

## RISK FACTORS

*An investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our Shares. In particular, we are a biotech company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment given the nature of biotech industry.*

*These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-looking Statements” in this document.*

### RISKS RELATING TO THE DEVELOPMENT OF OUR PIPELINE PRODUCTS

**A majority of our drug portfolio are currently in preclinical or clinical development, including our Core Products. If we are unable to successfully complete development, or experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed.**

Our business depends on the successful development of our drug and drug candidates for the treatment of viral infection, oncological and cardio-cerebrovascular diseases. We have invested a significant portion of our efforts and financial resources in the discovery and development of our drug and drug candidates, including our Core Products. The success of our drug and drug candidates in terms of preclinical or clinical development will depend on a number of factors, as applicable, including (1) successful completion of preclinical studies; (2) successful enrollment of patients in, and completion of, clinical trials; (3) favorable safety and efficacy data from our clinical trials or other studies; (4) receipt of regulatory approvals; (5) arrangements with third-party CMOs to ensure sufficient clinical supplies of our drug candidates; (6) our ability to design, manage and supervise multiple clinical trials across the site, regions or as part of MRCTs and various other jurisdictions; (7) reliance on CROs or other third parties across jurisdictions to conduct clinical trials safely and efficiently, and in a manner that complies with our protocols and applicable laws, and that protects the integrity of the resulting data; (8) the ability of our collaborators to carry out the development plans under our collaboration with them; (9) obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates; (10) ensuring we do not infringe, or otherwise violate the patent, trade secret or other intellectual property rights of third parties; and (11) alleviating effects of disruptions caused by man-made or natural disasters or public health pandemics or epidemics, or other business interruptions.

In addition, we must keep pace with new technologies and methodologies to maintain our competitive position. We may be unable to develop, enhance or adapt to new technologies or methodologies. Any failure to do so may make our techniques obsolete, which could harm our business and prospects. If we do not achieve one or more of the aforementioned factors in a timely manner, or at all, we could experience significant delays in completing or be unable to complete the preclinical or clinical development of and/or maintain or obtain approval for our drug candidates, which would materially harm our business, and we may fail to generate sufficient revenue or cash flows to continue our operations. In the past, the development of our Core Products and other drug candidates encountered certain delays, primarily due to inherent clinical trial uncertainties such as patient enrollment, protocol amendments and data review. See “Business—Research & Development.” We cannot assure you that our future R&D activities will not experience delays and, if any similar delays take place in the future, we cannot guarantee that our business operation and financial position will not be materially adversely impacted. The aforementioned factors present uncertainty and material risks to our commercial success and may cause potential investors to lose a substantial amount, or substantially all, of their investments in us.

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We have built a comprehensive drug portfolio, which includes three Core Products: (i) azvudine, a conditionally approved drug for the treatment of HIV infection and COVID-19 in China; (ii) CL-197, for the long-acting treatment of HIV infection; and (iii) dosimertinib, for the treatment of NSCLC. In 2024 and 2025, we recorded revenue from our Core Product, azvudine of RMB237.9 million and RMB24.8 million, respectively. In light of the limited or lack of historical revenue generated from our Core Products for the treatment of HIV, the intense competition in the HIV treatment market, the significant decline in COVID-19 prevalence and the corresponding treatment market, and the early stage of development of our oncology pipeline, we cannot assure you that any of our Core Products will achieve commercial success or generate substantial revenue in the future, and their business prospects may be adversely affected.

**Clinical drug development involves a lengthy and expensive process with an uncertain outcome and results of earlier studies and trials may not be predictive of future trial results.**

Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain and may not be favorable. Failure can occur at any time during the clinical trial process. The results of preclinical studies or early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show desired safety and efficacy traits despite early progress. In some instances, there can be significant variability in safety and/or efficacy results between different studies and trials of the same drug candidate due to factors such as changes in trial protocols, patient populations (including genetic differences), patient compliance and the dropout rate. Therefore, our future clinical trial results may not be favorable.

Even if our future clinical trial results show favorable efficacy and safety profile, not all patients may benefit. For certain drug candidates, and in certain indications, it is possible that many patients may not respond to the agents at all, some responders may relapse after a period of response and may develop or appear particularly resistant.

