adjunctive treatment for schizophrenia in adults who inadequately respond to atypical antipsychotics in the fourth quarter of 2021. Additionally, Karuna also plans to initiate a Phase 3 program evaluating KarXT for the treatment of psychosis in Alzheimer's disease in mid-2022 following encouraging results from the completed Phase 1b healthy elderly volunteer trial, which suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile. Zai Lab will work with Karuna to design the optimal strategy to accelerate the development and regulatory timeline of KarXT in Greater China.

Under the terms of the agreement, Karuna will receive a $35 million upfront payment and is eligible to receive up to an additional $80 million in development and regulatory milestones. Karuna is also eligible to receive up to $72 million in sales milestones and low-double-digit to high-teens tiered royalties based on annual net sales of KarXT in Greater China. Zai Lab will fund substantially all development, regulatory, and commercialization activities in Greater China.

“We are thrilled to collaborate with Zai Lab, who shares our commitment to bringing transformative medicines to people living with psychiatric conditions globally,” said Steve Paul, M.D., chief executive officer, president, and chairman of Karuna Therapeutics. “With their proven record of successfully developing and commercializing novel therapies in Greater China, we believe that Zai Lab is the ideal partner to expand the global footprint for KarXT alongside our ongoing efforts in the U.S., with the goal of providing meaningful treatments to millions of people living with mental illness globally.”

“Our collaboration with Karuna is a significant milestone for Zai Lab, marking the expansion and diversification of our development and commercial portfolio into neuroscience, our fourth therapeutic area,” said Samantha Du, Ph.D., founder, chairperson and chief executive officer of Zai Lab. “KarXT is well positioned to serve as the anchor asset in our new neuroscience franchise. Zai Lab’s mission is to deliver innovative medicines to address unmet medical needs of patients, and we look forward to working with Karuna to bring KarXT to patients in need in Greater China as soon as possible.”

“There is a significant need for new and more effective therapies with improved safety to treat serious psychiatric conditions in Greater China,” said Gang Wang, M.D., Director of National Clinical Research Center for Mental Disorders, Dean of Beijing Anding Hospital, Capital Medical University. “Currently, more than 8 million people in Greater China are living with schizophrenia, yet fewer than half are receiving treatment, and even fewer are obtaining adequate symptom improvement from current treatment. We believe KarXT has the potential to provide a meaningful new treatment option for many patients living with schizophrenia and other conditions with disabling symptoms of psychosis.”

Goldman Sachs & Co. LLC is acting as financial advisor to Karuna Therapeutics.

**About KarXT**

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 bind to the $D_2$ dopamine receptor. KarXT has the potential to usher in a new class of treatment for schizophrenia and dementia-related psychosis based on its differentiated mechanism of action.

**About Karuna Therapeutics**

Karuna Therapeutics is a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions. At Karuna, we understand there is a need for differentiated and more effective treatments that can help patients navigate the challenges presented by these severe and disabling disorders. Utilizing our extensive knowledge of neuroscience, we are harnessing the untapped potential of the brain in pursuit of novel pathways to develop medicines that make meaningful differences in peoples' lives. For more information, please visit www.karunatx.com.

**About Zai Lab**

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in 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 vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

**Karuna Therapeutics Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the potential benefits and results that may be achieved through our collaboration with Zai Lab, our ongoing and planned clinical trials and regulatory filings, our goals to develop and commercialize our product candidates, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to obtain necessary funding, our ability to generate positive clinical trial results for our product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, risks relating to business interruptions resulting from the coronavirus (COVID-19) pandemic, and other risks set forth under the heading "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

**Zai Lab Forward-Looking Statements**

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of KarXT; the clinical development of KarXT; the potential treatment of schizophrenia and dementia-related psychosis; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Karuna Therapeutics, Inc. and other risks and uncertainties associated with drug development and commercialization. These forward-looking statements may contain words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

**Karuna Contact**

**Investor Relations:**

Alexis Smith
+1 (518) 338-8990
asmith@karunatx.com

**Zai Lab Contacts**

**Investor Relations:**

Ron Aldridge
+1 (781) 434-8465
ronald.aldridge@zailaboratory.com

Lina Zhang
+86 136 8257 6943
lina.zhang@zailaboratory.com

**Media:**

Danielle Halstrom
+1 (215) 280-3898
danielle.halstrom@zailaboratory.com /

Xiaoyu Chen
+86 185 0015 5011
xiaoyu.chen@zailaboratory.com

*Exhibit 21.1*

**Subsidiaries of Registrant**

| Name | Chinese Name (where applicable) | Jurisdiction of Incorporation of Organization |
|---|---|---|
| Zai Lab (Hong Kong) Limited | 再创医药(香港)有限公司 | Hong Kong |
| Zai Lab (Shanghai) Co., Ltd. | 再鼎医药（上海）有限公司 | Shanghai |
| Zai Lab International Trading (Shanghai) Co., Ltd. | 再鼎国际贸易（上海）有限公司 | Shanghai |
| Zai Lab (Suzhou) Co., Ltd. | 再鼎医药（苏州）有限公司 | Suzhou |
| Zai Lab Trading (Suzhou) Co., Ltd. | 再鼎医药贸易（苏州）有限公司 | Suzhou |
| Zai Biopharmaceutical (Suzhou) Co., Ltd | 再创生物医药（苏州）有限公司 | Suzhou |
| Zai Lab (Aust) Pty., Ltd. | N/A | Australia |
| Zai Lab (US) LLC | N/A | USA |
| ZLIP Holding Limited | N/A | Cayman |
| ZL Capital Limited | N/A | BVI |
| ZL China Holding Two Limited | N/A | Hong Kong |
| Zai Auto Immune Limited | N/A | Cayman |
| Zai Auto Immune (Hong Kong) Limited | N/A | Hong Kong |
| Zai Anti Infectives Limited | N/A | Cayman |
| Zai Anti Infectives (Hong Kong) Limited | N/A | Hong Kong |
| Zai Lab (Taiwan) Limited | 再鼎台湾医药有限公司 | Taiwan |

* All subsidiaries are wholly owned, directly or indirectly, by Zai Lab Limited.

**Exhibit 23.1**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements No. 333-221616, No. 333-239223 and No. 333-258630 on Form S-8 of our reports dated March 1, 2022, relating to the financial statements of Zai Lab Limited and the effectiveness of Zai Lab Limited's internal control over financial reporting, appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, the People's Republic of China
March 1, 2022

**Exhibit 31.1**

**Certification by the Principal Executive Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Samantha (Ying) Du, certify that:

1. I have reviewed this annual report on Form 10-K of Zai Lab Limited;

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2022

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

**Exhibit 31.2**

**Certification by the Principal Financial Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Billy Cho, certify that:

1. I have reviewed this annual report on Form 10-K of Zai Lab Limited;

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

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

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

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

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

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

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

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

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

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

Date: March 1, 2022

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

**Exhibit 32.1**

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

In connection with the annual report on Form 10-K of Zai Lab Limited (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha (Ying) Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: March 1, 2022

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

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

**Exhibit 32.2**

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

In connection with the annual report on Form 10-K of Zai Lab Limited (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Chief Financial Officer

Date: March 1, 2022

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

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