

Risk Factors Comparison 2025-02-27 to 2024-02-27 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text** Section

Data Privacy and Data Protection: Since our subsidiaries located in mainland China operate computer networks as part of their normal operations, we are required to comply with the requirements of mainland China's cyber security, data protection, privacy, and data transfer laws and regulations. In addition, in the ordinary course of our business, we collect and store personal information, including personal information about our clinical trial subjects, customers, and employees in mainland China. We may need to share such personal information with our subsidiaries, licensors, partners, or contractors located outside of mainland China. Mainland China's network and data protection regime is evolving, and we continue to face uncertainties as to whether our efforts to comply with these requirements will be sufficient. Although we develop and maintain compliance protocols and controls designed to maintain compliance with these requirements, development, implementation, improvement, and maintenance of these protocols and controls is costly and requires significant effort, resources, and time. In addition, in certain cases, our CROs, licensors, licensees, partners, contractors, and other third parties with which we do business are also required to comply with these laws, and our agreements with them require them to comply with these requirements, but there is a risk that they may not fully comply with them. Foreign Investment: Chinese laws and regulations govern the establishment, operation, and management of corporate entities in mainland China, as well as investment activities by foreign investors in mainland China. To comply with these rules, we must periodically submit certain information regarding our Company and certain investment information to relevant administrative authorities. **-16-** Competition Laws: Under Chinese laws governing competition, commercial bribery is prohibited and subject to criminal liability. Further, under certain circumstances, a pharmaceutical company's products may not be purchased by public medical institutions where that pharmaceutical company is involved in a criminal investigation or administrative proceedings related to bribery. These laws also protect "trade secrets," meaning technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders and is maintained as a secret by its legal owners or holders. Unlawfully obtaining or disclosing trade secrets is prohibited. Additionally, a company whose concentration of business violates the anti-monopoly rules in mainland China may be subject to fines of up to 10% of the last year's sales revenue, in addition to other remedial measures. Product Liability: In addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in mainland China. Under current Chinese law, manufacturers, and vendors of defective products in mainland China may incur civil and liability for loss and injury caused by such products as well as revocation of business licenses. ~~-17-~~ Tort Law: Under the PRC Civil Code, producers and sellers of defective products are required to take remedial measures such as the issuance of a warning, the recall of products, etc. in a timely manner, and may be held liable under tort law for any failure to do so, or to do so timely. Intellectual Property Rights: Mainland China has comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights, and domain names. We hold patent rights from third parties for some of our programs as described in the Overview of Significant License and Collaboration Agreements. Under certain of our agreements, we rely on third parties to file and prosecute patent applications, maintain patents, and otherwise protect the licensed intellectual property. Labor Protection: Under applicable rules in mainland China, employers must establish a comprehensive management system to protect the rights of their employees and ensure manufacturing safety, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards, and status of safe production as well as remuneration and other conditions. Employers are also required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, and maternity insurance. Additionally, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process. Regulations Relating to Foreign Exchange: Approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of mainland China to pay capital expenses such as repayment of foreign currency-denominated loans. For more information, see Dividends and Other Distributions. Regulations on Securities Offering and Listing Outside of China: Laws in mainland China regulate overseas securities offering and listing activities by domestic companies. These regulations include the requirement to submit filing documents including the offering prospectus to the CSRC. Overseas offering and listing are prohibited under certain circumstances, including where (i) the offering and listing are expressly forbidden by applicable Chinese laws, regulations, and rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council; or (iii) there are material disputes with regard to the ownership of the equity held by the domestic company's controlling shareholder or by other shareholders that are controlled by the controlling shareholder and / or actual controller. If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they may be warned and fined up to RMB10 million. ~~The controlling shareholders and actual controllers of such domestic companies that organize or instruct the aforementioned violations may be fined up to RMB10 million and directly liable persons in charge and other directly liable persons may be fined up to RMB5 million.~~ Rules for the Regulations on Supervision and Administration of Medical Devices: Laws and regulations in mainland China govern certain aspects of the production, distribution, and clinical trials of medical devices, including **-17-** reporting, establishment, and maintenance of quality management and quality control measures covering the distribution process, self-

inspection, and ethics review. Other Chinese National- and Provincial- Level Laws and Regulations: We are subject to changing requirements under many other laws and regulations administered by governmental authorities at the national, provincial, and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases or by us to third parties. We are also subject to numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, and fire hazard control. Anti- Corruption Laws and Regulations: We are subject to anti- corruption laws and rules in China and the United States, including the FCPA. These laws generally prohibit companies and their representatives from making improper payments to government officials for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. The health care professionals we regularly interact with ~~18~~ may be considered government officials under Chinese anti- corruption laws or the FCPA. In 2023, Chinese authorities increased their anti- corruption enforcement efforts with respect to the health care sector. Our Customers We rely on independent third- party distributors in Greater China to sell our ~~commercialized~~ **commercial** products, which is consistent with the pharmaceutical industry norm. This allows us to execute marketing strategies that are specifically tailored to each product and the geographic location of the hospitals located within the distribution territories of our customers across mainland China. **Our** ~~During 2023 and 2022, our~~ five largest customers accounted for approximately **32.4 % and 35.0 % and 37.7%** of our total product revenue **in 2024 and 2023**, respectively. We select distributors based on their business qualifications and distribution capabilities, such as distribution network coverage, quality, number of personnel, cash flow conditions, creditworthiness, logistics, compliance standard, past performance, and capacity for customer management. We offer rebates to our distributors, consistent with pharmaceutical industry practice. We retain no ownership control over the products sold to our distributors, and all significant risks (including inventory risks) and rewards associated with the products are generally transferred to our distributors upon delivery to and acceptance by the distributors. Manufacturing, Suppliers, and Quality Control As discussed below, we manufacture or source from third parties our commercial products, product candidates, and materials **in accordance with the terms of our license and collaboration agreements**. We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing, and testing of our commercial products and product candidates. Our Manufacturing Facilities ~~We currently manufacture or have rights to manufacture our internally developed products and certain of our licensed commercial products and product candidates under the terms of our licensing agreements, including ZEJULA (other than for commercial use in Hong Kong), NUZYRA, and xanomeline-trospium.~~ We operate two manufacturing facilities in Suzhou, China, which support the commercial and clinical production of certain of our products and product candidates, including ZEJULA. • We have a small molecule facility that manufactures ZEJULA. The oral solids production line is cGMP- compliant and is capable of performing the entire production process, including blending, granulation (i. e., wet granulation process, fluidized bed process, and roller compaction), tableting, coating, and packaging for oral solid drug products. The facility has capacity to produce up to 50 million units per year for oral solid dosage form. ~~We also have an early clinical manufacturing workshop for oral solids with additional capacity to produce approximately 30,000 units / batch.~~ We have a large molecule facility for which we have successfully obtained permits and passed inspections to manufacture supplies for certain product candidates. The facility has a biological processing ~~and~~ formulation ~~18~~ production line with an annual production capacity of up to 12 to 22 ~~200L or 1000L~~ clinical batches, **each batch for 200L or** respectively. ~~The production line consists of a 1000L drug substance production line from Cytiva and a self- clean / autoclave automatic drug product production line from Tofflon Science.~~ Our two manufacturing facilities comply with both the PRC and PIC / S drug manufacturing standards. We procure our manufacturing equipment from leading domestic and international suppliers. We believe our two manufacturing facilities are sufficient to support our commercial and clinical needs and our business growth in the near term. **CMOs** ~~19~~ ~~Contract Manufacturing Organizations~~ ~~We outsource to~~ **have engaged** a limited number of external ~~contract manufacturing organizations ("CMOs to produce")~~ the production of certain drug substances and products to meet pre- clinical, clinical, and commercial requirements of our products and product candidates. For example, we have obtained the necessary licenses and engaged CMOs to locally manufacture NUZYRA and ~~ZL-1102~~ in mainland China. By outsourcing a portion of our manufacturing activities, we can increase our focus on core areas of competence such as product candidate development, commercialization, and research. We have adopted procedures to promote compliance by our CMOs with relevant regulatory requirements and internal guidelines with respect to production qualifications, facilities, and processes. When selecting our CMOs, we consider a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability, and proposed terms for the production arrangement. Our CMOs provide services to us on a short- term and project- by- project basis. Our agreements with CMOs typically specify requirements, including product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. Our CMOs procure the necessary raw materials ~~themselves~~. Suppliers Our suppliers may consist of (i) third- party licensors from which we have licenses for commercial products and product candidates; (ii) suppliers of raw materials in our supply chain; and (iii) CROs to support our clinical trials. • Licensors: We are dependent on some of our third- party partners for the manufacture and supply of certain of our commercial products and product candidates. For example, we source **VYVGART and VYVGART Hytrulo from argenx**, OPTUNE from NovoCure, QINLOCK from Deciphera, **VYVGART XACDURO** from argenx **Innoviva**, **AUGTYRO** tisotumab vedotin from Pfizer, ~~adagrasib and repotrectinib~~ from BMS, bezarituzumab from Amgen, and **TIVDAK SUL- DUR** from **Innoviva Pfizer**. • Other Suppliers: We are dependent on third parties for certain raw materials in our supply chain. For example, we obtain raw materials for our clinical trial activities from multiple suppliers who we believe have sufficient capacity to meet our demands. We also believe we would have access to adequate alternative sources for such supplies, if needed. We typically order raw materials and services on a purchase order basis and do not enter into long- term dedicated capacity or minimum supply arrangements. While

we experience price fluctuations associated with our raw materials, we have not experienced material disruptions in the supply of our raw materials. We have suppliers in both China and the United States. • CROs: We may depend on certain CROs to support our clinical trials. Quality Control and Assurance We have established a strict quality control system in accordance with NMPA regulations. We monitor our operations in real time throughout the entire production process, from inspection of raw and auxiliary materials to manufacture and delivery of finished products to clinical testing at hospitals. Our quality assurance team is also responsible for our compliance with applicable regulations, standards, and internal policies. Our senior management team is actively involved in setting quality policies and managing the internal and external quality performance of the Company. - 19-

For information on risks related to our manufacturing and commercialization activities as well as our reliance on third parties, including our third- party partners, CMOs, and suppliers, see Risk Factors. Competition in the biopharmaceutical industry is intense. There are many companies, including biotechnology and pharmaceutical companies, engaged in developing products for the approved indications of our commercial products and the therapeutic areas we are targeting with our research and development activities. Some of our competitors may have substantially greater financial, marketing, research and development, and other resources than we do. -20- We believe that competition and leadership in the industry is based on managerial and technological excellence and innovation as well as established patent and other proprietary positions through research and development. The achievement of a leadership position also depends largely upon our ability to maximize the approval, acceptance, and use of our product candidates and the availability of adequate financial resources to fund facilities, equipment, personnel, clinical testing, manufacturing, and marketing. Another key aspect of remaining competitive in the industry is recruiting, motivating, and retaining global leaders and top talent to support our research, development, and commercial activities. Competition among approved products may be based, among other things, on patent position, product efficacy, safety, patient convenience, delivery devices, reliability, availability, reimbursement, and price. In addition, early entry of a new pharmaceutical product into the market may have important advantages in gaining product acceptance and market share. Accordingly, the relative speed with which we can develop products, complete the testing and approval process and supply commercial quantities of products can have a significant impact on our competitive position. The introduction of new products or technologies, including the development of new processes or technologies by competitors or new information about existing products or technologies, results in increased competition for, and pricing pressure on, our commercial products. The development of new or improved treatment options or standards of care in our therapeutic areas could reduce or eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates. We also face increased competitive pressures from the introduction of generic versions, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways. Such products are likely to be sold at substantially lower prices than branded products, which may significantly reduce both the price that we are able to charge for our products and the volume of products we sell. In addition, in some markets, when a generic or biosimilar version of one of our products is commercialized, it may be automatically substituted for our product and significantly reduce our revenues in a short period of time. We believe our long- term competitive position depends upon our success in discovering and developing innovative, cost- effective products that serve unmet medical needs, along with our ability to manufacture products efficiently and to launch and market them effectively in a highly competitive environment. For information on significant risks we face from competition, see Risk Factors.

Insurance We maintain insurance policies that are required under Chinese laws and regulations as well as based on our assessment of our operational needs and industry practice. We maintain liability insurance for certain clinical trials, which covers the patient human clinical trial liabilities such as bodily injury, product liability insurance, general insurance policies covering property loss due to accidents or natural disasters, and director and officer (“D & O”) insurance. We do not maintain insurance to cover intellectual property infringement or misappropriation. - 20-

Human Capital Resources Our employees are integral to our success, and we are committed to building and maintaining a strong and engaged workforce that is focused on delivering on our mission to become a leading global biopharmaceutical company and to positively impact human health in China and beyond. We seek to attract, retain, and motivate our employees through competitive compensation programs, professional development opportunities, and employee engagement. In evaluating our human capital management, we consider various factors, including employee performance, development, and our ability to recruit well qualified employees to support our business and operations. As of January 31, 2024-2025, we had 2-1, 175-869 full- time employees, of which 2-1, 088-799 were located in Greater China. The number of full- time employees by function as of such date was as follows: -21-

Function	Number of Employees
Research and Development	757
Commercial	11
Development	578
Commercial	11
Manufacturing	178
General	70
Manufacturing	090
General	68
Administrative *	170
Total	2-133
Total	1, 175-869

* Includes finance, legal, human resources, information technology, and other general and administrative functions. Our management executive team is comprised of our CEO and her direct reports who, collectively, have management responsibility for our business. Our management team places significant focus and attention on matters concerning our human capital assets, with a focus on being an employer of choice as well as on diversity, employee capabilities and growth, and succession planning. The competition for top talent in our industry is intense. To help attract, motivate, and retain well qualified employees, we strive to provide competitive compensation programs and benefits, including cash compensation, stock- based compensation, and other benefits to support the financial, physical, and emotional health of our employees. For our employees in China, consistent with Chinese regulations, we participate in a housing fund and various employee social security plans that are organized by applicable local municipal and provincial governments, including housing, pension, medical, work- related injury, maternity, and unemployment benefit plans, under which we make contributions at specified percentages of the salaries of our employees. For our U. S.- based employees, we provide in addition to our health and welfare benefits and, paid parental leave, and we provide retirement benefits in the form of certain matching contributions to tax- qualified 401 (k) plans. We also provide professional development and training opportunities to our employees to help enhance their competencies and capabilities. These opportunities include formal and comprehensive company- level and department- level training for new employees

followed by on-the-job training; periodic trainings to promote awareness and compliance with our policies and procedures; **leadership development programs to cultivate leadership excellence**; and cross-functional trainings to strengthen and reinforce employee collaborations across different functions, groups, and departments that work together to support our day-to-day operations. We have a performance management and talent development process through which managers provide regular feedback and coaching to develop employees. This process also helps the Company identify our pipeline of talent as well as areas in potential need of additional resources or support. We also engage our employees through employee resource groups, such as our women's leadership community and local diversity, equity, and inclusion committees. We seek to bring together employees with different backgrounds and expertise ~~to support our growth~~ while also creating an inclusive culture. We are proud of the diversity, skills, and achievements that our employees bring to our business from various parts of the world. In addition, we are committed to being an equal opportunity employer, where everyone is treated equally and respected, regardless of their gender, nationality, marital status, age, disability, or religious **belief beliefs**. **Our commitment to diversity is reflected in the composition of our workforce. For example, with respect to gender diversity, the majority of our full-time employees are women, and the majority of STEM-related positions are held by women.** Our worldwide teams are united by a common mission to improve human health. We strive to maintain a good working relationship with our employees. We are committed to encouraging a culture of open communication where employees can ask questions, raise concerns, and contribute creative solutions. Our management team routinely makes themselves available to all employees, including in regular town hall events that encourage open dialogue. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we have not experienced any material work stoppages or labor disputes. ~~Further, we have been able to recruit strong employees to support our business and operations.~~

22- Risk Management We are committed to acting ethically, which includes identifying and responsibly managing risk. As a result, we have adopted a consolidated risk management methodology and program, which includes a three lines of defense **for risk management that framework** to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an on-going basis, and, **We have also established** a risk governance structure that includes oversight by the Board of Directors (the "Board"), the Audit Committee of the Board of Directors (the "Audit Committee"), and management. Management oversight includes a Risk Coordination Council that is comprised of leaders of governance and quality functions along with operational line leaders and serves as a forum to discuss and monitor risks across the organization as well as other regional, divisional, or functional risk management committees or working groups, as deemed appropriate. We conduct an annual enterprise risk assessment to identify our top tier risks and, based on that assessment, will develop an enterprise risk management strategy and plans to manage those risks. Our risk management strategy takes into account various factors including our corporate strategic goals and objectives, our risk tolerance levels and thresholds, and applicable legal and regulatory requirements. We also develop and implement risk strategies for new or evolving risks during the year, as deemed appropriate. Management discusses with the Board of Directors or the Audit Committee the results of its annual enterprise risk assessments as well as its enterprise risk management methodology and guidelines and key risk-related developments. The following provides additional information on our three lines of defense **framework**:

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

- **Risk Coordination Council:** The Risk Coordination Council, which is ~~co-chaired by the Chief Compliance Officer and another rotating member and is~~ comprised of governance function leaders as well as business operations leaders, provides a forum to discuss and identify, monitor, and manage **22-** risks across the organization. Potential risks identified through this forum are escalated and managed **both** at the functional line level and **communicated** through the Chief Compliance Officer directly to executive leadership and / or the Audit Committee, as deemed appropriate.
- **Audit Committee:** The Audit Committee is responsible for assisting the Board of Directors in its oversight of the Company's risk management and internal controls; the integrity of our financial statements; compliance with ~~23-~~ applicable legal and regulatory requirements; the qualifications, independence, and performance of our auditors; and our internal audit and compliance functions.
- **Board of Directors:** The Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies and is responsible for **establishing overseeing** our enterprise risk management and internal control system and reviewing its effectiveness. The Board of Directors performs its oversight role through several different levels of review. For example, management reports to the Board on our business strategies, operations, and corporate functions, and each of the Board's Committees reports to the Board on the risks within their areas of responsibility. Investment Risk Management To help meet our liquidity needs without significantly increasing our risk, we have an investment policy, which was approved by the Audit