**If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in clinical trials, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.**

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy. We may experience unexpected events during, or as a result of, the various stages of our clinical trials that could delay or prevent regulatory approval or commercialization of our drug candidates, including (1) regulators, institutional review boards or ethics committees may not authorize the commencement or conduct a clinical trial; (2) inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; (3) clinical trials of our drug candidates may produce negative, inconclusive or insufficient results and additional clinical trials or abandoning or modifying our R&D programs (including targeted patient groups or indications) may be required; (4) requiring a larger-than-anticipated number of patients for clinical trials of our drug candidates or experiencing insufficient or slower enrollment or higher dropout rates; (5) failure by our third-party contractors, including CROs and clinical investigators, to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; (6) voluntary or involuntary suspension or termination of clinical trials, including lack of clinical response, or other unexpected characteristics, or a finding that participants are being exposed to unacceptable health risks; (7) higher-than-anticipated cost of clinical trials of our drug candidates; and (8) insufficient or inadequate supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates.

If additional clinical trials or testing are required, we fail to complete clinical trials or testing, or results are negative or raise safety concerns, we may (i) be delayed in obtaining regulatory approval; (ii) not obtain or maintain the regulatory approval; (iii) obtain approval for narrower indications; (iv) have the drug removed from the market; (v) be subject to additional post-marketing testing requirements; or (vi) be subject to restrictions on distribution or use of such drug. As such, our business may be materially harmed, and we may not be able to generate sufficient revenues and cash flows to continue our operations and may experience a decline in the market price of our Shares.

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**Our conditional approvals of azvudine from the NMPA may be revoked if we fail to complete the post-approval requirements.**

We have obtained conditional approvals of azvudine from the NMPA for treating HIV infection and COVID-19 in July 2021 and July 2022, respectively. While we are authorized to market azvudine for the treatment of HIV infection and COVID-19 in China, we are required to conduct post-approval trials, complete ongoing trials, collect efficacy and safety clinical data, and submit required materials within three years of approval. There can be no assurance that we can complete the post-approval clinical studies in a timely manner, or at all. If we fail to submit required safety or clinical reports within the required time limits, the conditional approvals of azvudine may be revoked, which could materially harm our business and future growth, and we may not be able to generate sufficient revenue and cash flows to continue our operations and may experience a decline in the market price of our Shares. We have completed all of the required R&D work and submitted an application for a conversion of the conditional approval of azvudine for the treatment of COVID-19 to a regular approval in July 2025, and we expect to obtain the regular approval in the first half of 2026. We completed the last visit of the last patient for the Phase III clinical trial of azvudine for the treatment of HIV infection and we expect to complete the clinical study report within 2025. See “Business—Our Product Portfolio—Azvudine—Our Core Product” in this document for details.

**Our current and future drug candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects, which could halt clinical development or result in potential liability.**

Our drug pipeline includes novel therapeutics for treating viral infections, oncological and cardio-cerebrovascular diseases. The results of our clinical trials could reveal a high and unacceptable severity and prevalence of undesirable side effects. The delivery methods or dosage levels of our drug candidates may cause undesirable side effects, which could halt clinical development or result in potential liability, adversely impact our ability to obtain regulatory approvals, and harm our ability to generate revenue. In addition, if our drug candidates cause injury or death or are found to be otherwise unsuitable during clinical trials, our reputation may be damaged and we may face substantial liabilities related to product or other liability claims.

**Interim, top-line and/or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.**

From time to time, we may publish or use interim, top-line and/or preliminary data from our clinical trials that may materially change as patient enrollment continues and more patient data become available. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data may significantly harm our business prospects and may cause the trading price of Shares to fluctuate significantly.

**If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.**

The timely completion of clinical trials depends, among other things, on our ability to enroll sufficient number of patients. We may face patient enrollment challenges due to factors such as patient population, eligibility criteria, patient consents and external disruptions. Competition from other trials may further reduce the number and types of patients available to us. Any delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, adversely affect the development of our drug candidates, and may also shorten our commercialization period or allow our competitors to bring drugs to market before we do, which may materially harm our business, financial condition, results of operations and prospects.

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**We may fail to identify, discover or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.**

Continuous building our pipeline to identify new drug candidates and disease targets and pursuing the development of our drug candidates for additional indications require substantial technical, financial and human resources without guaranteed ultimate success. Even if we are successful in continuing to build our pipeline and developing next-generation drug candidates or expanding into additional territories, the potential product candidates may not be suitable for clinical development and may not receive marketing approval, achieve market acceptance or be reimbursed from third-party payors for their purchase. We cannot provide you any assurance that we will be able to successfully advance any of our additional drug candidates through the development process.