Committee and provides guidelines and specific instructions for the investment of our funds. Our investment strategy aims to minimize risks by reasonably and conservatively matching the maturities of the portfolio to anticipated operating cash needs. We make our investment decisions on a case-by-case basis after considering a number of factors, including, but not limited to, our cash flow levels, operational needs, and capital expenditures; the macro-economic environment; general market conditions; and the expected profit or potential loss of the investment. In accordance with our investment policy, we may engage in short-term investments with surplus cash on hand. Our investment portfolio primarily consists of time deposits. We are prohibited from investing in high-risk products, and proposed investments must not interfere with our business operations or capital expenditures. Zai Lab Limited is a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or holders of our ADSs or to service any debt we may incur. If any of our Chinese subsidiaries incur debt on their own behalf in the future, the instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from our Chinese subsidiaries to our subsidiaries located in or outside of mainland China. In addition, as of the date of this report, none of our subsidiaries have ever issued any dividends or distributions to us or their respective shareholders in or outside of mainland China, and neither Zai Lab Limited nor any of our subsidiaries has ever directly or indirectly paid dividends or made distributions to U. S. investors. Zai Lab (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$ 466. 5 million in capital contributions via 24 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to 2023-2024 to fund its business operations in mainland China. Zai Lab International Trading (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB1. 0 million in capital contributions via contributions from Zai Lab (Shanghai) Co., Ltd., its sole shareholder, in 2019 to fund its business operations in mainland China. Zai Lab (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB166. 5 million in capital contributions via ten separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2015 to 2019 to fund its business operations in mainland China. Zai Lab Trading (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB1. 0 million in capital contributions via contributions from Zai Lab (Suzhou) Co., Ltd., its sole shareholder, in 2020 to fund its business operations in mainland China. Zai Biopharmaceutical (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$ 15. 0 million in capital contributions via four separate contributions from Zai Lab (Hong Kong) Limited, its sole -23- 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- 24- 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 the SAFE for cross- border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of mainland China or pay dividends in foreign currencies to holders of our securities. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, the SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries. See~~

Risk Factors for a detailed discussion of the Chinese legal restrictions on the payment of dividends, our ability to transfer cash within the Company, and the potential for holders of our securities to be subject to Chinese taxes on dividends paid by us in the event we are deemed a Chinese resident enterprise for Chinese tax purposes. Available Information We file reports and other information with the ~~Securities and Exchange Commission (“SEC”)~~ and ~~the The Stock Exchange of Hong Kong Limited (“Hong Kong Stock Exchange”)~~. We make available on our website our annual reports on Form 10- K ~~(and previously on Form 20- F)~~, our quarterly reports on Form 10- Q, ~~and~~ our current reports on Form 8- K ~~(and previously on Form 6- K)~~, and all other SEC reports and amendments to those reports. Additionally, we make available on our website our securities filings with the Hong Kong Stock Exchange. We make this information available on our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC and the Hong Kong Stock Exchange, as applicable. We use our website as a means of disclosing material non- public information – including information on our products; business activities and partnerships; research; Trust for Life strategy, commitments, and reports; and other events and developments – and for complying with our disclosure obligations under Regulation FD. Our website address is ~~-25-~~www.zailaboratory.com. We do not incorporate the information on or accessible through our website into this report, and you should not consider any information on, or that can be accessed through, our website as part of this report. ~~- 24-~~ Item 1A. Risk Factors

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

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

- Changes in relations between the United States and China, as well as relations between China and other countries, may adversely impact our business, ~~our operating financial condition, and~~ results, ~~our ability to raise capital on favorable terms or at all, and the market price of~~ **operations** our securities;
- We are subject to extensive laws, rules, and regulations. Compliance with these laws, including China’s Counter- Espionage Law, Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, Regulation on the Administration of Human Genetic Resources, Biosecurity Law, Security Assessment Measures, and any other future laws and regulations or amendments to such laws and regulations may entail significant expenses and could materially affect our business. Our failure to comply with such laws and regulations, as a result of uncertainties in the Chinese legal system with respect to recent anti- corruption enforcement efforts or otherwise, could lead to government enforcement actions and significant penalties against us, which could materially and adversely impact our ~~operating business, financial condition, and~~ results **of operations**;
- We could be adversely affected by risks of doing business globally. For example, business disruptions or other adverse effects caused by economic, political, and social conditions, including market conditions, changing legal and regulatory requirements and government policies, political instability, trade policies and sanctions, public health crises, international war or conflict, natural disasters, extreme weather events, and other geopolitical events or significant disruptions could adversely affect our business, liquidity, and access to capital;
- We have incurred ~~significant~~ losses since our inception and anticipate that we will continue to incur losses for at least the next ~~year~~ **few quarters**. If we are unable to generate sufficient revenue from our approved commercial products, on the anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability;
- We rely on our licensors, CMOs, and other third parties for the commercial and clinical supply of ~~certain of~~ our products and product candidates. Failure of our third parties to supply us with a sufficient quantity of ~~such~~ products, in a timely matter or at all, will adversely affect us;
- Chinese manufacturing facilities have historically experienced issues operating in line with established GMPs and international best practices, and passing FDA, NMPA, and EMA inspections, which may result in a longer and costlier current GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third- party contract manufacturers;
- We rely on third parties to conduct our pre- clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates, on the anticipated timeline or at all, and our business could be substantially harmed;
- ~~-26-~~ If we are unable to obtain and maintain ~~patent~~ **intellectual property** protection for our products and product candidates ~~(e. g., through intellectual patent property rights)~~, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us; ~~- 25-~~
- We may not be able to protect our systems and networks, or the confidentiality of our confidential or other information (including personal information), from cyberattacks and other unauthorized access, disclosure, and disruption, which may materially and adversely affect us;
- The pre- approval of, filing, or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether ~~or when~~ we will be able ~~, 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 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;
- Certain of our investments may be subject to CFIUS review, which may delay or block a transaction from closing;
- Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies;
- We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our Chinese subsidiaries to make payments to Zai Lab Limited could have a material and adverse effect on our ability to conduct our business;
- Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign- owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries’ ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us;
- Chinese

regulations establish complex procedures for some acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China; • ~~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; and~~ It may be difficult to enforce against us or our management in mainland China any judgments obtained from foreign courts or for overseas regulators to conduct investigations or collect evidence within mainland China; **and • Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.** Risks Related to Doing Business in China Uncertainties in the Chinese legal system could materially and adversely affect us. The Chinese government has promulgated a comprehensive system of laws and regulations governing economic matters. Although such legislation has enhanced protections afforded to foreign investments in mainland China, mainland China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in mainland China. In particular, the Chinese legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the Chinese legal system continues to evolve, the interpretations of many laws, regulations, and rules may not be uniform and enforcement of these laws, regulations, and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until after an alleged violation has occurred. In addition, any administrative ~~and~~ court proceedings in mainland China may be protracted, resulting in substantial costs and diversion of resources and management attention. In recent years, the General Office of the Communist Party of China Central Committee and the General Office of the State Council have focused on enhancing enforcement against illegal activities in the securities markets and promoting the development of capital markets, which, among other things, requires the relevant governmental authorities to strengthen ~~cross- border oversight of law- enforcement and judicial cooperation, to enhance supervision over Chinese companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws.~~ There are uncertainties with respect to how soon legislative or administrative regulation- making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us. It is especially difficult for us to accurately predict the potential impact on the Company of new legal requirements in mainland China because the Chinese legal system is a civil law system and, unlike common law systems, prior court decisions have limited precedential value. Uncertainties with respect to the scope and interpretation of existing laws, rules, and regulations in China, as well as future laws, rules, and regulations or amendments to such laws, rules, and regulations, may adversely affect our business and results of operations. Changes in relations between the United States and China, as well as relations between China and other countries, may adversely impact our business, ~~operating financial condition, and results, ability to raise capital, and the market price of our securities.~~ **operations**. The U. S. government, including the SEC, has made statements and taken certain actions that have impacted, and may continue to impact, companies like us with a substantial presence in mainland China, including by 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 or the possibility of legislation that restricts or prohibits U. S. investment in certain companies operating in mainland China. **The Chinese government has, from time to time, responded by imposing its own tariffs, trade restrictions, and other regulations in response.** It is unknown whether and to what extent new legislation, executive orders, tariffs, laws, or regulations will be adopted **by the United States or China**, or the effect that any such actions would have on companies with a significant presence in mainland China, our industry, or us. We conduct pre- clinical and clinical activities and have significant business operations in mainland China. Any unfavorable **legislation, laws, regulations, executive orders,** government policies on cross- border relations and / or international trade, including increased scrutiny on companies with significant China- based operations, capital controls, or tariffs, may ~~affect the competitive position of our commercial products and product candidates, the hiring of scientists and other research and development personnel, the demand for or our ability to sell our commercial products, the import or export of raw materials in relation to drug development, our ability to raise capital, and the market price of our securities.~~ If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated, or if the U. S. or Chinese government take retaliatory actions due to recent or increased tensions between the United States and mainland China, such changes could have an adverse effect on our business, financial condition, and results of operations, **such as by affecting the competitive position of our commercial products and product candidates, the hiring of scientists and other research and development personnel, the demand for or our ability to sell our commercial products, the import or export of raw materials in relation to drug development,** our ability to raise capital, and the market price of our securities. The Chinese government may intervene in or influence our **business operations at any time,** which could result in a material change in our operations ~~and significantly and adversely impact the value of our securities, including potentially making those securities worthless~~ **strategy, research and development activities, commercial activities, business, financial condition, results of operations, and prospects.** The Chinese government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political, and societal goals. The Chinese government has published policies that significantly affect certain industries, such as the education and internet industries, and it may in the future release regulations or policies regarding the life sciences industry that could require us to seek permission from Chinese authorities to continue to

operate our business **or that may affect our strategy, research and development activities, or commercial activities**, which may adversely affect our business, financial condition, **and** results of operations, **and prospects**. Furthermore, recent statements made by the Chinese government have indicated an intent to increase the government's oversight and control over **securities** offerings of companies with significant operations in mainland China that are to be conducted in foreign markets, including the United States, as well as foreign investment in China-based issuers ~~like us~~. Any such action by the Chinese government could significantly limit or ~~28~~ completely hinder our ability to offer or continue to offer our securities to our investors and could cause the value of our securities to significantly decline or become worthless. Because the majority of our operations are ~~in mainland China and our auditor for prior fiscal years was located~~ in mainland China, there have been concerns regarding oversight of audits of our financial statements filed with the SEC. In recent years, the U. S. Congress and regulatory authorities have expressed concerns about challenges in their oversight of financial statement audits of U. S.- listed companies with significant operations in mainland China and with auditors located in mainland China. For example, inspections by the **Public Company Accounting Oversight Board** (the "PCAOB") of auditors located in mainland China and ~~27~~ Hong Kong have at times identified deficiencies in those auditors' audit procedures and quality control procedures, and limitations on the ability of the PCAOB to inspect or investigate auditors in mainland China or Hong Kong could deprive investors of the benefits of PCAOB inspections, ~~which could adversely affect the ability of companies using such auditors to access U. S. capital markets. As part of the continued focus on access to audit and other information for companies with substantial operations in China, has resulted in legislation~~ December 2020, **such** the United States enacted the **Holding Foreign Companies Accountable Act** (as amended, the "HFCAA"), which requires the SEC to identify issuers that have filed an annual report with an audit report issued by a registered public accounting firm that is located in a **certain** foreign jurisdiction **jurisdictions** and that the PCAOB has determined it is unable to **prohibit any issuers so identified** inspect or investigate completely because of a restriction imposed by a non-U. S. authority in the auditor's local jurisdiction (a "Commission-Identified Issuer"). Under the HFCAA, if the SEC conclusively identifies an issuer as a Commission-Identified Issuer for two consecutive years **from**, the SEC is required to prohibit the trading of the **their** issuer's securities on a national securities exchange or through any other method that is within the jurisdiction of the SEC to regulate, including over-the-counter markets, **market** in the United States. In March 2022, SEC staff conclusively identified the **past, we have used** Company as a Commission-Identified Issuer because our former auditor **auditors**, which filed an audit report with our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, was located in mainland China. ~~In~~; **however, in** May 2022, the Company engaged KPMG LLP ("KPMG"), an auditor located in the United States that is inspected by the PCAOB, as our independent registered public accounting firm, **and KPMG LLP has been our auditor** for **all of** the fiscal year ended December 31, 2022. In addition, in December 2022, the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB-registered public accounting firms in mainland China. As a result, until such time as the PCAOB issues a new determination, the SEC staff has stated that ~~there--~~ **the periods presented in this report** are no issuers currently at risk of having their securities subject to a trading prohibition under the HFCAA. Although we are not currently at risk of delisting pursuant to the HFCAA, **our** if the PCAOB were to issue a new determination regarding limitations on its ability to **access** inspect or investigate our independent auditor and we were to fail to meet the **U. S. capital** audit requirements of the HFCAA for two consecutive years, our securities may be prohibited from trading on a national securities exchange or over-the-counter market **markets** in the United States, and this could result in our ADSs being delisted from the Nasdaq Global Market ("Nasdaq"). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The foregoing could adversely affect the market price of our securities and our ability to raise capital. The market price of our securities could also be adversely affected as a result of **new legislation, different interpretations of existing legislation, or the** anticipated negative impacts of **such** legislative or executive **or regulatory** actions upon, **or** as well as negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States, **regardless of whether such actions are implemented and regardless of our actual operating performance**. We may be subject to additional approval, filing, and compliance obligations with Chinese authorities in connection with our engagement of KPMG **LLP**, a U. S. auditor that is subject to PCAOB inspection. In the first quarter of 2023, the CSRC adopted the **Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies** (the "Archives Rules"). According to the Archives Rules, we may be required to complete certain approval, filing, and regulatory procedures if it becomes necessary for us to disclose or provide to KPMG **LLP**, our U. S. auditor that is subject to inspection by the PCAOB, any documents or materials relevant to KPMG **LLP**'s audit that are deemed to have a sensitive impact (i. e., be detrimental to national security or the public interest if divulged) or contain state secrets or governmental authority work secrets. Under ~~29~~ those circumstances, KPMG **LLP** would also be required to abide by corresponding approval, filing, and compliance procedures. Due to the lack of further interpretation, we are not certain about the scope of materials that would be deemed to have a sensitive impact or contain state or governmental authority work secrets. We are subject to extensive data protection, privacy, and information security laws, regulations, and policies in China. Compliance with such laws, rules, and regulations, and any other future laws and regulations in these areas, may entail significant expenses and could materially affect our business and results of operations, including as a result of government enforcement actions and significant penalties. We are subject to extensive data protection, privacy, and information security laws, rules, and regulations in China, such as the Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, Regulation on the Administration of Human Genetic Resources, Biosecurity Law, and Security Assessment Measures. These laws, rules, and regulations require us to take certain measures to promote the security of our networks and data stored on our networks (including with respect to collection, storage, processing, and transfer), to monitor and manage related risks, and to disclose certain incidents to affected parties and appropriate regulators. Establishing and maintaining such systems and complying with such requirements takes substantial time, effort, and cost. These laws, rules, and regulations also impose certain requirements on, and may limit our ability to, transfer certain data, such as personally

identifiable information of persons located within mainland China and de-identified or anonymized health data for clinical trials, outside of China, including to our third-party partners and foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. Certain violations of these laws, rules, and regulations could lead to enforcement actions, significant fines, and / or criminal, civil, or administrative penalties. If we are not able to transfer data outside of mainland China to comply with our contractual requirements or requirements of judicial or law enforcement authorities outside of mainland China, as a result of our requirements in China, it could materially and adversely affect our business and operating results. Although we believe we are compliant with our material legal obligations in these areas, the interpretation, application, and enforcement of these laws, rules, and regulations may evolve over time or change. Our compliance with such existing laws, rules, and regulations, or any future related laws and regulations, could significantly increase our compliance costs, require significant changes to our operations, result in suspensions or delays of our clinical trials or ~~28-~~ impair or ability to initiate new clinical trials, or even prevent us from providing certain products in jurisdictions in which we currently operate or may in the future wish to operate. Any actual or perceived failure on our part to comply with such laws, regulations, or obligations relating to privacy, data protection, information security, or national security in China could result in investigations, fines, suspension, or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition, results of operations, and reputation. Further, legal uncertainty created by such laws, rules, and regulations as well as recent Chinese government actions could adversely affect our ability to raise capital in the U. S. on favorable terms or at all. The economic, political, and social conditions in mainland China, as well as governmental policies, could affect the business environment and financial markets in mainland China ~~and~~ our ability to operate our business, ~~our liquidity~~ **financial condition**, **results of operations**, and **prospects** ~~our access to capital~~. A substantial portion of our operations, and all of our commercial operations, are conducted in mainland China. Accordingly, our business, ~~results of operations~~, **financial condition**, **results of operations**, and prospects may be significantly influenced by economic, political, legal, and social conditions in mainland China. Mainland China's economy differs from the U. S. economy in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange, and allocation of resources. While mainland China's economy has experienced significant growth, such growth has been uneven across ~~different~~ regions and sectors. The Chinese government has implemented various measures to encourage economic development and allocation of resources. Some of these measures may benefit the overall economy in mainland China but may have a negative effect on our business. For example, our financial condition and results of operations may be adversely affected by government control, perceived government interference, and / or changes in tax, cyber and data security, capital investments, cross-border transactions, and other regulations that are currently or may in the future ~~apply~~ **be applicable** to us. Recently, Chinese regulators have announced ~~30-~~ regulatory actions aimed at providing the Chinese government with greater oversight over certain sectors of mainland China's economy, including the for-profit education and technology sectors. Although the biotech industry is already highly regulated in mainland China and there has been no indication of such actions or oversight in our sector, the Chinese government may in the future take regulatory actions that materially adversely affect our business, financial **condition**, results **of operations**, **liquidity**, or **prospects** ~~access to capital~~ or the business environment and financial markets in mainland China more broadly. ~~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 securities 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 securities may decline or become worthless.~~ We are required to obtain certain approvals and licenses from Chinese authorities to operate our Chinese subsidiaries. The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. For example, to conduct our business activities in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the ~~State Administration for Market Regulation, or~~ SAMR. Our ability to operate in mainland China could be undermined if our Chinese subsidiaries are not able to obtain or maintain required approvals from Chinese authorities to operate in mainland China. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied. The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could require additional expenditures and efforts on our part to comply with such regulations or interpretations. If in the future our Chinese subsidiaries do not receive or maintain required approvals, such as because we inadvertently conclude that approvals are not required or because of changes in applicable laws and regulations or interpretations of such laws and regulations, the operations of our Chinese subsidiaries, and as a result our business, results of operations, financial condition, and prospects, could be adversely affected ~~and the value of our securities could significantly decline or become worthless.~~ **The approval of Under Chinese laws and regulations, we may be required by** submission of certain filings to, or other procedures with the CSRC or other Chinese regulatory authorities ~~may be required in connection with issuing~~ **to obtain approval or follow certain procedures to issue our** securities to foreign investors ~~under Chinese law~~, and, if required, we cannot predict whether ~~or when~~ we will be able ~~, or how long it will take us,~~ to obtain such approval or complete such ~~filing or other~~ procedures. We are not currently required under Chinese laws and regulations to obtain prior approval or prior permission from the CSRC or any other Chinese regulatory authority to issue securities to foreign investors, and we do not believe we will be required to submit an application to the CSRC for our previous

issuances of securities to foreign investors. Under recent guidelines, however, we ~~are~~ may be required to submit filings to the CSRC following the submission of future overseas listings and ~~- 29-~~ the completion of future offerings of our equity securities to foreign investors, including for future securities offerings in the same overseas markets as our previous issuances. ~~There remains uncertainty as~~ ~~For example, we were required to file with the CSRC with respect~~ interpretation and implementation of regulatory requirements related to overseas securities ~~the registered offerings~~ offering and other capital markets activities of our ADSs in November 2024. If, for any reason, we were to fail to obtain any approvals or to complete any filings or other procedures required by the CSRC or other Chinese regulatory authorities, future offerings of our equity securities to foreign investors may be delayed or prevented or we may face sanctions, fines, and / or other penalties; limitations on our ability to pay dividends outside of mainland China; limitations on our operations in mainland China; delays or restrictions on the repatriation of the proceeds from our public offerings into mainland China; or other actions that could have a material adverse effect on our business, financial condition, results of operations, and prospects ~~as well as the value of our securities~~. ~~-31-~~ We may be exposed to liabilities under anti- corruption, ~~anti-bribery, and anti-fraud~~ laws in China and the United States, including the ~~FCPA~~ U.S. Foreign Corrupt Practices Act, and any ~~allegation, investigation, or~~ determination that we, ~~or our employees or contracted third parties,~~ have violated such laws could have a material adverse effect on our business or reputation. We, ~~our employees, and our contracted third parties~~ are subject to anti- corruption laws in China and the United States, including the FCPA, which generally prohibit ~~us from, among other things,~~ making improper payments to government officials for the purpose of obtaining or retaining business, ~~and Chinese laws governing competition, which prohibit commercial bribery.~~ In addition, we, our employees, and our contracted third parties are subject to laws targeted at medical insurance and other fraud in China and the United States. Although we have implemented controls and procedures to promote compliance with such laws ~~by our Company~~, if we fail ~~employees, and contracted third parties, any failures~~ to comply ~~may harm~~; due to either our own deliberate or our business and ~~inadvertent acts or those of others,~~ our reputation could be harmed and we could ~~may cause us to~~ incur criminal or civil ~~liabilities,~~ penalties, sanctions, and / or other significant expenses, which could ~~may~~ have a material adverse effect on our business, results of operations, financial condition, ~~cash flows~~ results of operations, and prospects. For example, under certain circumstances, a pharmaceutical company's products may not be purchased by public medical institutions if that pharmaceutical company is involved in a criminal investigation or administrative proceeding related to bribery. In addition, Chinese authorities have become increasingly active in enforcing laws affecting the pharmaceutical industry. Specifically, the Chinese authorities have recently increased anti- bribery and anti- fraud efforts to address improper payments and ~~the other benefits received by physicians, staff, hospital administrators, and other individuals in connection with the sales, marketing, and purchase of pharmaceutical products.~~ The scope and intensity of the ~~such~~ recent anti- corruption and medical insurance fraud enforcement efforts in China have led to increased uncertainty in the healthcare industry, which have impacted and may continue to impact hospital and physician practices. Such uncertainty, and related evaluations and adjustments by hospitals and physicians and other market participants, may adversely affect our business and results of operations. Furthermore, we have been, and may in the future be, involved in inquiries or investigations by Chinese authorities as part of these enforcement efforts or otherwise. Although we have not experienced a material adverse impact to the Company from such an inquiry or investigation to date, there can be no such assurance that such inquiries or investigations will not have a material adverse effect on our business, reputation, or operations in the future. For example, there have been public reports of recent investigations by Chinese authorities in relation to alleged medical insurance fraud and potential violations of China's data privacy and other laws by a number of persons affiliated with AstraZeneca. Certain of our former and current employees were formerly employed with AstraZeneca. Some of our current and former employees in our ZEJULA sales team are under criminal investigations by Chinese authorities in their personal capacity and have been detained for questioning or otherwise under police compulsory measures in connection with alleged medical insurance fraud, a crime under Chinese law that can be prosecuted only against individuals and not against companies. Such investigations, allegations, and the reporting thereof, and any potential enforcement actions, formal convictions, or administrative penalties or fines in connection therewith, may materially adversely affect our business and reputation. In addition, such investigations may lead to additional allegations or findings or may implicate or expand to additional employees. While we are not currently aware of any allegations or investigations into actions which may result in the criminal liability of the Company, there can be no assurance that such allegations or investigations will not result in a material adverse effect on our business.

Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies effectively. ~~- 30-~~ The ability of our Chinese subsidiaries to exchange currency is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and / or registration with Chinese government authorities, including the ~~state administration of foreign exchange, or SAFE.~~ In particular ~~For example,~~ if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, ~~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 ~~the~~ SAMR or its local branch, reporting of foreign investment information with the ~~MOFCOM~~ Chinese Ministry of Commerce, or registration with other governmental authorities in mainland China. In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China- based entities by offshore holding companies, we may not be able to complete the necessary government formalities or obtain the necessary government approvals on timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our Chinese operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund ~~and or~~ expand our business. We may rely on dividends and other distributions on equity paid by our Chinese subsidiaries to fund any cash and financing requirements we may have,

and any limitation on the ability of our Chinese subsidiaries to make payments to us could have a material ~~and~~ adverse effect on our ~~ability to conduct our~~ business **operations**. Zai Lab Limited is a holding company, and we may rely on dividends and other distributions on equity paid by our Chinese subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to ~~our shareholders or~~ holders of our **ADSs** ~~securities~~ or to service any debt we may incur. **Certain** ~~if any~~ of our Chinese subsidiaries **have incur** ~~incurred~~ debt on their own behalf, **and these or others may do so** in the future, ~~the~~. **The** instruments governing such debt may restrict their ability to pay dividends to us. To date, there have not been any such dividends or other distributions from our Chinese subsidiaries to our subsidiaries located in or outside of mainland China. In addition, none of our subsidiaries have issued any dividends or distributions to us or their respective shareholders in or outside of mainland China, and neither we nor any of our subsidiaries have directly or indirectly paid dividends or made distributions to U. S. investors. Zai Lab (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received \$ 466. 5 million in capital contributions via 24 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2014 to ~~2023~~ **2024**, to fund its business operations in mainland China. Zai Lab International Trading (Shanghai) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB1. 0 million in capital contributions via contributions from Zai Lab (Shanghai) Co., Ltd., its sole shareholder, in 2019 to fund its business operations in mainland China. Zai Lab (Suzhou) Co., Ltd., an operating subsidiary of ours that is domiciled in mainland China, received RMB166. 5 million in capital contributions via 10 separate contributions from Zai Lab (Hong Kong) Limited, its sole shareholder, domiciled outside of mainland China, from 2015 to 2019 to fund its business operations in mainland China. ~~32~~ 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-~~ **31-** ~~tax profits based on Chinese accounting standards to a discretionary reserve fund.~~ RMB is not freely convertible into other currencies. As a result, any restriction on currency exchange may limit the ability of our Chinese subsidiaries to use their potential future RMB revenues to pay dividends to us. The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of mainland China. Shortages in availability of foreign currency may then restrict the ability of our Chinese subsidiaries to remit sufficient foreign currency to our offshore entities for those offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign- currency- denominated obligations. RMB is currently convertible under the “ current account, ” which includes dividends, trade, and service- related foreign exchange transactions, but not under the “ capital account, ” which includes foreign direct investment and foreign debt (which may be denominated in foreign currency or RMB), including loans we may secure for our Chinese subsidiaries. Currently, our Chinese subsidiaries may purchase foreign currency for settlement of current account transactions, including payment of dividends to us, without the approval of the SAFE by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. The Chinese government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by **the** SAFE for cross- border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of mainland China or pay dividends in foreign currencies to holders of our securities. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, **the** SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries. Chinese regulations relating to the establishment of offshore special purpose companies by residents in mainland China may subject our China resident beneficial owners or our wholly foreign- owned subsidiaries in mainland China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit the ability of these subsidiaries to increase their registered capital or distribute profits to us, or otherwise adversely affect us. Our shareholders ~~that are residents of mainland China are required to register with local branches of~~ **the** SAFE or competent banks designated by **the** SAFE in connection with their direct establishment or indirect control of an offshore entity, ~~33-~~ for the purpose of overseas investment and financing, with such residents’ legally owned assets or equity

interests in domestic enterprises or offshore assets or interests, being considered a “special purpose vehicle **company**.” If such shareholders do not complete their registration with the local SAFE branches or otherwise fail to comply with **the SAFE** registration requirements, the Chinese subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer, or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its Chinese subsidiaries. Moreover, failure to comply with SAFE registration requirements could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and ability to distribute profits could be materially and adversely affected. Chinese regulations establish complex procedures for certain acquisitions of mainland China based companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in mainland China. Chinese regulations establish certain additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, companies must notify the ~~Chinese Ministry of Commerce (the “MOFCOM”)~~ in advance of any change-of-control transaction in which a foreign investor takes control of a Chinese domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national security, (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or Chinese time-honored brand, or (iv) such transaction involves the concentration of business undertakings by way of mergers, acquisitions, or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player. In the future, we may grow our business by acquiring complementary businesses. Complying with the necessary notification and review requirements to complete such transactions may be time consuming, and our ability to obtain any necessary approvals, such as from the MOFCOM or its local counterparts, may delay or **- 32-** prevent our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises national security concerns. If our business is deemed to be in an industry subject to national security review, our future acquisitions in mainland China may be closely scrutinized or prohibited, and our ability to expand our business through future acquisitions would be materially and adversely affected. Completing the necessary inspection and approval processes for our Chinese manufacturing facilities, such as by the FDA, NMPA, and EMA, may be time consuming and costly. As part of obtaining required regulatory approvals for our product candidates, such as by the NMPA in mainland China, FDA in the United States, and EMA in the ~~European Union (the “EU”)~~, we will need to undergo strict pre-approval inspections of our manufacturing facilities or the manufacturing facilities of our CMOs, including those located in mainland China and elsewhere. Historically, some manufacturing facilities in mainland China have had difficulty meeting required standards. When inspecting Chinese manufacturing facilities, our regulator (s) might cite GMP deficiencies, both minor and significant. Our efforts to remediate deficiencies to the satisfaction of our regulator (s) can be laborious, time-consuming, and costly and may be unsuccessful. If we cannot satisfy our regulator (s) as to our compliance with GMP, marketing approval for our product candidates could be significantly delayed or prevented, which in turn would delay or prevent commercialization of our product candidates. Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our **business, financial condition, and** results of operations. Local governments within mainland China have granted certain financial incentives to our Chinese subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount, and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty. We received government grants and subsidies of **\$ 8.2 million and \$ 2.4 million and \$ 11.5 million in 2024 and 2023 and 2022**, respectively. Local governments may decide to reduce or eliminate incentives that we are receiving at any time. In addition, some government financial incentives are granted on a project basis and **are** subject to the satisfaction of certain conditions, including compliance with ~~the applicable financial incentive agreements and completion of the specified~~ **project-projects (s)**. If we fail to satisfy the necessary conditions, we may be deprived of the relevant incentives. Any reduction or elimination of government incentives ~~would~~ **may** have an adverse effect on our business, **financial condition,** and results of operations. ~~-34-~~ It may be difficult for shareholders and regulators outside of mainland China to conduct investigations or collect evidence in mainland China. It may be difficult for shareholders to pursue claims or for regulators outside of mainland China to conduct regulatory investigations in mainland China as a matter of law or practicality. For example, in mainland China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside of mainland China. Although authorities in mainland China may establish a regulatory cooperation mechanism with authorities of another country or region to implement cross-border supervision and administration, such cooperation with authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanisms. Furthermore, under Chinese securities laws, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities in mainland China, which may further increase difficulties shareholders may face in protecting their interests. If we are classified as a Chinese resident enterprise for Chinese income tax purposes, such classification could result in unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders. Under the ~~Enterprise Income Tax Law of the People’s Republic of China (the “EIT Law”)~~, an enterprise incorporated outside of mainland China whose “de facto management bodies” are located in mainland China is considered a “resident enterprise” and will be subject to a uniform 25% enterprise income tax, or EIT, rate on its global income. We believe that neither Zai Lab Limited nor any of our subsidiaries outside of mainland China is a Chinese resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by Chinese **- 33-** tax authorities, and uncertainties remain with respect to the interpretation of the term “de facto management body.” If Chinese tax authorities determine that Zai Lab Limited or any of our subsidiaries outside of mainland China is a Chinese resident enterprise for EIT purposes that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly owned subsidiaries in mainland China, a 25% EIT on its global income may increase our tax burden. In addition, if Zai Lab Limited is classified as a Chinese resident enterprise for Chinese tax purposes, we may be required to

withhold tax at a rate of 10 % from dividends we pay to our shareholders, including the holders of our ADSs that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10 % Chinese withholding tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within mainland China. Furthermore, gains derived by our non-Chinese individual shareholders from the sale of our **securities 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-Chinese shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and mainland China in the event that Zai Lab Limited is treated as a Chinese resident enterprise. We and our shareholders may face tax consequences and other requirements in mainland China with respect to indirect transfers of equity interests in Chinese resident enterprises. The indirect transfer of equity interests in Chinese resident enterprises by a non-Chinese resident enterprise, or Indirect Transfer, is potentially subject to income tax in mainland China at a rate of 10 % on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The Chinese State Administration of Taxation has issued several rules and notices to tighten scrutiny over such acquisition transactions in recent years and has provided certain factors and criteria that will be considered in determining whether an indirect transfer has a bona fide commercial purpose. Failure to withhold and remit required taxes may result in tax liability and a penalty of 50 % to 300 % of the unpaid tax. ~~-35-~~ It is unclear how these rules and regulations affect future private equity financing transactions, share exchange, or other transactions involving the transfer of shares in Zai Lab Limited by investors that are non-Chinese resident enterprises or the sale or purchase of shares in other non-Chinese resident companies or other taxable assets by us. As a result, we may be required to expend valuable resources to determine whether we or our non-Chinese resident investors are subject to filing, withholding, or tax obligations for certain transactions, such as offshore restructuring transactions or acquisition transactions, and to otherwise comply with these rules and regulations. This may have a material adverse effect on our financial condition, results of operations, and ability to complete such transactions with non-Chinese resident investors. Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, which may delay or block a transaction from closing. The CFIUS has jurisdiction over investments in which a foreign person acquires control over a U. S. company, as well as certain non-controlling investments in U. S. businesses that deal in critical technology, critical infrastructure, or sensitive personal data. Some transactions involving U. S. businesses that deal in critical technology are subject to a mandatory filing requirement. Accordingly, to the extent the U. S. portion of our business decides to take investments from foreign persons, or we decide to invest in or acquire, in whole or in part, a U. S. business, such investments could be subject to CFIUS' s jurisdiction. To date, none of our investments have been subject to CFIUS review, but depending on the particulars of ongoing or future investments, we may be obligated to secure CFIUS approval before closing, which could delay the time period between signing and closing. If we determine that a CFIUS filing is not mandatory (or otherwise advisable), there is a risk that CFIUS could initiate its own review, if it determines that the transaction is subject to its jurisdiction. If an investment raises significant national security concerns, CFIUS has the authority to impose mitigation conditions or recommend that the President block a transaction. ~~-34-~~ In September 2022, President Biden issued an executive order to instruct CFIUS to consider national security factors when evaluating transactions, specifically a deal' s effect on critical U. S. supply chains, U. S. technological leadership in biotechnology and biomanufacturing, cybersecurity risks, or risks to U. S. persons' sensitive data. As a result, companies with significant operations in China will likely face heightened regulatory scrutiny from CFIUS in conducting acquisition of U. S. biotech companies. Changes in United States and international trade policies and relations, particularly with regard to ~~mainland~~ **mainland**-China, may adversely impact our business, **financial condition**, and ~~operating~~ **results of operations**. The U. S. government has recently made statements and taken certain actions that **have** led to changes to United States and international trade policies and relations, including imposing several rounds of tariffs affecting certain products manufactured in ~~mainland~~ **mainland**-China and imposing certain sanctions and restrictions in relation to ~~mainland~~ **mainland**-China. **The Chinese government has, from time to time, responded by imposing its own tariffs, sanctions, and restrictions in response**. It is unknown whether and to what extent new tariffs or other new executive orders, laws, or regulations will be adopted, or the effect that any such actions would have on us or our industry. We conduct pre-clinical and clinical activities and have business operations both in the United States and mainland China, and any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our products, the competitive position of our products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development or may prevent us from selling our products in certain countries. If any new tariffs, legislation, executive orders, and / or regulations are implemented, ~~or if~~ existing trade agreements are renegotiated, ~~or, in particular, if~~ the U. S. or Chinese ~~governments~~ **government** 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. ~~Zai Lab Limited is a company organized under the laws of the Cayman Islands, and a substantial portion of our assets and operations are located in mainland China. In addition, some of our directors and officers are nationals and residents of countries or regions other than the United States or Hong Kong, and a substantial portion of their assets is located outside of the United States and Hong Kong. As a result, it may be difficult 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 of a disagreement, that they believe that their rights have been infringed under applicable federal securities laws, or otherwise. Even if shareholders are a third party successful in bringing an action of this kind obtains a foreign judgment against us or these individuals,~~ the laws of the Cayman Islands and mainland China may render them unable to enforce a judgment

against our assets or the assets of our directors and officers. There is uncertainty as to whether the courts of the Cayman Islands or mainland China would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of securities laws of the United States or any state. Although there are some protections with respect to enforcement in mainland China of judgments rendered by Hong Kong courts as a result of reciprocal recognition and enforcement of judgment arrangements, mainland China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, most other western countries, or Japan. **In addition, according to PRC Civil Procedures Law, mainland China courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of Chinese laws or national sovereignty, security, or public interest.** Hence, the recognition and enforcement in mainland China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible. Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business. We lease properties for our offices and manufacturing facilities. We may not be able to successfully extend or renew such leases upon expiration of the current term on commercially reasonable terms or at all and may therefore be forced to relocate our affected operations. This could disrupt our operations and result in significant relocation expenses, which could adversely affect our business, financial condition, and results of operations. In addition, we compete with other businesses for premises at certain locations or of desirable sizes. As a result, even though we could extend or renew our leases, rental payments may significantly increase as a result of the high demand for the leased properties. In addition, we may not be able to locate desirable alternative sites for our current leased properties as our business continues to grow and failure in relocating our affected operations could adversely affect our business and operations.