Our R&D programs may fail to yield drug candidates or be forced to abandon our development efforts for a R&D program or programs, or we may not be able to identify, discover, develop or commercialize additional drug candidates, which would have a material adverse effect on our business. Further, because of our limited financial and managerial resources, we are required to focus our R&D programs on certain drug candidates and on specific diseases. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success.

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

As we have limited financial and managerial resources, we focus our pipeline on technology platforms and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. For instance, we terminated three R&D programs out of commercial reasons as we considered other programs are more promising in terms of market acceptance or more cost-effective. Our spending on current and future technology platforms and drug candidates may not yield commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on other commercial opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

### **RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR PRODUCTS**

**The manufacture of pharmaceutical products is a complex process which requires significant expertise and capital investment. If we encounter problems in utilizing or expanding our manufacturing capabilities in the future and/or our CMOs encounter problems manufacturing our future products, our business could suffer.**

The manufacture of pharmaceutical products requires significant expertise and capital investment. Problems may arise during the manufacturing process due to volume pressure, equipment malfunction and/or damage, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction or expansion of any future manufacturing facilities, among others. Manufacturing issues may lead to, among other things, increased costs, lost revenue, damage to customer relationships and additional time and expense investigating the cause. If problems are not discovered before the product is released to the market, such product may be recalled and product liability costs may also be incurred. Upon the occurrence of any of the foregoing, our manufacturing activities may be delayed or suspended and alternative manufacturers may not be available. Such occurrences could delay our clinical trials and/or the availability of our products for commercial sale and may harm our market reputation and relationship with business partners. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production.

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In addition, we may fail to utilize or expand our manufacturing capabilities in the future. We have our own manufacturing facilities which is used for in-house productions of azvudine. We may be subject to problems arising during the manufacturing process for a variety of reasons as discussed in the preceding paragraph. Given that we have limited experience in managing the manufacturing process, we cannot assure you that we will be able to sufficiently utilize our manufacturing capabilities or expand such capabilities in the future.

**We may not be able to precisely predict the market size and opportunities for our drug candidates.**

We currently focus on drug candidates for the treatment of viral infections, oncological and cardio-cerebrovascular diseases, and our estimated market size depends on assumptions that may differ from actual results. Our estimates of disease prevalence and eligible patients are based on our beliefs and analyses. These estimates have been derived from a variety of sources and may prove to be incorrect. Likewise, the potentially addressable patient population may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

For instance, the commercialization outlook of azvudine for COVID-19 remains materially uncertain. With the change in the COVID-19 situation in China, including a decline in the number of infections driven by strengthened public health management, vaccination and population immunity, the actual clinical demand for COVID-19 treatment may fluctuate and remains uncertain going forward. In addition, future changes in national policies, procurement arrangements, reimbursement policies and clinical treatment guidelines may further affect the market environment of COVID-19 drugs, bringing uncertainty to the potential sales performance and contribution of azvudine for the COVID-19 indication.

**Even if we are able to commercialize our approved drug and/or any future drug candidates for which we will receive regulatory approval, our drug and drug candidates may be subject to unfavorable pricing regulations and unavailable or limited reimbursement, which could harm our business.**

The regulations that govern pricing and reimbursement for new therapeutic products vary widely. Market acceptance and sales of our current or future approved drugs will depend significantly on the availability of adequate coverage and reimbursement from governmental and private third-party payors and may be affected by existing and future health care reforms. As a result, we might obtain regulatory approval for a drug, but then be subject to price regulations that delay or otherwise limit our commercial launch of the drug and negatively impact our revenues.

A primary trend in the global healthcare industry is cost containment. In China, the NHSA or provincial healthcare security authorities, together with other government authorities, review the inclusion or removal of drugs from the China's national drug catalog for basic medical insurance, or the NRDL, or provincial or local medical insurance catalogues for the national medical insurance program, or the PRDL, regularly, 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. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or PRDLs, our sales channels may be limited and our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive. Moreover, if reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug that we successfully develop.

In addition, there may be significant delays in obtaining reimbursement for our current or future approved drugs. Our inability to promptly obtain coverage and profitable payment rates from both governmental and private third-party payors for any current or future approved drugs and any additional drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial condition.