Risks Related to Our Financial Position We have incurred significant losses since our inception and anticipate that we will continue to incur losses for at least the next few quarters. If we are unable to generate sufficient revenue from our commercial products, on the anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability. We currently have seven commercial programs with products that are approved and marketed for certain indications in mainland China, and we are pursuing regulatory approval of new products and additional indications for our existing products in coming years in mainland China and other licensed territories and worldwide for our internally developed product candidates **global and regional pipelines**. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through revenues from the sales of our commercial products and offerings on Nasdaq and the Hong Kong Stock Exchange, **including a registered offering of our ADSs in November 2024**, as well as private placements. Although our annual product revenues have been increasing for the last few years and we continue to focus on efficiency and productivity, we continue to incur significant development, commercialization, and other expenses related to our ongoing operations. As a result, we have incurred net losses since our inception, including \$ ~~334.257~~ **6.1** million for ~~2023~~ **2024**. If we are unable to generate sufficient revenue from sales of our approved commercial products, on our anticipated timeline or at all, at a level that more than offsets our expenses, we will be unable to achieve or maintain profitability. There are several factors that could impact our ability to achieve and maintain profitability, including the success and costs of our commercial products; our ability to obtain approvals for and commercialize new products or additional indications for existing products and costs of our clinical trials; our ability to build and strengthen our pipeline through internal discovery and business development activities and costs related to **such any related** license and collaboration arrangements; the costs and efficiency of our commercial and R & D teams and other personnel; and our ability to overcome unforeseen challenges or absorb unforeseen expenses that may adversely affect our business. Our failure to become and remain profitable would decrease the value of the Company or our securities and could impair our ability to raise capital, maintain our research and development and commercialization efforts, or expand or maintain our business. We may seek additional funding, such as for our product development programs and commercialization efforts, which may not be available on acceptable terms or at all. If we are unable to raise capital on acceptable terms when needed, we could ~~incur losses or~~ be forced to delay, reduce, or terminate certain programs or activities. Since inception, we have incurred significant costs for our commercialization efforts with respect to our approved products, our research and development efforts related to our product candidates and related clinical or pre-clinical trials, our business development activities and related upfront or milestone fees or royalty payments in our license and collaboration arrangements, and other costs to develop the infrastructure and otherwise support our operations. To date, we have financed our activities primarily through revenues from the sales of our commercial products and offerings on Nasdaq and the Hong Kong Stock Exchange, **including a registered offering of our ADSs in November 2024**, as well as private placements. **Additionally, as discussed below, we and our subsidiaries have also entered into certain debt arrangements with financial institutions in mainland China to support our working capital needs in mainland China.** We may require or seek to obtain additional funding in ~~connection with our operations through public or private equity offerings, debt financing, collaborations or licensing arrangements, or other sources.~~ If we are unable to raise capital when needed or on acceptable terms, we could incur losses or be forced to delay, reduce, or terminate certain programs or activities. Although we believe our cash and cash equivalents and short-term investments as of December 31, ~~2023~~ **2024** will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months, we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: **36** • revenues from our approved commercial products and related product costs; • the cost and timing of future commercialization activities for our products and any other product candidates for which we receive regulatory approval; • the cost, timing, and outcome of seeking, obtaining, and maintaining regulatory approval for our products and product candidates; • the scope, progress, timing, results, and costs of researching and developing our product candidates, including additional indications for our existing commercial products, and conducting pre-clinical and clinical trials; • our ability to establish and

maintain strategic partnerships, including collaboration, licensing, or other arrangements and the economic and other terms, timing, and success of such arrangements, such as with respect to any upfront fees, development and regulatory milestones that may be payable prior to commercialization or before we have generated any revenue from the related product, and sales- based milestones or royalty payments **that may be payable after commercial launch**; • the cost, timing, and outcome of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property related claims; • cash requirements of any future acquisitions; • resources and costs required to promote compliance with applicable laws and regulations by us and our third- party partners; • costs of our personnel; and • the costs of operating as a public company in both the United States and Hong Kong. We and our subsidiaries have entered into debt arrangements with certain financial institutions in China, and we may in the future consider additional debt arrangements, to fund our business or working capital needs. Such debt arrangements may restrict our future operations. We may, ~~from time to time~~, enter into debt arrangements with certain financial institutions to support our business and working capital needs. ~~To As of the date hereof~~, we have entered into certain debt arrangements with Chinese financial institutions that allow certain of our wholly- owned subsidiaries to borrow up to approximately \$ ~~164-240.5-2~~ million (or RMB1, ~~171-721~~, 7 million) to support our working capital needs in mainland China, and Zai Lab Limited has agreed to guarantee approximately \$ ~~142-217.0-7~~ million (or RMB1, ~~011-561~~, 7 million) of this debt. Such debt requires us or our subsidiaries to dedicate a portion of our or their cash flow to service interest and principal payments and, if interest rates rise, this amount may increase. As a result, our existing debt may limit our ability to use our cash flow to fund capital expenditures, to engage in transactions, or to meet other capital needs. Additionally, our subsidiaries' debt service obligations may limit their ability to make future distributions to us. Our debt could also limit our flexibility to plan for and react to changes in our business or industry and may increase our vulnerability to general adverse economic and industry conditions, including a downturn in our business or the economy. This debt is denominated in RMB, and some bears interest at variable rates. As a result, increases in market interest rates and changes in foreign exchange rates could require a greater portion of our cash flow to be used to pay interest, which could further hinder our operations. We may also have difficulty refinancing our existing debt or incurring new debt on terms that we would consider commercially reasonable or at all. To the extent that we incur additional indebtedness, the foregoing risks could increase. ~~-38-~~ We may enter into certain capital raising, business collaboration, or other arrangements that may cause dilution to our shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. We may seek business opportunities or additional funding in the future through equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances, and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, **such as our registered offering of our ADSs in November 2024**, our shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect rights of our security holders. The incurrence of additional indebtedness or the ~~-37-~~ issuance of certain equity securities could result in increased fixed payment obligations and additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our securities to decline. Additionally, to finance any acquisitions, licensing arrangements, or strategic alliances, we may choose to issue our securities as consideration, which could dilute the ownership of our shareholders. In the event that we enter into collaboration or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or product candidates. We may not be able to access the capital and credit markets on terms that are favorable to us. We may seek access to the capital and credit markets to supplement our existing funds and cash generated from operations for working capital, capital expenditure and debt service requirements, and other business initiatives. The capital and credit markets are experiencing, and have in the past experienced, extreme volatility and disruption, which leads to uncertainty and liquidity issues for borrowers and investors. That volatility and unpredictability in the financial markets has adversely affected, and may in the future adversely affect, access to capital and credit for life sciences companies, particularly for companies like ours with significant operations in China as a result of geopolitical tensions between the United States and China or otherwise. In the event of adverse market conditions, we may be unable to obtain adequate capital or credit market financing, obtain that capital or credit on favorable terms, or access such capital or credit in the market (s) or manner most favorable to the Company. Our results of operations may be adversely affected by sustained periods of increased inflation. The global economy, including the U. S. economy, has experienced rising inflation in recent years. We source our products, product candidates, and key materials from third parties located in the United States, including our licensors, other suppliers, and CROs. For example, we rely on **argenx for VYVGART and VYVGART Hytrulo**, NovoCure for OPTUNE, Deciphera for QINLOCK, **Innoviva and argenx for VYVGART XACDURO, and BMS for AUGTYRO**. Although we have not been materially affected by inflation in the past, sustained or increased inflation may result in increased product costs or other expenses. As a result, our results of operations may be adversely affected. Risks Related to Our Business and Industry Our ability to generate revenues is highly dependent on the success of our commercial products and our ability to obtain regulatory approvals for our product candidates. Our ability to generate product revenues depends on the success of our commercial products, including our ~~five~~ current commercial products as well as new products or additional indications for our current commercial products that we may launch in the future. Our ability to successfully generate revenue from our commercial products will depend on, among other things, our ability to: • maintain sufficient manufacturing or supply arrangements with third- party licensors or manufacturers; • produce through a validated process or procure internally or from third- party manufacturers sufficient quantities and inventory of our commercial products; • build and maintain sufficient internal sales, distribution, and marketing capabilities; ~~-39-~~ • increase awareness and education for our commercial products to promote acceptance from physicians, healthcare payors, patients, and the medical community; • improve access to, and affordability of, our commercial products, such as through NRDL listings or supplemental insurance coverage in the private- pay

market; • maintain compliance with ongoing regulatory labeling, packaging, storage, advertising, promotion, recordkeeping, safety, and other post-~~market~~ **marketing** requirements; ~~-38-~~ • manage our growth and spending as costs and expenses increase due to commercialization; and • manage business interruptions resulting from the occurrence of any public health crisis, international war or conflict, natural disaster, extreme weather event, or other significant or catastrophic event outside of our control. We have several product candidates in late- stage clinical development and various others in earlier stage clinical and pre- clinical development. Our ability to generate revenue from our product candidates is dependent on the results of clinical and pre- clinical development, our receipt of regulatory approval, and successful commercialization of such products, which may not occur on the anticipated timeline or at all. The success of our product candidates will depend on several factors, including the following: • successful enrollment of patients in, and completion of, clinical trials and pre- clinical studies; • receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing, and commercialization; • successful completion of all safety and efficacy studies required to obtain regulatory approval in Greater China, the United States, and other jurisdictions for our product candidates; • adapting our commercial manufacturing capabilities to the specifications for our product candidates for clinical supply and commercial manufacturing and / or making and maintaining necessary arrangements with third- party manufacturers or suppliers; • obtaining, maintaining, and successfully enforcing or defending patent, trade secret, and other intellectual property protection and / or regulatory exclusivity for our product candidates; • launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; • the success of our marketing efforts and market acceptance of the product candidates by patients, the medical community, and third- party payors; • effectively competing with any competing products or therapies; • obtaining and maintaining healthcare coverage and adequate reimbursement; • successfully enforcing and defending intellectual property rights and claims; and • maintaining a continued acceptable safety, tolerability, and efficacy profile of the product candidates following regulatory approval. We are not permitted to market any of our products or product candidates in mainland China, the United States, the EU, or any other jurisdictions until we have received required regulatory approvals. The process to develop, obtain regulatory approval, and commercialize product candidates is long, complex, and costly and varies among countries. The successful completion of clinical trials or regulatory approval in one country does not mean that clinical trials will be successful ~~in~~, or regulatory approval will be obtained, in any other country. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following: • disagreement regarding the number, design, size, conduct, or implementation of our clinical trials; ~~-40-~~ • failure to demonstrate to the satisfaction of the regulator (s) that a product candidate is safe and effective for its proposed indication, including as a result of safety issues, product recalls, or other incidents related to products approved and marketed in other jurisdictions; • failure of CROs, clinical study sites, or investigators to comply with the ICH- good clinical practice, or GCP, requirements imposed by the regulator (s); • failure of the clinical trial results to meet the required level of statistical significance; ~~-39-~~ • failure to demonstrate that clinical and other benefits outweigh safety risks; • disagreement regarding the interpretation of data from pre- clinical studies or clinical trials; • insufficient data collected from clinical trials to support the submission of an NDA, PMA, or other submission required to obtain regulatory approval in Greater China, the United States, the EU, or elsewhere; • failure to obtain approval of the manufacturing processes for our clinical and commercial supplies; • changes in the approval policies or regulations; and • actions by our CROs or licensors that materially and adversely affect the clinical trials. If we are not successful in gaining broad acceptance of our commercial products, our business would be harmed. Sales of our commercial products will depend on our ability to educate and increase physician awareness of the benefits, safety, and cost- effectiveness of such products, in general and relative to any competing therapies. The degree of market acceptance of our commercial products among physicians, patients, healthcare payors, and the medical community may depend on a number of factors, including: • acceptable evidence of safety and efficacy; • relative convenience and ease of administration; • prevalence and severity of any adverse side effects; • availability of alternative treatments; • pricing, cost effectiveness, and value propositions; • effectiveness of our sales and marketing capabilities and strategies; • ability to obtain sufficient insurance coverage and reimbursement; • the clinical indications for which such product are approved, as well as changes in the standard of care for their targeted indications; • the effectiveness of manufacturing and supply chain; • warnings and limitations contained in the approved labeling; • safety concerns with respect to similar or competing products marketed by others; • our ability to comply with regulatory post- marketing requirements; • the market size for such product, which may be larger or smaller than expected; • entry timing and price for any competing products; and ~~-41-~~ • our ability to manage complications or barriers that inhibit our commercial team from reaching the appropriate audience to promote our product (s), such as because of government actions or business disruptions caused by public health crises, natural disasters, extreme weather events, and other significant or catastrophic events. We may not obtain regulatory approval of our product candidates, on the anticipated timeline or at all, which could delay or limit our ability to realize the full potential of our product pipeline. In order to market products in any given jurisdiction, we must obtain regulatory approval and comply with numerous and varying regulatory requirements regarding safety, efficacy, and quality. We have obtained approval for our ~~five~~ **current** commercial products for certain indications in certain jurisdictions in Greater China. We may not obtain regulatory ~~-40-~~ approval for our product candidates, including new products or additional indications for our current commercial products, on the anticipated timeline or at all, which could delay or limit our ability to realize the full potential of our pipeline. We have limited experience manufacturing our products and product candidates on a large clinical or commercial scale. We rely on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacture of our products or product candidates could be delayed, which could harm our business and results of operations. We currently manufacture, or have rights to manufacture, our internally developed products and certain of our licensed commercial products and product candidates under the terms of our licensing arrangements. We rely on our two manufacturing facilities in Suzhou to support the clinical development and commercial production of such products and product candidates, including ZEJULA. If our ~~two~~ manufacturing facilities are unable to meet our intended production capacity in a

timely fashion, we may have to engage a CMO (s) for the production of clinical supplies of our products or product candidates. We may not be able to identify qualified CMOs or alternative suppliers that are able to meet our product production needs on commercially reasonable terms, in a timely manner, or at all. If we are not able to maintain sufficient quantity of our manufactured products and product candidates, our business and results of operations could be adversely affected. If our manufacturing facilities are damaged or destroyed, or production at such facilities is otherwise interrupted, or if any new manufacturing facilities are not approved by regulators, our business and prospects would be negatively affected. We have two manufacturing facilities in Suzhou that have received required approvals from our regulators and, and accordingly, we intend to rely on these facilities for the manufacture of clinical and commercial supply for certain of our products and product candidates. If either our facility-facilities were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capabilities. In such event, we would be forced to identify and rely partially or entirely on third- party CMOs for an indefinite period. Any new facility needed to replace an existing production facility would need to comply with necessary regulatory requirements and be tailored to our production requirements and processes. We also would need regulatory approvals before using any products or drugs manufactured at a new facility in clinical trials or selling any products or drugs that have been approved. Any disruptions or delays at our facilities or their failure to comply with regulatory requirements would impair our ability to develop and commercialize certain of our products or product candidates, which may adversely affect our business and results of operations. We have a limited operating history, which may make it difficult for you to evaluate the success of our business and to assess our future prospects. We are a commercial- stage biopharmaceutical company with a relatively limited operating history. Consequently, any predictions about our future success, performance, or prospects are subject to significant uncertainty, particularly in light of the dynamic and evolving industry in which we operate. We will encounter risks and difficulties frequently experienced by companies in our industry as we continue to expand or enhance our commercial activities. In addition, as a commercial- stage business, we may be more likely to encounter unforeseen expenses, difficulties, complications, and delays. If we do not address these risks and difficulties successfully, our business will suffer. -42- We may decide to pursue a particular product, product candidate, or indication and fail to pursue other products, product candidates, or indications that may later prove to be more profitable or for which there is a greater likelihood of success. We may decide to focus our licensing, research -and development, and commercialization programs to specific products and product candidates or to specific indications for those products and product candidates based on our expectations with respect to the potential benefits of the therapies, patient needs and the potential markets, synergies with our existing business, the competitive landscape, or otherwise. We may incorrectly assess the benefits, costs, and risks for any potential product or product candidate. As a result, we may forego or delay pursuit of opportunities for other products or product candidates or for other indications that later prove to have greater commercial potential, and our resource allocation -41- decisions may cause us to fail to capitalize on promising commercial drugs or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Such developments would have an adverse effect on our business, results of operations, financial conditions, results of operations, and prospects. The market opportunities for certain of our products and product candidates may be small, such as when those opportunities are limited to patients who are ineligible for other treatment options or who have not responded to prior treatments, and our estimations with respect to these populations may be inaccurate. The potential markets for certain indications of our commercial products and product candidates may be small, such as when we are seeking approval of our product candidates as a later stage therapy for patients who are ineligible for other treatment options or who have not responded to prior treatments or other approved treatments. We may consider such indications or market indications as an initial entry point for certain of our product candidates or as an additional indication for our current commercial products. We may not be able to achieve such regulatory approval or to generate sufficient revenue from such opportunities to recover related costs, without obtaining regulatory approval for additional indications. In addition, as part of our evaluation of the commercial prospects for our products and product candidates, we periodically make estimates regarding the incidence and prevalence of our target populations, including with respect to the number of people who have the indications we are targeting, as well as the subset of people with those indications who may be in a position to receive our therapies and who have the potential to benefit from treatment with our products. We also make projections regarding sales, revenues, costs, and reimbursement for our products and product candidates. We may also use such estimates in making decisions regarding our product development strategy, including business development opportunities as well as our research and development activities and the focus of pre- clinical and clinical trials. These estimates and projections are based on our beliefs, internally generated analyses, and third- party sources, and they may prove to be inaccurate or based on imprecise data. For example, the actual size of the potential market opportunity and patient population for a product or product candidate will depend on a variety of factors, including acceptance by the medical community, patient access, product pricing, reimbursement, and availability of other treatment options. Further, new studies or market data may change the estimated incidence or prevalence of these indications. The number of patients may turn out to be lower than expected, such as because patients may not be amenable to treatment with our products and product candidates or new patients may become increasingly difficult to identify or reach. All of this could significantly harm our business, financial condition, results of operations, and prospects. The pharmaceutical industry is highly regulated, and such regulations are subject to change, which may affect the approval and commercialization of our products and product candidates, and any failure to comply with such regulations could have adverse legal and financial impact. The pharmaceutical industry in Greater China, the United States, the EU, and some other jurisdictions is subject to extensive and comprehensive regulation and oversight by numerous regulatory authorities, including with respect to approval, manufacturing, distribution, marketing, and other activities related to new drug candidates and certain other therapies and treatments. -43- In recent years, there have been a number of legislative and regulatory changes in our

industry that could prevent or delay regulatory approval of our products and product candidates, restrict or regulate post-approval activities, and affect the commercial prospects of our products and product candidates, including in our primary market of mainland China. We expect the evolution in the Chinese healthcare industry to continue. Any changes or amendments, or proposed further changes or amendments, with respect to applicable laws, rules, and regulation and supervision of the pharmaceutical industry in mainland China, including recent anti-corruption enforcement efforts, may result in uncertainties with respect to the interpretation and implementation of applicable the relevant laws and regulations and may adversely affect the development or commercialization of our drugs products and product candidates in mainland China. Efforts to comply with these extensive regulatory requirements may involve substantial costs. If our operations were found to be in violation of applicable legal and regulatory requirements, we could be subject to significant civil, criminal, and administrative penalties, including, - 42- without limitation, damages, fines, imprisonment, and exclusion from participation in government healthcare programs or contracting with government authorities and the curtailment or restructuring of our operations, which could significantly harm our business. In addition, the commercial success of our approved products depends, in part, on adequate insurance coverage and reimbursement by third party payors, including government health benefit programs and authorities. We expect that healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the reimbursement available for any approved product which could adversely affect pricing for such product. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may adversely affect our ability prevent us from being able to generate revenue or attain profitability for our commercial products or to successfully commercialize launch our products and product candidates. If safety, efficacy, manufacturing, or supply issues arise with any therapy or treatment that we use in combination with our products and product candidates, such as chemotherapy drugs, we may be unable to market such products or product candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed. Certain of our products are approved for treatment, and certain of our product candidates are being evaluated as a potential treatment, in combination with other products, such as chemotherapy drugs. For example, we have commercially launched OPTUNE GIO or TTFIELDS in combination with TMZ for the treatment of patients with newly diagnosed GBM, and we are evaluating TTFIELDS OPTUNE as a combination therapy in gastric cancer, adagrasib as a combination therapy for colorectal cancer and NSCLC, and becharituzumab as a combination therapy for gastric and GEJ cancers. If the NMPA, FDA, or another regulatory agency were to revoke its approval of any therapeutic we use in combination with our products and product candidates, we would not be able to market our products and product candidates in combination with such revoked therapeutics. If safety or efficacy issues arise with the therapeutics that we seek to combine with our products and product candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the related clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any combination therapeutic, we may not be able to successfully commercialize our products or product candidates on our anticipated timeline or at all. We face substantial competition, which may result in our competitors discovering, developing, or commercializing drugs before or more successfully than we do, or developing products or therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our products and product candidates. The development and commercialization of new drug products or medical devices is highly competitive. We face competition with respect to our current products and product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, and medical device companies. Some of these competitive drugs and therapies are based on scientific approaches that are similar to that of our products and product candidates. Potential competitors also include academic institutions, government agencies, and other public and private research -44- organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. Many of the companies against which we are competing or may in the future compete have significantly greater financial resources and may have additional resources or capabilities with respect to research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Additionally, some of our competitors may successfully adopt or use emerging technologies, including artificial intelligence, to enhance their clinical or business operations before we are able to do so, which could leave us at a competitive disadvantage or with higher costs relative to our peers. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in resources being further concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through - 43- collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining global leaders and qualified scientific and management personnel; establishing clinical trial sites and patient registration for clinical trials; and acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than our products or if they are more successful in their marketing and distribution efforts. Our commercial opportunities also may be adversely affected if the availability of competitor products limits or reduces the price prices we are able to charge for our products. Our competitors also may obtain regulatory approvals in our target markets before we do, which could allow them to establish a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our products or product candidates uneconomical or obsolete. We may also be adversely affected as a result of the expiration or successful challenge of our patent rights with respect to the validity and / or scope of patents relating to our competitors' products. **Any such development could adversely affect our business, financial condition, results of operations, and prospects.** Clinical development involves a lengthy and expensive process with an uncertain outcome. There is a risk of failure for each of our product candidates. It is difficult to

predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval, our product candidates must complete pre-clinical studies and extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. The outcomes of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Future clinical trials of our product candidates may not be successful. Before commencing clinical trials, we must finalize the trial design based on ongoing discussions with the NMPA for trials in mainland China, the FDA for trials in the United States, and any other applicable regulatory authorities. The regulatory authorities may subsequently change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose unexpected additional approval conditions. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or equivalent filing) to the NMPA, FDA, or other applicable regulatory authorities and to the ultimate approval and commercial launch of our products or product candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. There are inherent uncertainties associated with the development of our products and product candidates. We do not know whether the clinical trials for our product candidates will begin or be completed on schedule or at all or whether the clinical trial results will be favorable. ~~45~~ We may incur additional costs or experience delays in completing pre-clinical or clinical trials or ultimately be unable to complete the development and commercialization of our product candidates. We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, such clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- ~~44~~ • clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of our products and product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may not be able to conduct a companion diagnostic test to identify patients who are likely to benefit from our products and product candidates in a timely manner or at all;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- our products and product candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs, or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other therapies that raise safety or efficacy concerns about our products and product candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or the ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA, FDA, or other applicable regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols; a failure to obtain the regulatory approval and / or complete record filings with respect to the collection, preservation, use, and export of mainland China's human genetic resources; inspection of the clinical trial operations or trial site by the NMPA, FDA, or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects; failure to demonstrate a benefit from using a product candidate; changes in government regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the NMPA, FDA, or other applicable regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for ~~46~~ approval even after it has reviewed and commented on the design for our clinical trials. Our business will be adversely affected if we are unable to successfully complete clinical development, obtain regulatory approval, and successfully commercialize our products and product candidates. If we are required to conduct additional clinical trials or other testing of our products or product candidates beyond those that are currently contemplated, or if we are unable to successfully complete clinical trials of our products or product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our products and product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- ~~45~~ • be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of our products and product candidates;
- be subject to restrictions on the distribution and / or commercialization of our products and product candidates; or
- have our products and product candidates removed from the market after obtaining

regulatory approval. Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products and product candidates and may harm our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and prospects significantly. If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our products and product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA, or applicable regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future clinical trials, to include some patients with the applicable genomic mutation with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genomic mutation. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials. In addition, some of our competitors have ongoing clinical trials for products or product candidates that treat the same indications as our products or product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' products or product candidates. ~~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; • the availability of an appropriate genomic screening test; -47-~~ ~~• 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 public health crisis, international war or conflict, natural disaster, extreme weather event, or other significant or catastrophic event 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 ~~any~~ 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 with respect to product liability, additional regulatory scrutiny and requirements for additional labeling or safety monitoring, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician, patient, and / or investor confidence in our products and our reputation. Any of these events could result in liability, loss of revenues, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges, or other adverse impacts on our results of operations. Furthermore, undesirable side effects could cause us to interrupt, delay, or halt clinical trials or could cause regulatory authorities to interrupt, delay, or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA, or other applicable regulatory authorities. For example, side effects, such as fatigue, nausea, and low blood cell levels, are common in the case of oncology products or product candidates. If trial results for our products or product candidates reveal a high and unacceptable severity and prevalence of these or other side effects, trials of our products or product candidates could be suspended or terminated, and the NMPA, FDA, or other applicable regulatory authorities could order us to cease further development or deny approval of our products or product candidates for any or all targeted indications. The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly. ~~-46-~~ Additionally, our products and product candidates could cause undesirable side effects related to off-target toxicity. For example, many of the currently approved PARP inhibitors have been associated with off-target toxicities. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our products or product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. Even after a product or product candidate receives regulatory approval, if we, our partners, or others identify undesirable side effects caused by such product candidates (or any other similar product candidates) after such approval, a number of significant negative consequences could result, including: • our revenue may be negatively impacted; • our regulatory authorities may withdraw or limit their approval of such products or product candidates; • our regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication; ~~-48-~~ • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we may be required to change the way such products or product candidates are distributed or administered, conduct additional clinical trials or change the labeling of our products or product candidates; • our regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS (or analogous requirement), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools; • we may be subject to regulatory investigations and government enforcement actions; • we may decide to remove such products or product candidates from the marketplace; • we could be sued and held liable for injury caused to individuals exposed to or taking our products or product candidates; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected products or product candidates, could substantially increase the costs of commercializing our products and product candidates, if approved, and could otherwise significantly impact our ability to successfully commercialize our products and product candidates and

generate revenue. If we are unable to obtain NMPA approval for our products and product candidates to be eligible for an expedited registration pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive a Category 1 drug designation, it may not lead to a faster development, review, or approval process. The NMPA ~~can designate~~ **designate** innovative ~~drug drugs~~ as Category 1 drugs. To qualify for a Category 1 designation, a drug needs to have a new and clearly defined structure, pharmacological property, and apparent clinical value and ~~has to have~~ not been marketed anywhere in the world. Our CTAs for ZEJULA and NUZYRA were approved as Category 1 drugs by the NMPA. A Category 1 designation by the NMPA may not be granted for any of our other product candidates that will not be first approved in mainland China or, if granted, such designation may not lead to ~~a~~ faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our product or product candidates will receive regulatory approval. Furthermore, despite positive regulatory changes in mainland China which have significantly accelerated time to market for innovative drugs, the regulatory process is still relatively ambiguous and unpredictable. The NMPA might ~~-47-~~ require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our product candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions, or contraindications, or we may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our product candidates in our target markets, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our other product candidates or to in-license, acquire, or develop additional product candidates in the future. We continue to be subject to ongoing obligations and continued regulatory review with respect to our commercial products, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our commercial products, we may be subject to penalties. After obtaining regulatory approval, our commercial products ~~are 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. **These requirements include submissions of safety and other post-marketing information** and reports, registration, and continued compliance with cGMPs and GCPs. Such post-approval ~~-49-~~ development and regulatory requirements may limit how our commercial products are manufactured and marketed, and could materially impair our ability to generate revenue. As such, we and our partners and any of our and their respective contract manufacturers will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. To the extent we want to make changes to the approved products, product labeling, or manufacturing processes, we will need to submit new applications or supplements to the applicable regulatory authority and obtain their approval. Additionally, any regulatory approvals that we receive for our products or product candidates may be subject to limitations on the approved indications for which the products may be marketed or to the conditions of approval, ~~or may~~ contain requirements for potentially costly post-marketing studies, including Phase IV studies for the surveillance and monitoring ~~of~~ the safety and efficacy of the products. For example, we are collecting additional safety and efficacy data for post-market safety and efficacy analysis for OPTUNE and monitoring adverse effects related to skin irritation, and we continue to collect safety events for all approved products. In addition, once a product is approved by the applicable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the product, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products, it may result in, among other things:

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

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change, or additional government regulations may be enacted, that could prevent, limit, or delay regulatory approval of our products or product candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost, and we may not achieve or sustain profitability, which may harm our business, financial condition, and prospects significantly. ~~-48-~~ Our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel. We are highly dependent on the expertise of our global leaders, including Samantha (Ying) Du, our ~~founder~~ **Founder**, Chief Executive Officer, and Chairperson of the Board of Directors, **our executive management team**, and ~~on~~ members of our research and development and commercial teams. Although we have entered into employment agreements with our executive officers, they may terminate their employment with us at any time following a reasonable notice of not less than thirty days. We do not maintain “key person” insurance for any of our executives or employees. Recruiting and retaining qualified management, scientific, clinical, manufacturing, and sales and marketing personnel is critical to our success. **In addition, our management will be required to devote significant time to compliance initiatives from our dual primary listing on Nasdaq and the Hong Kong Stock Exchange.** The loss of the services of certain of our executive officers or other key employees could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing certain of our executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate ~~these~~ key personnel on acceptable terms given the competition among numerous pharmaceutical and ~~-50-~~ 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 compliance initiatives from our dual primary listing on Nasdaq and the Hong Kong Stock Exchange.~~ Failure ~~failure~~ to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. ~~We~~ **As the Company develops globally, we** may further increase the size and capabilities of our organization, and we may experience difficulties in managing such growth. ~~We~~ **As the Company develops globally, we** may experience further growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of product development, product commercialization, regulatory affairs, and business development. To manage future growth, we may continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and could have a materially adverse effect on our business. We may explore additional regional or global licensing or collaboration arrangements for the development and / or commercialization of product candidates, which may expose us to significant additional costs, such as upfront fees, milestone payments, royalty payments, and the costs of related clinical or pre-clinical trials, may divert management attention or resources away from our other products and product candidates, and may expose us to additional risks of conducting business in additional international markets. The majority of our products and product candidates are in-licensed for development and commercialization in Greater China. We have and may in the future explore additional global or regional licensing or collaboration agreements, including in territories outside of Greater China. Efforts to enter into license or collaboration with third parties may divert our management's attention away from other corporate strategic goals or objectives, business operations, or potential acquisition or development opportunities for additional product candidates. Further, these arrangements involve significant costs, including upfront fees; development, regulatory, and sales-based milestones; and certain royalties at tiered percentage rates based on annual net sales. Such milestone payments are contingent on product performance, and upfront fees, certain development and regulatory milestones, and costs of clinical or pre-clinical trials may occur before we have commercialized or received any revenue from the related product candidate. Moreover, international business relationships subject us to additional risks that may materially adversely affect our business, including: ~~- 49-~~ • difficulty of effective enforcement of contractual provisions in other jurisdictions; • potential third-party patent rights or potentially reduced protection for intellectual property rights; • unexpected changes in tariffs, trade barriers and regulatory requirements, including the loss of normal trade status between mainland China and the United States; • economic weakness, including inflation; • compliance with tax, employment, immigration, and labor laws for employees traveling abroad; • the effects of applicable foreign tax structures and potentially adverse tax consequences; • currency fluctuations, which could result in increased operating expenses and reduced revenue; • workforce uncertainty and labor unrest; ~~-51-~~ • failure of our employees and contracted third parties to comply with anti-bribery laws in mainland China, Office of Foreign Asset Control rules and regulations and the **FCPA Foreign Corrupt Practices Act** and other anti-bribery and corruption laws; and • business interruptions resulting from geopolitical actions, including trade disputes, public health crises, international war or conflict, natural disasters, extreme weather events, and other significant or catastrophic events outside of our control. These and other risks may materially adversely affect our business, results of operations, and financial condition. We may engage in future partnerships, in-licensing arrangements, joint ventures, or other types of ~~future~~ business acquisitions that could disrupt our business, cause dilution to holders of our securities, and harm our financial condition and operating results. We have engaged, and may again in the future engage, in partnership or strategic collaboration opportunities or investments, including those that require acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current business and corporate strategic goals. In connection with such partnership or collaboration opportunities, acquisitions, or investments, we may: • issue **securities ordinary shares** that would dilute the percentage of ownership of the holders of our securities; • incur debt and assume liabilities; and • incur amortization expenses related to intangible assets or incur large and immediate write-offs. For example, in January 2021, we entered into a strategic collaboration with argenx ~~BV~~ pursuant to which we obtained an exclusive license for the development and commercialization of efgartigimod in Greater China in exchange for a combination of cash and ordinary shares. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our research, development, and commercialization efforts with respect to our products and product candidates ~~and any future products and product candidates that we may develop~~. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. Additionally, establishment of a joint venture involves significant risks and uncertainties, including (i) our ability to cooperate with our strategic partner, (ii) our strategic partner having economic, business, or legal interests or goals that are inconsistent with ours, and (iii) the potential that our strategic partner may be unable to meet its economic or other obligations, which may require us to fulfill those obligations alone. We may be unable to find suitable acquisition candidates, and we may not be able to complete partnership or strategic collaboration opportunities or investments on favorable terms, if at all. If we do enter into partnerships or strategic collaborations or make other investments, such arrangements may not ultimately strengthen our competitive position or ~~- 50-~~ may be viewed negatively by customers, financial markets, or investors. Further, future partnerships, strategic collaborations, or other investments could also pose numerous additional risks to our operations, including: • problems integrating the purchased business, products, personnel, or technologies; • increases to our expenses; • failure to have discovered undisclosed liabilities of the acquired asset or company; • diversion of management's attention ~~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 ~~-52-~~ • potential loss of key employees, ~~particularly~~ **including** those of the acquired entity. We may not be able to realize the benefit of current or future