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**Even if reimbursement is available, we may need to significantly concede on prices for our current or future approved drugs in China and face uncertainty of profitability.**

In November 2024, the NHTSA organized a price negotiation for new drugs not yet included in the NDRL, resulting in an average price reduction by over 63% for 89 drugs that passed the negotiation. We may also need to attend the price negotiation with the NHTSA of our current or future approved drugs in China, which may lead to a reduction in our prices, and to negotiate with each of the local healthcare security administrations on reimbursement ratios. Even if our current or future approved drugs are included in the NDRL or the PRDL, our potential revenue or profitability from the sales of such drug may still decrease as a result of lower prices. Even if our current or future approved drugs were included in the NDRL or the PRDL without any price deduction, the degree of market acceptance and demand would still remain uncertain.

**We have limited experience in launching and marketing drug candidates. If we are unable to strengthen marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, our revenue could be adversely affected.**

We have obtained a conditional approval of azvudine from the NMPA for treating HIV infection in July 2021 and a conditional approval for COVID-19 indication expansion in July 2022, and have launched commercial sales of azvudine for both indications. However, our ability to successfully commercialize our drug candidates is subject to risks and may be more time-consuming and costly due to our limited commercialization experience.

We also may seek opportunities of strategic cooperation with leading pharmaceutical companies with extensive experience in the sales and marketing of drug candidates in both domestic and overseas markets. We granted Fosun Pharmaceutical Industrial an exclusive commercialization right of azvudine in Chinese Mainland in July 2022, and terminated such arrangement in September 2024, after which we regained the full commercialization right of azvudine in Chinese Mainland. For details, see “Business—Our Technology Transfer Arrangements and Collaborations—Fosun Pharma Strategic Cooperation Agreement” in this document. If we enter into similar arrangements in the future, there can be no assurance that we will be able to establish or maintain such collaborative arrangements or, even if we are able to do so, that such arrangements will enhance our ability to successfully launch and commercialize our drugs. In addition, part of our revenue may depend upon the efforts of such third parties. Our reliance on third parties, over whom we have limited control, may also adversely affect our revenue.

**We may derive a portion of our future revenue from sales to government agencies. If we are unable to procure such government sales, our business, financial condition, operating results and cash flows would be materially harmed.**

We may derive a portion of our future revenues from sales to governmental agencies of the PRC and other jurisdictions. We may also participate in the centralized volume procurement organized by the government agencies but may not be successful during the public tender process. The government contracting process (which may involve a competitive bidding process) involves unique risks and requirements, including (1) stringent procurement requirements, which we may not always satisfy; (2) potential ineligibility to participate in tenders; (3) significant time and resources spent on unsuccessful bids; (4) the need to accurately estimate resources and costs; and (5) third-party or competitor challenges, which may cause delays, additional costs, or changes to awarded contracts.

Even if we are able to procure governmental contracts initially, upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product for a similar product volume, period of performance, pricing or other terms, or at all. Moreover, government contracts are subject to extensive laws and regulations, which may impose additional costs and obligations on our operations.

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**Mutations to pathogens may negatively affect the effectiveness of our antiviral products and thereby reduce demand for such products.**

Antiviral products are our key commercialized products currently. The efficacy of our antiviral products may be affected by mutated pathogens, including those that develop resistance against certain chemical compounds over time. Mutations of viruses may happen over time or suddenly. For example, as a virus replicates, small genetic changes in the viral genome may occur. As these changes accumulate over time, the virus may become genetically different from the original virus type. We have developed and obtained conditional approvals for azvudine for the treatment of HIV infection and COVID-19, and are investigating potential further indication expansions to certain types of tumor. The effectiveness of our antiviral products may be adversely affected if target mutates or develops resistance against the relevant products (or the chemical compound associated with the relevant products). If the effectiveness of our antiviral products in respect of the treatment against the relevant pathogen type is diminished, it may reduce the demand for our antiviral products and in turn, adversely affect the turnover generated from such antiviral products.

**We may be subject, directly or indirectly, to applicable anti-commercial bribery, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.**

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Commercializing our drugs in China, our operations may be subject to various fraud and abuse laws, including the PRC Anti-Unfair Competition Law and the PRC Drug Administration Law and its implementing regulations. These laws and regulations may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government. In addition, the approval and/or commercialization of any of our drug candidates outside China may also likely subject us to equivalents of the healthcare laws mentioned.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines.

Further, if any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from possible government funded healthcare programs, which may also adversely affect our business.