collaborations, strategic partnerships, or ~~the license licensed 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. Following a strategic transaction or license, we may not be able to achieve sufficient revenue or net income to justify such transaction. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop ~~or commercialize~~ our products and product candidates ~~or bring them to market and generate product sales revenue~~, which would harm our business prospects, financial condition, ~~and~~ results of operations, ~~and prospects~~. 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 adversely affect our profitability. The regulations that govern pricing and reimbursement for pharmaceutical drugs and devices vary widely from country to country. In mainland China, the National Healthcare Security Administration (“NHS A”) is responsible for administering mainland China’s social security system, including price negotiations with drug companies seeking to include their products in the NRDL. Such price negotiations have resulted in average price reductions ranging from around ~~50-53~~ % to ~~60-63~~ % over the past few years. The NHS A, together with other government authorities, review the inclusion or removal of drugs from the NRDL, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. In connection with obtaining NRDL listing for ZEJULA, ~~VYVGART, NUZYRA, QINLOCK, NUZYRA, and VYVGART AUGTYRO~~ for certain indications, we lowered the selling price of each product in preparation. Although NRDL listing may increase patient access to, and demand for, our commercial products, the lower reimbursement rate could negatively affect our revenues or product margins and may not be sufficient to cover our costs, including licensing fees and research, development, manufacturing, marketing, and distribution expenses. We may also continue to experience additional pricing pressure for our products, including as a result of the centralized tender process or otherwise, which may further adversely affect our revenues or results of operations. Prior to any potential NRDL listing, revenues for our commercial products will depend on sales that are self-paid by patients or otherwise covered by insurance in the private-pay market. Higher patient prices or lower patient access may reduce demand for, and sales of, our commercial products. Companies in mainland China that manufacture or sell drugs and medical devices are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our ~~products and~~ product candidates. ~~- 51-~~ The life sciences industry in mainland China is subject to extensive government regulation and supervision. In order to manufacture and distribute drug and medical device products in mainland China, we are required to: • obtain a manufacturing permit for each production facility from the NMPA and its relevant branches for the manufacture of drug and device products domestically; • obtain a marketing authorization, which includes an approval number, from the NMPA for each drug or device for sale in mainland China; • obtain a Pharmaceutical Distribution Permit from the provincial medical products administration if we were to sell drugs manufactured by third parties; and ~~-53-~~ • renew the Pharmaceutical Manufacturing Permits, the Pharmaceutical Distribution Permits, and marketing authorizations every five years, among other requirements. **Laws governing medical devices continue to evolve in China, including with the publication of the draft Medical Devices Administration Law in 2024. New or revised regulations may be more onerous or costly for us to comply with and may expose us to additional regulatory oversight.** If we are unable to obtain or renew such permits or any other permits or licenses required for our operations, we will not be able to engage in the commercialization, manufacture, and distribution of our products and product candidates and our business may be adversely affected. If we fail to maintain our licenses or other intellectual property-related agreements for our products or product candidates or if we otherwise experience disruptions ~~or disputes relating~~ to our business relationships, we could lose the ability to continue the development and commercialization of our products and product candidates, ~~and such disputes could cause us to use substantial resources~~. Our business relies, in large part, on our ability to develop and commercialize products and product candidates from third parties in accordance with our license and collaboration agreements and other intellectual property-related agreements. If we fail to maintain such licenses or other intellectual-property-related agreements that are relevant to our products and product candidates, we may be unable to develop and commercialize the affected products or product candidates, and our business, ~~results of operations, financial condition~~, ~~results of operations~~, and prospects could be materially harmed. If we fail to comply with our obligations under such agreements or if our licensors or collaboration partners fail to comply with obligations under such agreements or other agreements from which our rights are based, we may be unable to successfully develop and commercialize the affected products or product candidates, and our business, ~~results of operations, financial condition~~, ~~results of operations~~, and prospects could be materially harmed. Failure to meet obligations under any of the aforementioned agreements may result in termination of same by the other contracting party. Even though we may exercise all rights and remedies available to us and otherwise seek to preserve our rights, we may not be able to do so in a timely manner, at an acceptable cost, or at all. Any uncured, material breach under such agreements could result in loss of our rights and may lead to a complete termination of our rights to ~~the~~ applicable products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, ~~we have had, and may in the future have,~~ disputes ~~may arise~~ regarding our rights under license, collaboration, or other intellectual-property related agreement, including but not limited to: • the scope of rights granted under such agreement; • the use of intellectual property ~~right rights~~ under such agreement; • the satisfaction of diligence obligations under such agreement; • the ownership of inventions or know-how resulting from such agreement; and • the payments due under such agreement. ~~- 52-~~ Such dispute may disrupt our business relationships or otherwise hinder our ability to successfully develop and

commercialize the affected products or product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. **Such disputes may also require or result in substantial costs and diversion of resources, including the consumption of significant management and other personnel time, to defend or assert our contractual rights or interpretation or to settle, arbitrate, or litigate such disputes. Any such settlements of contractual disputes, and the negotiations in connection therewith, could have a material adverse effect on our business, reputation, financial condition, results of operations, and prospects.** In addition, the resolution of any disputed contractual interpretation of any of the foregoing agreements could result in a narrower interpretation of the scope of our rights or increase our financial or other obligations and thereby may prevent or impair our ability to maintain our current agreement on commercially acceptable terms. Accordingly, we may be unable to successfully develop and commercialize the affected products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects. Reputational harm to our products, including product liability claims or lawsuits against us or any of our licensors, could cause us to incur substantial liabilities or loss of revenue or harm our reputation. We face an inherent risk related to the use of our products and product candidates anywhere in the world. If we or our licensors cannot successfully defend the reputation of our licensed products, including against product liability or other claims, then we may incur substantial liability, loss of revenue, or loss of reputation. Regardless of merit or eventual ~~-54-~~outcome, the consequences to us from those claims (whether resulting from our sales in our licensed territories, or those of our licensors' sales elsewhere in the world) may result in: • significant negative media attention and reputational damage; • withdrawal of clinical trial subjects and inability to continue clinical trials; • significant costs to defend related litigation; • substantial monetary awards to trial subjects or patients; • the inability to commercialize any products or product candidates that we may develop; • initiation of investigations by regulators; • a diversion of management' s time and our resources; and • a decline in the market price of our securities. Any litigation or investigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), product liability insurance to cover our product liability claims and general liability and D & O insurance to cover other commercial liability claims, these insurance policies may not fully cover our potential liabilities. Additionally, inability to obtain sufficient insurance coverage at an acceptable cost could prevent or inhibit the successful commercialization of products or drugs we develop, alone or with our collaborators. Any negative reputational harm to our licensors' products anywhere in the world may have an adverse impact on our ability to sell those same products in our licensed territories. If our licensors incur such harm or liability, it may also cause damage to our revenues and reputation which may not be covered by insurance. ~~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 of time and resources 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 sufficient manufacturing supply; development of a commercialization strategy; and significant marketing efforts before such products will generate any revenue. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the NMPA, the FDA, or applicable regulatory authorities, and we may never receive such regulatory approval. Clinical development of any product candidates from our internal discovery programs may not be successful. We may not be able to obtain regulatory approvals or to successfully commercialize or generate revenue from any of our product candidates. Even if we have success in pre-clinical testing, our clinical trials may not 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 delay or abandon further development of any of our product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs or other similar applications with the NMPA for approvals in mainland China, the FDA for approvals in the United States, or other applicable regulatory authorities for approval in other target markets, which will adversely affect our ability to commercialize or generate revenue from the related product candidates.~~ ~~-55-~~

Potential cybersecurity threats are changing rapidly and advancing in sophistication. We may not be able to protect our systems and networks, or the confidentiality of our confidential or other information (including personal information), from cyberattacks and other unauthorized access, disclosure, and disruption. Cybersecurity risks for companies like ours have significantly increased in recent years, in part because of the proliferation of new technologies, the use of the internet and certain technologies to conduct business, and the increased ~~-53-~~sophistication and activities of organized crime, hackers, terrorists, and other external parties, including foreign state- sponsored actors. Like many companies, from time to time we have been, and expect to continue to be, the target of attempted cyberattacks and other cybersecurity incidents. Such incidents may include malware, ransomware, denial- of- service attacks, social engineering, unauthorized access, human error, theft or misconduct, fraud, and phishing, as part of an effort to disrupt operations, potentially test cybersecurity capabilities, or obtain confidential, proprietary, or other information (including personal information). Our cybersecurity risk and exposure depend on various factors, including the evolving nature and increasing frequency, levels of persistence, sophistication, and intensity of these threats, the outsourcing of some of our business operations, and the current global economic and political environment. The increase in remote work environments also may increase our cybersecurity risk if our employees, vendors, service providers, and other third parties with which we interact are working remotely on less secure systems and environments. Because we are dependent on third parties for certain elements of our business and operations, we could also be adversely affected if any of them are subject to a successful cyberattack or other cybersecurity incident. Third parties with which we do business may also be sources of cybersecurity or other technology risks. We routinely transmit and receive confidential, proprietary, and other information (including personal information) by electronic means. This information could be subject to interception, misuse, or mishandling. Our exposure to these risks could increase as a result of our migration of core systems and applications to a third-

party cloud environment. While we generally perform cybersecurity diligence on our key vendors, because we do not control third parties with whom we do business and our ability to monitor their cybersecurity posture is limited, the cybersecurity measures they take may not be sufficient to protect any information we share with them. Although we devote significant resources to protect our systems, network, and information, the security measures we have implemented may not provide effective security. Our internal computer systems, software, devices, and networks – and those of our CROs, CMOs, and other third- party providers – may be vulnerable to cyberattacks and other cybersecurity incidents, business or supply chain disruptions, or other attempts to harm our business or reputation or misuse or steal information (including personal information). We routinely identify cybersecurity threats as well as vulnerabilities in our system and work to address them, but these efforts may be insufficient. Outside parties may attempt to induce employees, third- party partners, vendors, service providers, or other users of our systems or networks to disclose confidential, proprietary, or other information (including personal information) in order to gain access to our systems and networks and the information they contain. Unauthorized access or disclosure, or breaches of our security, also may result from human error. We may not be able to anticipate, prevent, detect, recognize, or react to threats to our systems, networks, and assets, or implement effective preventative measures against cyberattacks or other security incidents, especially because the techniques used change frequently or are not recognized until launched. A cyberattack or other cybersecurity incident could occur and persist for an extended period of time without detection. We expect that any investigation of such an incident would take time, during which we would not necessarily know the extent of the harm or how best to remediate it. Although we have not experienced any such incident resulting in a material impact to the company to date, our cybersecurity risk management program may not prevent such an incident from having a material impact in the future. We have obtained insurance coverage relating to cybersecurity risks, but this insurance may not be sufficient to provide adequate loss coverage (including if the insurer denies future claims) and may not continue to be available to us on economically reasonable terms, or at all. Further, any limitations of liability provisions in our agreements with vendors, customers, and other third parties with which we do business may not be enforceable or adequate or otherwise protect us from any liabilities or damages with respect to any particular claim in connection with a cyberattack or other security incident of a third party on which we rely. ~~–56–~~The occurrence of one or more cyberattacks or other cybersecurity incidents could result in the unauthorized disclosure, misuse, or corruption of confidential, proprietary, and other information (including personal and other information about our employees and patients and company and vendor confidential data) or could otherwise cause interruptions or malfunctions in our operations or the operations of our partners, customers, vendors, and other third parties with which we do business. This could result in significant losses or reputational damage, adversely affect our relationships ~~- 54-~~ with our partners, customers, vendors, and other third parties, negatively affect our competitive position, or otherwise harm our business. We could also face regulatory and other legal action, including for any failure to provide timely disclosure concerning, or appropriately to limit trading in our securities following, an incident. We may be required to expend significant additional resources to repair or replace information systems or networks, modify our internal controls, and implement or enhance other protective measures or to investigate or remediate vulnerabilities or other exposures. We also may be subject to litigation and financial losses that are not fully insured. We **, our employees, and our contracted third parties** are subject to laws and government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future laws and regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data. We **, our employees, and our contracted third parties** are subject to data privacy and security laws in the various jurisdictions in which we operate, obtain **,** or store personally identifiable information, including in mainland China, the United States, and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We could be subject to regulatory actions and /or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims under the laws described, as well as for alleged unfair or deceptive practices. If our operations are found to be in violation of any of the privacy laws, rules, or regulations that apply to us, we could be subject to penalties, including civil penalties, damages, injunctive relief, and other penalties, which could adversely affect our ability to operate our business and our financial results. We will continue to review these and all future privacy and other laws and regulations to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data **. While we maintain and enforce policies and practices designed so that we and our employees comply with such data privacy and security laws in the various jurisdictions in which we operate, we have identified, and may in the future identify, instances of non- compliance with such policies and practices by our employees. Such non- compliance may result in a material adverse effect on our business, reputation, or operations, and our policies and practices may not prevent such an incident from having a material adverse impact in the future. In addition, our employees and contracted third parties may become subject to regulatory actions involving privacy issues related to data collection and use practices and other data privacy laws and regulations. Such regulatory actions may result in criminal or civil penalties, convictions, or sanctions, which may materially adversely affect our business and reputation. Such investigations of our employees and contracted third parties could also lead to allegations against, or investigations into, the Company and our practices with respect to such data and privacy laws and regulations**. We may face further restrictions (or even prohibitions) on our ability to transfer our scientific data abroad if Chinese regulators impose new restrictions (or change their interpretation of existing restrictions) on life sciences companies like us and the scientific data we obtain, generate, and maintain. The Scientific Data Administrative Measures promulgated by the General Office of the State Council provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality, and security of scientific data. **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 broad, and the Chinese government has not issued further guidance to clarify if clinical study data would fall within this definition. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government- designated data center or prevented the cross- border transmission and sharing of clinical study data. None of our clinical study or other scientific data has been created or managed with government funds or funded by any source that concerns state secrets, national security, or social and public - 55- interests. To date, we have received requisite permissions to transfer clinical study data abroad. We are closely monitoring legal and regulatory developments in this area to see how scientific data is interpreted, and we may be required to comply -57- with additional regulatory requirements for sharing clinical study or other scientific data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

Risks Related to Our Dependence on Third Parties We rely on third parties, including our licensors, CMOs, and other suppliers, to support the commercial and clinical supply of our products and product candidates. Failure of such third parties to supply us with a sufficient quantity of products, in a timely matter or at all, may adversely affect our business. We rely on third-party manufacturers to manufacture some of our products and product candidates. For example, with respect to our commercial products, we rely on **argenx for VYVGART and VYVGART Hytrulo**, **NovoCure for OPTUNE or TTFields**, **Deciphera for QINLOCK**, **Innoviva and argenx for VYVGART XACDURO, and BMS for AUGTYRO**. We also rely on CMOs for the local production in mainland China of certain drug substances and products, including NUZYRA. Such reliance on third- party manufacturers entails risks to which we would not be subject to if we manufactured **products or** product candidates **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 products or product candidates in accordance with our specifications), and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the NMPA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP standards. Any failure by our third- party manufacturers to comply with cGMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. Any significant disruption in our supplier relationships could harm our business. We currently source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers, as well as through our licensors. Any significant disruption in our potential supplier relationships, whether due to price increases, manufacturing, or supply- related issues, could harm our business. We anticipate that, in the near term, our key materials will be sourced through third parties. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture some of our products and product candidates. Such suppliers may not sell these key materials to us or our manufacturers at the times we need them or on commercially reasonable terms. We currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product or product candidate or its key materials could considerably delay completion of our clinical studies, product or drug testing, and potential regulatory approval of our products or product candidates. If we or our manufacturers are unable to purchase key materials after regulatory approval has been obtained, the commercialization or the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of such products. Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost, in quantities, or in a timely manner necessary to make our products commercially successful. In addition, as our product pipeline develops, we may have a greater need for clinical study and commercial manufacturing capacity or third- party supply of our products and product candidates. We may not be able to increase our scale of production or supply on commercially reasonable terms, in a timely manner, or at all. - 58-56- We rely on third parties to conduct our pre- clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or product candidates and our business could be substantially harmed. Our internal capacity to perform pre- clinical and clinical trials is limited. As a result, we have relied upon and plan to continue to rely upon third- party CROs to monitor and manage data for some of our ongoing pre- clinical and clinical programs. We rely on these third parties for execution of our pre- clinical and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocols and legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our pre- clinical studies in accordance with Good Laboratory Practices (“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 other applicable regulatory authorities for all of our products or product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data

generated in our clinical trials may be deemed unreliable, and the NMPA and other applicable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products or drugs produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our on-going clinical, nonclinical, and pre-clinical programs. Our CROs may not perform contracted services to our standards, may not produce results in a timely manner, or may fail to perform at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products or product candidates. As a result, our results of operations, and the commercial prospects for our products and product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed or compromised. If we lose our relationships with CROs, our product or drug development efforts could be delayed. We rely on third-party vendors, including CROs, for some of our pre-clinical studies and clinical trials related to our product 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 they can reasonably demonstrate that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs in a timely manner, on commercially reasonable terms, or at all. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Any such developments could cause our drug product development efforts to be delayed, which could adversely affect our business and operations. We depend on other parties to manage certain intellectual property rights that are material to our business. Any failure to effectively protect these rights could adversely affect our business and operations. We depend on other parties to manage certain of our intellectual property rights that are material to our business. In accordance with certain of our licensing agreements, we rely on other parties to manage responsibility for protection of certain intellectual property rights that we hold rights to for our products and product candidates. If such parties fail to procure or maintain intellectual property rights, the rights we hold may be reduced or eliminated, which could materially harm our business, financial conditions, results of operations, and prospects. - 59-57 - Pursuant to the terms of certain of our licensing agreements, we may rely on others to procure, maintain, enforce, or defend certain patent rights we hold that are material to our business. Additionally, even if we are contractually permitted to pursue the enforcement or defense of a patent we hold rights to under an agreement, we require the cooperation of any applicable patent owners to enforce such patent, and such cooperation may not be provided to us. Furthermore, even if we are able to participate in any such legal actions, an adverse outcome could materially harm our business, financial conditions, results of operations, and prospects. We rely on third-party distributors to sell our commercial products, and a limited number of customers have generated a substantial portion of our revenue. If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected. We rely on third-party distributors to sell our commercial products, which is consistent with the general practices of the pharmaceutical industry. A substantial amount of our revenue is derived from sales to a limited number of customers, which are distributors. For 2024 and 2023 and 2022, our five largest customers accounted for approximately 32.4% and 35.0% and 37.7% of our product revenue, respectively. Product revenue generated from our largest customer for the same periods accounted for approximately 19.16%, 9% and 22.19%, 4.9% of our product revenue, respectively. We have relatively limited control over our distributors, and they may fail to distribute our products in a timely manner or in the manner we contemplate. Further, while we believe alternative distributors are readily available, if any of our major customers significantly reduces its purchase volume or ceases to purchase from us, and we are not able to identify new customers in a timely manner, our business, financial condition, and results of operation may be materially and adversely affected. In addition, our major customers may seek to negotiate more favorable terms for them in the future. Under such circumstances, we may have to agree to less favorable terms in order to maintain the ongoing cooperative relationships with our major customers. If we are unable to reduce our production costs accordingly, our profitability, results of operations, and financial condition may be materially and adversely affected. The illegal distribution and sale by third parties of counterfeit versions of our products or stolen products could have a negative impact on our reputation and business. Third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit products sold under our or our collaborators' brand name (s). In addition, thefts of inventory at warehouses, plants, or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation, and our business. Our business, results of operations, and financial condition may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and our deposits and impairment in the carrying value of our short-term investments could may be negatively affect affected our consolidated results of operations by fluctuations in interest rates. We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure, or other reasons. As our business evolves, the amount and duration of our credit exposure may increase, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee. The carrying amounts of cash and cash

equivalents, restricted cash, and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, **2024 and 2023 and 2022**, we had cash and cash equivalents of \$ **449.7 million and \$ 790.2 million**, **restricted cash of \$ 101.1 million** and \$ 1,008.5 million, **restricted cash of \$ 1.1 million and \$ 0.8 million**, and short-term investments of \$ **330.0 million and \$ 16.3 million and nil**, respectively, most of which are deposited in financial institutions outside of mainland China. Although our cash and cash equivalents in mainland China, Hong Kong, Australia, **Taiwan**, and the United States are deposited with various major reputable financial institutions, deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our ~~60~~ deposits back in full. **As of December 31, 2023 and 2022, We are also exposed to risks related to changes in interest rates on our cash and 58-cash equivalents, restricted cash, and short-term investments consisted of time deposits with original maturities between three months, as a decrease in interest rate may impact our investment income and one-year-related cash flows.** Although we believe that U. S. Treasury securities are of high credit quality, concerns about, or a default by, one or more institutions in the market could lead to significant liquidity problems, losses, or defaults by other institutions, which in turn could adversely affect us. Risks Related to Intellectual Property If we are unable to obtain and maintain protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us. Our success depends, in part, on our ability to protect our products, product candidates, and technologies from competition by obtaining, maintaining, and enforcing our intellectual property rights. We seek to protect our products and product candidates as well as technologies that we consider commercially important through intellectual property rights, such as patents and trade secrets. We do not own or hold an exclusive license to patent rights in all of the territories in which we plan to commercialize certain of our products and product candidates. Further, we cannot predict whether patent applications that we hold rights to or any of our other owned or in-licensed pending patent applications will result in the issuance of patents that effectively protect our products, product candidates, and technologies, **or whether our issued patents will effectively exclude competitors.** It is also possible that we do not identify and / or secure patent rights to certain patentable aspects of our products, product candidates, or technologies. If we do not secure patent rights with respect to our products, product candidates, and technologies, our business, financial condition, results of operations, and prospects could be materially harmed. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, license, or defend all necessary or desirable patent rights at a reasonable cost or in a timely manner, and patents may be invalidated, in whole or in part, and thereby rendered unenforceable. In addition, our licenses may not provide us with exclusive rights to products and product candidates in all relevant fields of use and in all territories in a manner which we may wish to develop or commercialize products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. **The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future have issued or do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit the scope and / or duration of patent protection for our product (s) or product candidate (s). Consequently, we may not be able to exclude others from using certain technology without compensating us or possibly may be unable to exclude a competitor from commercializing a competitive product which may materially adversely impact our sales and may also cause us to reduce, more than we otherwise might, the price at which we sell our products. For example, granted claims in two Chinese patents that pertain to certain aspects related to OPTUNE have been the subject of a successful invalidation proceeding, which is currently being appealed. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology, products or product candidates will be protectable or remain protected by valid and 59-enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.** Furthermore, the term of a patent is finite and generally expires 20 years from its earliest non-provisional filing date provided that associated fees are timely paid. Given the amount of time required for the development, testing, and regulatory review of products and new product candidates, patents protecting such products and product candidates might expire before or shortly after such products or product candidates are commercialized. **For example, certain of our in-licensed patents related to OPTUNE will be expiring over the next two years.** As a result, the patent rights we hold may be insufficient to protect our products and product candidates from competitors' products, including those that are generic. Moreover, in the case of any patent rights that are jointly owned by us and another party, if we are unable to obtain an exclusive license or otherwise limit the other party' s right to license such patent rights to a third party, such patent rights may be licensed to third parties, including our competitors. In addition, we may need the cooperation of any joint owner of such jointly-owned patent to enforce it against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court or before the U. S. Patent and Trademark Office or other foreign authority. We or our licensors or collaboration partners may become involved in patent

litigation against third parties, for example, to enforce our patent rights, to invalidate patents held by such third parties, or to defend against such claims. Further, third parties could claim that we infringed, misappropriated, or otherwise violated their intellectual property rights or that a patent we or our licensors or collaboration partners have asserted against them is invalid or unenforceable. In ~~-61-~~ patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are common, and there are numerous grounds upon which a party can assert invalidity or unenforceability of a patent. In addition to court proceedings, in certain jurisdictions, parties may initiate legal proceedings before administrative bodies to assert challenges to intellectual property rights, including patent rights. Such proceedings could result in revocation, cancellation, or amendment to the scope of our patent rights and could negatively affect our business. The outcome of any such proceeding is generally unpredictable. Furthermore, even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time. ~~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 may lack sufficient patent coverage of our products or product candidates to prevent others from marketing competing products. Any of these outcomes could have a material adverse effect on our business, financial condition, results of operations, and prospects. **For example, granted claims in two Chinese patents that pertain to certain aspects related to OPTUNE have been the subject of a successful invalidation proceeding, which is currently being appealed.** We may not be able to protect our intellectual property. The extent to which intellectual property rights provide adequate protection as available under the relevant intellectual property laws is uncertain, particularly in light of possible challenges to any patents in a given jurisdiction. Any such challenge to our patent rights could have a material adverse effect on our business, results of operations, and prospects. Notably, the experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant financial expenditure and could divert management's attention from other aspects of our business and operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, financial condition, results of operations, prospects, and reputation. ~~-60-~~ Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including mainland China. The legal systems, particularly in certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to enforce our intellectual property and proprietary rights generally. Proceedings to enforce such intellectual property and proprietary rights could result in substantial costs, divert our efforts and attention from other aspects of our business, put our patents at risk of being invalidated or interpreted narrowly, and provoke third parties to assert counterclaims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we hold rights to. Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Developments or uncertainties in patent law could have a negative impact on our business. Changes in either the patent laws or interpretation of the patent laws could diminish the value of patents, thereby impairing our ability to protect our products, product candidates, and technologies. Changes in patent laws and regulations in various ~~countries or~~ jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces them may weaken our ability to obtain new patents or patent rights through our licensors or to enforce any patents in the future. We cannot predict future changes in the interpretation of patent laws or changes to ~~-62-~~ patent laws that might be enacted into law by any legislative body. Such changes could materially affect our patent rights and could have a material adverse effect on our business, results of operations, and prospects. If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed. We rely upon proprietary ~~confidential~~ confidential information, including trade secrets and know-how to maintain our competitive position. However, such ~~confidential~~ confidential information can be difficult to protect. We seek to protect our proprietary confidential information, in part, by entering into confidentiality agreements with parties that have access to such information, including our partners, collaborators, scientific advisors, employees, consultants, and other third parties. We may not be able to enter into such agreements with each party that may have or have had access to our trade secrets or ~~other~~ proprietary technologies information. Further, we may not be able to prevent the unauthorized disclosure or use of our trade secrets or ~~other~~ proprietary information (such as know-how) by the parties to these agreements, despite their existence and any other contractual restrictions. If any of these parties breaches or violates the terms of such agreement or otherwise discloses our proprietary confidential information, we may not have adequate remedies for such breach or violation and could lose any competitive advantage such confidential information afforded us. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets is difficult, expensive, and time-consuming, with the outcome being unpredictable. Our trade secrets could become known or even be independently discovered by other parties, including our competitors. If any of our trade secrets were to be disclosed or independently developed, we would have no right to prevent others from using that information to compete against us, which may have a material adverse effect on our business, financial condition, results of operations, and prospects. If our products or product candidates infringe, misappropriate, or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell or commercialize these products and product candidates. Our success depends significantly on our ability

to develop, manufacture, market, and sell our commercial products and use our proprietary technologies without infringing, misappropriating, or otherwise violating the patents and other **-61-** proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, litigation or other proceedings regarding intellectual property rights with respect to our products, product candidates, or technologies that could negatively affect our business. Third parties may assert claims of patent infringement against us, regardless of merit, based on their existing patents or based on later issued patents. Even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of patent infringement or counterclaims pertaining to the underlying patent (s) asserted against us. A court of competent jurisdiction could hold that a third- party patent is valid, enforceable, and infringed by us, which could have a material adverse effect on our business. If we are found to have infringed a third party' s patent rights, and we are unsuccessful in demonstrating that such patent (s) are invalid or unenforceable, we could be required to: • obtain royalty- bearing licenses from such third party to the relevant patent (s), which may not be available on commercially reasonable terms, require substantial licensing and royalty payments, or may not be available at all, and even if we were able to obtain such licenses, they could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; • defend against additional litigation or administrative proceedings in the same and / or other jurisdiction (s); • reformulate affected product (s) so that they do not infringe the intellectual property rights of others, which may not be possible or could be expensive and time consuming; ~~-63-~~ • cease developing, manufacturing, and commercializing any infringing products, product candidates, or technologies; and • pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed their patent. Similarly, claims by third parties that we have misappropriated their confidential information, such as trade secrets, could have a material adverse effect on our business. Even if we are ultimately successful in defending against such claims via litigation (s) or administrative proceeding (s), any such litigation or proceeding may be costly and could result in a substantial diversion of management resources. Consequently, any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, and prospects. Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other such legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Additionally, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can, for example, because of greater financial or other resources. Moreover, uncertainties resulting from the initiation and continuation of such litigation or other proceedings could have a material adverse effect on our business. We may be subject to claims that we or our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or are in breach of confidentiality, non- disclosure, non- use, non- competition, or non- solicitation agreements with such current or former employers, some of whom may be our competitors or potential competitors. **-62-** We could in the future be subject to claims that we or our employees, consultants, or advisors have inadvertently or otherwise improperly used or disclosed alleged trade secrets or other proprietary information of current or former employers of our employees, consultants, or advisors. For example, many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to prevent our employees, consultants, and advisors from improperly using the intellectual property ~~, or other~~ proprietary information, ~~know- how, or trade secrets~~ of their current or former employers in their work for us, these efforts may not be successful. Litigation may be necessary to defend against such claims, and even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using certain technologies or features that are essential to our products and product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another party. An inability to incorporate such technologies or features could have a material adverse effect on our business and may prevent us from successfully commercializing our affected products and product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat of such litigation may adversely affect our ability to hire employees or contract with necessary personnel. A loss of key personnel or their work product could hamper or prevent our ability to develop or commercialize our products and product candidates, which would have a material adverse effect on our business, ~~results of operations,~~ financial condition, **results of operations**, and prospects. In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in enforcing such agreements. The assignment of intellectual property rights may not be self- executing, or the assignment ~~-64-~~ agreements may be breached, and we may be forced to bring claims against our employees, contractors, or other third parties, or defend claims that they may bring against us, to determine the ownership of certain intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may not be successful in obtaining intellectual property rights for acquired or in- licensed product candidates. Our business model depends, in part, on our ability to successfully identify and acquire or in- license product candidates to enhance and strengthen our product pipeline. For such acquired or in- licensed product candidates, we may be unable to secure intellectual property rights relating to, or necessary for, commercialization of any such product candidates from third parties on commercially reasonable terms or at all. In such

event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify product candidates that we believe are an appropriate strategic fit for the Company and / or obtain intellectual property protection relating to such product candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations, and prospects. The in-licensing and acquisition of intellectual property rights for product candidates is a competitive area, and a number of other companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for product candidates that we may consider attractive or necessary. These other companies may have a competitive advantage over us, for example due to their size, cash resources, and clinical development and commercialization capabilities. Furthermore, certain companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations, and prospects could suffer. If we or our licensors or collaboration partners do not obtain patent term extension and data exclusivity for our products or their products or any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration, and specifics of any regulatory marketing approval of our products or any product candidates we may develop, one or more of our owned or in-licensed patents may be eligible for limited patent term extension in a particular jurisdiction. For example, in the United States, a single patent (provided it claims the approved drug or method for using it, or a method for manufacturing the drug) may be eligible for patent term extension of up to five years, although it cannot extend the remaining term of a patent beyond a total of 14 years from the date of ~~- 63-~~ product approval. However, ~~we may~~ **patent term extension might** not be granted ~~any patent term extension~~ due to failure to meet applicable requirements ~~;~~ (for example, **due to failure to meet applicable deadlines or prior to expiration of the relevant patent) or might be less than requested (for example, due to** failure to exercise due diligence during the testing phase or regulatory review process ~~) or failure to apply for patent term extension within the applicable deadlines or prior to expiration of the relevant patents. Moreover, any patent term extension approved could be less than the period we requested.~~ The China Patent Law provides for patent term extension ~~and~~, **patent term adjustments – adjustment, for patents** and a patent linkage system. However, ~~to be implemented, the patent term extensions and adjustments require further promulgation of regulations and detailed implementation measures. Additionally, in mainland China, there –~~ **the** is currently no effective law or regulation providing for **lack of operational guidelines has hindered enforcement of the 6- year period of** data exclusivity **protection for eligible drugs containing** ~~– although Chinese regulators have proposed a framework for integrating new~~ **chemical entity in China. Likewise, expansion of the 6- year period of** data exclusivity **into has been proposed for biologics but has not yet been implemented in practice due to** the Chinese regulatory regime **absence of detailed guidelines and rules** . 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, a lower- cost generic or biosimilar drug can emerge onto the market more quickly. Consequently, the absence of currently implemented laws and regulations on ~~patent term extension and adjustment and~~ data exclusivity or the cancellation of the previous five- year administrative exclusivity for domestically manufactured new drugs could result in much weaker protection for us against generic competition in mainland China. **If** For instance, if we are unable to obtain patent term extension or **patent term** adjustment **for any eligible patent** or the term of any such **patent term** extension or **patent term** adjustment is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. If we were to pursue patent linkage litigation, such litigation could take several months to conclude and require additional months thereafter for the decision to be made publicly available. We will monitor future administrative rulings / court decisions on patent linkage in mainland China. Any decision against our interests could adversely affect our business. ~~-65-~~ Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Over the lifetime of any patent rights we hold, certain government fees will be paid to a patent office in the respective jurisdiction for any patent application (s) and on any patent (s) resulting therefrom. In some of our licensed matters, we rely on our licensors to pay these fees. In addition to the payment of fees, during the patent application process, the patent office of any given jurisdiction requires compliance with procedural and documentary provisions. In some of our licensed matters, we rely on our licensors to comply with these requirements. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules of a jurisdiction. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction, which may have a material adverse effect on our business, financial condition, results of operations, and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our products or product candidates or utilize similar technology that are not covered by the claims of the patents that we hold rights to; • patent rights we currently hold or that we may hold in the future might be from inventors that are not the first to ~~make the inventions covered by such patent rights;~~ • ~~patent rights we currently hold or that we may hold in the future might be from inventors that are not the first to~~ file patent applications covering such inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights; • patent rights we currently hold to any patent applications that are pending or such patent applications that we may hold patent rights to in the future may not result in issued patents; • issued patents that we hold rights to may be held invalid or unenforceable; ~~- 64-~~ • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may impede our ability to exploit

our innovations and may harm our business; and • we may choose to maintain certain trade secrets or know-how, and a third party may discover such trade secrets or know-how through independent research and development, which may harm our business. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

~~66~~ **Risks Related to Our ADSs and Ordinary Shares** If we fail to maintain proper internal control over financial reporting, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and / or delays in our financial reporting, which could require us to restate our operating results. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete, and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control. If we fail to maintain effective internal control over financial reporting in the future, our management and our independent registered public accounting firm may not be able to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of our securities could decline, and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, our ADSs may not be able to remain listed on Nasdaq. We have incurred losses and have not paid dividends on our securities since our inception, and we do not currently intend to pay dividends on our securities. The success of an investment in our securities will depend on appreciation in the price of our securities. We have incurred losses since inception and have never declared or paid any dividends on our securities. We currently intend to invest our future earnings, if any, to fund our business. Therefore, investors are not likely to receive any dividends on their securities, at least in the near term, and the success of an investment in our securities will depend upon any future appreciation in their value compared to their purchase price. There is no guarantee that our securities will appreciate in value or even maintain the price at which they were purchased. Further, investors may need to sell all or part of their holdings of our securities to realize any future gains on their investment. The market price of our securities may be volatile, which could result in substantial losses for our investors. The market price of our securities has been volatile, and will likely continue to be volatile and subject to wide fluctuations in response to a variety of factors, including the following: • announcements of competitive developments; ~~65~~ • regulatory developments affecting us, our licensors and partners, our customers, or our competitors; • announcements regarding litigation or administrative proceedings involving us or our licensors and partners; • actual or anticipated fluctuations in our period-to-period operating results; • changes in financial estimates by securities research analysts; • additions or departures of our executive officers; • fluctuations of exchange rates between the RMB and the U. S. dollar; • release or expiration of lock-up or other transfer restrictions on our outstanding securities; and ~~67~~ • sales or perceived sales of additional securities. In addition, the securities markets have experienced, and may in the future experience, significant price and volume fluctuations that are not related to the operating performance of particular companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. For example, in the last few years, **tensions between the United States and China**, the COVID-19 pandemic, ~~tensions between the United States and China~~, and other geopolitical factors have negatively affected stock market and investor sentiment and resulted in significant volatility, including temporary trading halts. Prolonged global capital markets volatility may affect overall investor sentiment towards our securities, which would also negatively affect the trading prices for our securities. Fluctuations in the value of the RMB or Hong Kong dollars may have a material adverse effect on our results of operations and the value of our securities. The value of the RMB or HK dollar against the U. S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. With the development of the foreign exchange market and progress towards interest rate liberalization and RMB internationalization, the Chinese government has announced, and may again in the future announce, changes to the exchange rate system. There is no guarantee that the RMB will not appreciate or depreciate significantly in value against the U. S. dollar. It is difficult to predict how market forces or Chinese or U. S. government policy may impact the exchange rate between the RMB and the U. S. dollar in the future. The value of our securities may, therefore, be affected by foreign exchange rates between U. S. dollars, HK dollars, and the RMB. For example, to the extent that we need to convert U. S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U. S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U. S. dollar or the HK dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U. S. dollars or HK dollars for the purpose of making payments for business purposes, appreciation of the U. S. dollar or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us. Since 1983, the **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 our

business. For example, to the extent that we need to convert U. S. dollars into RMB or HK dollars for our operations, appreciation of the RMB or HK dollar against the U. S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB or HK dollars into U. S. dollars for the purpose of making payments for business purposes, appreciation of the U. S. dollar against the RMB would have a negative effect on the U. S. dollar amount ~~66~~ 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.

~~68~~ Holders of our ADSs have fewer rights than shareholders and must act through the depositary to exercise their rights. Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our amended and restated articles of association, an annual general meeting and any extraordinary general meeting may be called with not less than fourteen days' notice. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date, and the depositary will send a notice to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to instruct the depositary to vote the ordinary shares underlying your ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a holder or beneficial owner of ADSs, you may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if you wish us or the depositary to participate in legal proceedings. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. Under the deposit agreement, for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying your ADS at shareholders' meeting if you do not give instructions to the depositary, unless (i) we have failed to timely provide the depositary with our notice of meeting and related voting materials, (ii) we have instructed the depositary that we do not wish a discretionary proxy to be given, (iii) we have informed the depositary that there is a substantial opposition as to a matter to be voted on at the meeting, or (iv) a matter to be voted on at the meeting would have a material adverse impact on shareholders. The effect of this discretionary proxy is that, if you fail to give voting instructions to the depositary, you cannot prevent the ordinary shares underlying your ADSs from being voted, except under the circumstances described above. This may adversely affect your interests and make it more difficult for ADS holders to influence the management of the Company. Holders of our ordinary shares are not subject to this discretionary proxy. Holders of our ADSs may not receive distributions or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distributions. Although we do not have any present plan to pay any dividends, if we achieve profitability and were to decide to pay dividends in the future, the depositary of our ADSs has agreed to pay our ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. Our ADS holders will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act of 1933, as amended (the "Securities Act") but are not so properly registered or distributed under an applicable exemption ~~67~~ 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. ~~69~~ Rights of our shareholders in the United States to participate in any future rights offerings may be limited, which may cause dilution to their holdings. We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to our shareholders in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to our U. S. shareholders unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, our U. S. shareholders may be unable to participate in our rights offerings and may experience dilution in their holdings. Taxing authorities could reallocate our

taxable income among our subsidiaries, which could increase our overall tax liability. We are organized under the laws of the Cayman Islands and currently have subsidiaries in mainland China, Hong Kong, Taiwan, the Cayman Islands, the United States, Australia, and the British Virgin Islands. If we further grow our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us, our parent company, and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows. A tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest, and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable. There is no assurance that we will not be a passive foreign investment company, or PFIC for U. S. federal income tax purposes for any taxable year, which could subject U. S. investors in our securities to significant adverse U. S. federal income tax consequences. ~~68-~~ In general, a non- U. S. corporation will be a PFIC for any taxable year in which (i) 75 % or more of its gross income consists of passive income, or (ii) 50 % or more of the value of its assets (generally determined on a quarterly average basis) consists of assets that produce, or are held for the production of, passive income (the "asset test"). For purposes of the above calculations, a non- U. S. corporation that directly or indirectly owns at least 25 % by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes interest, dividends, and gains from certain property transactions, rents, and royalties (other than certain rents or royalties derived in the active conduct of a trade or business). For these purposes, cash is generally a passive asset and the value of a non- U. S. corporation's ~~70-~~ goodwill (which may be determined by reference to the excess of the sum of its market capitalization and liabilities over its booked assets) generally should be an active asset to the extent attributable to business activities that produce non- passive income. Based on the current market price of our ADSs and our current and expected composition of income and assets, we do not expect the Company and its subsidiaries to be PFICs for our current taxable year. However, our assets other than goodwill are expected to consist primarily of cash and cash equivalents for the foreseeable future. Therefore, whether we will satisfy the asset test for the current or any future taxable year will depend largely on the quarterly value of our goodwill (which may be determined by reference to the market price of our ADSs, which could be volatile given the nature and early stage of our business). If our market capitalization declines while we continue to hold a significant amount of cash, the risk that we will be a PFIC will increase. Furthermore, we may be a PFIC for any taxable year in which our interest and other investment income constitutes 75 % or more of the sum of (i) such interest and investment income, and (ii) the excess of our revenue over cost of goods sold. In addition, a company's PFIC status is an annual determination that can be made only after the end of each taxable year. Therefore, we cannot give any assurance as to whether we are a PFIC for the current or any future taxable year. Subject to the discussion below, if we are or become a PFIC, U. S. investors generally would be subject to adverse U. S. federal income tax consequences, such as increased tax liabilities on capital gains and certain distributions, and interest charges on taxes deemed to be deferred. If we are a PFIC for any taxable year during which a U. S. investor owns our securities, we will generally continue to be treated as a PFIC with respect to such investor for all succeeding years during which the investor owns our securities (unless the investor timely makes a valid "deemed sale" election), even if we cease to meet the threshold requirements for PFIC status. A mark- to- market election may be available with respect our securities, which would result in U. S. federal income tax consequences to holders of our securities that are different from those described above. If a U. S. investor owns our securities during any year in which we are a PFIC, such investor generally will be required to file annual reports on IRS Form 8621 (or any successor form) with respect to us, generally with their U. S. federal income tax return for that year. U. S. investors should consult their tax advisors regarding the determination of whether we are a PFIC for any taxable year and the potential application of the PFIC rules. If a U. S. investor is treated as owning at least 10 % of our ordinary shares, such holder may be subject to adverse U. S. federal income tax consequences. If a U. S. investor is treated as owning (directly, indirectly, or constructively) at least 10 % of either the total value or total combined voting power of our ADSs or our ordinary shares, such U. S. investor may be treated as a "United States U. S. shareholder" with respect to each controlled foreign corporation, or CFC, in the Company (if any). Because the Company includes at least one U. S. subsidiary (Zai Lab (US) LLC), certain of our non- U. S. subsidiaries will be treated as CFCs (regardless of whether Zai Lab Limited is treated as a CFC). A United States U. S. shareholder of a CFC may be required to annually report and include in its U. S. taxable income its pro rata share of "Subpart F income," "global intangible low- taxed income" and investments in U. S. property by CFCs, regardless of whether we make any distributions. An individual that is a United States U. S. shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States U. S. shareholder that is a U. S. corporation. We may not assist investors in determining whether any of our non- U. S. subsidiaries are treated as a CFC or whether such investor is treated as a United States U. S. shareholder with respect to any of such CFCs.

Further, we may not furnish to any investors information that may be necessary to comply with the reporting and tax ~~- 69-~~ paying obligations discussed above. Failure to comply with these reporting obligations may subject a U. S. investor to significant monetary penalties and may prevent the statute of limitations with respect to their U. S. federal income tax return for the year for which reporting was due from starting. U. S. investors should consult their tax advisors regarding the potential application of these rules to their investment in our securities. Changes in tax law may adversely affect our business and financial results. Under current law, we expect to be treated as a non- U. S. corporation for U. S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position ~~- 71-~~ 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. ~~Generally Accepted Accounting Principles~~ (“U. S. GAAP”). Our corporate actions are substantially controlled by our directors, executive officers, and other principal shareholders, who can exert significant influence over important corporate matters, which may reduce the price of our securities. Our directors, executive officers, and other principal shareholders could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions, or other business combination transactions. This may discourage, delay, or prevent a change in control of the Company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of the Company and reduce the price of our securities. Such actions may be taken even if they are opposed by certain of our other shareholders. In addition, our directors, executive officers, and other principal shareholders could divert business opportunities away from us to themselves or others. You may have difficulty enforcing judgments obtained..... a court in the United States. Investors may be subject to limitations on transfers of their ADSs. ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer, or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason. ~~-72-~~ Substantial future sales or perceived potential sales of our ordinary shares, ADSs, or other equity or equity- linked securities could cause the price of our securities to decline. Sales of our ordinary shares, ADSs, or other equity or equity- linked securities, or the perception that these sales could occur, could cause the market price of our securities to decline significantly. All of our ordinary shares represented by ADSs were freely transferable by persons other than our affiliates without restriction or additional registration under the U. S. Securities Act. The shares held by our affiliates are also available for sale, subject to volume and other restrictions as applicable under Rule 144 of the U. S. Securities Act, under trading plans adopted pursuant to Rule 10b5- 1 or otherwise. Divestiture in the future of our securities by shareholders, the announcement of any plan to divest our securities, or hedging activity by third- party financial institutions in connection with similar derivative or other financing arrangements entered into by shareholders could cause the price of our securities to decline. Furthermore, any major disposal of our securities by any of our directors or executive officers (or the perception that such disposals may occur) may cause the prevailing market price of our securities to fall, which could negatively impact our ability to raise capital in the future. ~~- 70-~~ The different characteristics of the capital markets in Hong Kong and the United States may negatively affect the trading prices of our securities. We are dual primary listed on Nasdaq and the Hong Kong Stock Exchange. Nasdaq and the Hong Kong Stock Exchange have different listing rules and requirements, trading hours, trading characteristics (including trading volume and liquidity), trading rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares on the Hong Kong Stock Exchange and our ADSs on Nasdaq may not be the same, even after allowing for currency differences. Fluctuations in the price of our securities due to circumstances unique to the one market could materially and adversely affect the price of our securities on the other market. The depository for our ADSs is entitled to charge holders fees for various services, including annual service fees. Dealings in the ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty. The depository for our ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. In the case of ADSs issued by the depository into The Depository Trust Company, or DTC, the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time. Additionally, dealings in the ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty. Exchange between our ordinary shares and our ADSs may adversely affect the liquidity and / or trading price of our securities. Subject to compliance with U. S. securities law and the terms of the deposit agreement, holders of our ordinary shares may deposit such ordinary shares with the depository in exchange for the issuance of our ADSs. Any holder of ADSs may also withdraw the underlying ordinary shares represented by the ADSs pursuant to the terms of the deposit agreement for trading on the Hong Kong Stock Exchange. If a substantial number of our ordinary shares are deposited with the depository in exchange for ADSs or vice versa, the liquidity and trading price of our ordinary shares on the Hong Kong Stock Exchange and our ADSs on Nasdaq may be adversely affected. ~~-73-~~ The time required for the exchange between our ordinary shares and ADSs might be longer than expected and investors might not be able to settle or effect any sale of their securities during this period, and the exchange of ordinary shares into ADSs involves costs. There is no direct trading or settlement between Nasdaq and the Hong Kong Stock

Exchange on which our ADSs and ordinary shares are respectively traded. In addition, the time differences between Hong Kong and New York and unforeseen market circumstances or other factors may delay the deposit of ordinary shares in exchange of ADSs or the withdrawal of ordinary shares underlying the ADSs. Investors will be prevented from settling or effectuating the sale of their securities during such periods of delay. In addition, there is no assurance that any exchange of ADSs into ordinary shares (and vice versa) will be completed in accordance with the timelines investors may anticipate. Furthermore, the depository for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. As a result, shareholders who exchange ADSs into ordinary shares, and vice versa, may not achieve the level of economic return they may anticipate. There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of our ADSs. We have established a branch register of members in Hong Kong (the “ Hong Kong share register ”) for our ordinary shares that are traded on the Hong Kong Stock Exchange, and the trading of these ordinary shares on the Hong Kong Stock ~~-71-~~ Exchange will be subject to the Hong Kong stamp duty. In addition, to facilitate ADS- ordinary share conversion and trading between Nasdaq and the Hong Kong Stock Exchange, we have moved a portion of our issued ordinary shares from our register of members maintained in the Cayman Islands to our Hong Kong share register. Under the Hong Kong Stamp Duty Ordinance, any person who effects any sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2 % of the greater of the consideration for, or the value of, shares transferred, with 0.1 % payable by each of the buyer and the seller. To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual- listed companies constitutes a sale or purchase of the underlying Hong Kong- registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of our ADSs, the trading price and the value of any investment in our securities may be affected.

General Risk Factors We are subject to the risks of doing business globally, such as from economic or political tensions between the United States and China and other business disruptions or other adverse effects caused by economic downturns, market conditions, changing legal and regulatory requirements, political instability, trade sanctions, public health crises, international war or conflict, natural disasters, extreme weather events, and other geopolitical events or significant disruptions outside of our control. Because we operate in Greater China, the United States, and other countries, our business is subject to risks associated with doing business globally. For example, our business and financial results could be adversely affected by changes in global, economic, and industry conditions, including currency fluctuations, changes in interest rates, capital and exchange controls, inflation, recession, market volatility, and restrictive government actions such as changes in laws and regulatory requirements, intellectual property, legal protections and remedies, trade regulations, tax laws and regulations, and procedures and actions affecting approval, production, pricing, marketing, reimbursement, and access for our products or product candidates. ~~-74-~~ In addition, we, as well as our customers, vendors, partners, and patients, may be impacted by geopolitical events, including economic or political tensions between the United States and China; international war or conflicts, ~~such as the war in Ukraine and the conflict between Israel and Hamas~~; and other instances of political or civil unrest, such as major hostilities or acts of terrorism. For example, as a result of economic or political conditions or tensions between the United States and China, the United States and other nations have raised the possibility of **tariffs and** trade or other sanctions on China, Chinese banks, and companies with operations in China as well as legislation that restricts or prohibits U. S. investment in certain companies operating in China. Such actual or threatened sanctions on us or third parties with which we do business, such as customers, suppliers, intermediaries, services providers, or banks, and other geopolitical factors could adversely affect our business and financial results, including our ability to raise capital or raise capital on favorable terms and the market price of our securities. We, as well as our customers, vendors, partners, and patients, may also be impacted by public health crises, such as the COVID-19 pandemic, as well as earthquakes, hurricanes, floods, drought, wildfires, and other extreme weather or catastrophic events. The occurrence of one or more of the events described above could disrupt our studies, supply chain, manufacturing facilities, distribution network, and sales and marketing efforts or result in increased costs or decreased demand for our products. Such developments could have a material adverse effect on our business, including our clinical development, ~~results of operations,~~ financial condition, **results of operations**, ability to raise capital or raise capital on favorable terms, and the market price of our securities. If we or our CROs or CMOs fail to comply with applicable environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. ~~-72-~~ We, our CROs, CMOs, or other contractors are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health, and safety have been completed. Our development operations primarily occur in mainland China and the United States and involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We are therefore subject to Chinese and U. S. laws and regulations concerning the discharge of wastewater, gaseous waste, and solid waste during our research and development of our products and product candidates. We generally contract with third parties for the disposal of these materials and wastes. If we fail to comply with environmental regulations and contamination or injury from these materials results from our use of hazardous materials, we could be held liable for any resulting damages, and any such liability could exceed our resources or insurance coverage (such as workers’ compensation insurance for injuries to our employees). We also

could incur significant costs associated with civil, administrative, or criminal fines and penalties. Furthermore, the Chinese or U. S. government may adopt more stringent environmental regulations. If this occurs, we may incur substantial capital expenditures to install, replace, upgrade, or supplement our facilities and equipment or make operational changes to comply with such environmental protection laws and regulations. If such costs were to become prohibitively expensive, we may be forced to cease certain aspects of our business or operations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use, or disposal of biological or hazardous materials. In addition, we may be required to incur substantial costs to comply with current or future health and safety laws and regulations, which could impair our research, development, or production efforts. Failure to comply with such laws and regulations may result in substantial fines, penalties, or other sanctions. Because of volatility in the price of our securities and the share price of biotechnology and biopharmaceuticals companies more broadly, we may be at increased risk of securities class action litigation. In recent years, our company as well as other companies in our industry have experienced significant share price volatility. As a result, we may be at increased risk of securities class action litigation. Historically, securities class action litigation, whether warranted or not, often follows a decline in the market price of a company's securities. If we were to ~~-75-~~ become subject to class action litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. If analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price and / or trading value of our securities could decline. The market for our securities relies in part on research and reports that equity research analysts publish about us or our business. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, the market price for our securities would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our securities to decline significantly. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. **- 73-** There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Further, there is a risk that unmerited or unsupported claims about our products may circulate on social media. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions, or incur other harm to our business, including damage to the reputation of our products or Company.