**Even if any of our drug candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.**

Even if any of our drug candidates receive marketing approval, physicians, patients and third-party payors may prefer other products to ours. If approved for commercial sale, the degree of market acceptance of our drug candidates will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, clinics and patients considering our drug candidates as a safe and effective treatment;

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- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities and limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to take our drug candidates and to pay out-of-pocket in the absence of coverage and reimbursement by governmental and/or private third-party payors; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance in the medical community, we will not be able to generate significant revenue. Even if our drug candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received or more cost-effective than our drug candidates or render our drug candidates obsolete.

**We are developing certain drug candidates individually and as combination therapies and failure of development of one drug may materially and adversely affect our ability to develop our combination therapies involving such drug.**

We plan to conduct further R&D work to combine our drug candidates for combination use in the future. For combination of drug candidates, if we are unable to successfully develop a certain drug in the combination therapy, we will be unable to commercialize the combined drug. A combination therapy also depends on the safety, efficacy and the progress of development and regulatory approval of each component drug within each regimen.

Any safety, efficacy or other issues arising from any drug used in combination with or to facilitate the use of our drug candidates, such as undesirable side effects, could potentially cause significant negative consequences, including: (i) regulatory authorities could delay or halt pending clinical trials; (ii) we may suspend, delay or alter development of the drug candidate or commercialization of the drug; (iii) regulatory authorities may withdraw approvals or revoke licenses of the drug, or we may determine to do so even if not required; (iv) regulatory authorities may require additional warnings on the label; (v) we may be required to conduct post-market studies; (vi) we could be sued and held liable for harm caused to subjects or patients; and (vii) our reputation could be harmed.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

**Guidelines, recommendations and studies published by various organizations could disfavor our drug candidates.**

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' drugs and drug candidates. Any such guidelines could result in current or potential decreased use, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.



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**We are subject to certain risks associated with transportation and warehousing of our raw materials and drug products.**

Having a reliable transportation network is crucial for the delivery of our raw materials and drug products safely and timely. However, unforeseen events that are beyond our control, such as transportation bottlenecks, natural disasters or labor strikes, may disrupt available transportation networks. In addition, any poor handling by our carriers, contamination or deterioration in transport condition, such as fluctuation in temperature and humidity, may damage and/or affect the efficacy of our raw materials and drug products. If our raw materials were not delivered to our or our CMOs' manufacturing facilities in a timely manner, we may fail to deliver our products to our customers on time. If our drug products are not delivered on time, or were damaged, stolen or contaminated before reaching our customers, our market reputation and profitability may be materially and adversely affected, and we may be subject to claims or litigations if we fail to deliver the drug products in accordance with relevant agreements. Any of the aforementioned events would materially and adversely affect our business, financial condition or results of operations.

### **RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL**

**We incurred net losses and net operating cash outflows during the Track Record Period, expect to incur net losses and net operating cash outflows for the foreseeable future and may not achieve or maintain profitability.**

Results of investment in pharmaceutical drug development are highly uncertain. It entails substantial upfront capital expenditures and carries significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We recorded net losses and net operating cash outflows in 2024 and 2025, primarily due to our costs incurred in connection with our research and development activities, administrative expenses, selling and distribution expenses, finance costs and changes in fair value of convertible redeemable preferred shares.

We may continue to record a net loss and net operating cash outflows in the future as we continue and expand our development of, and seek regulatory approvals for, our current and future drug candidates. R&D expenses for a particular drug candidate typically increase significantly as the candidate moves from preclinical R&D to clinical trials. Our current and planned clinical trials will require significant further investments to complete. In addition, we will incur costs associated with operating as a public company. The size of our future net losses will depend, in part, on the number and scope of our R&D programs and their associated costs, the cost of commercializing any approved products, our ability to generate revenues, the timing and amount of payments under third-party arrangements and investment in our manufacturing facilities. Typically, it takes several years to develop one new drug from the drug discovery to commercialization. If any of our drug candidates fails in clinical trials or does not gain regulatory approval or, if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations.

Securing production capacity and building necessary product inventories in connection with clinical development and possible sales necessitates significant capital expenditures prior to revenue generation. If we fail to make sales as planned, we will incur costs associated with unsold product. As a result of the above, we may continue to incur significant and increasing operating losses and negative net cash flows for the foreseeable future, which may in turn have a material adverse effect on our financial condition and results of operations.

**We had net liabilities and net current liabilities during the Track Record Period.**

As of December 31, 2024 and 2025, we had net liabilities of RMB1,098.5 million and RMB1,404.9 million, respectively, and net current liabilities of RMB85.7 million and RMB1,345.7 million, respectively. Our deficit position and the significant increase of net current liabilities as of December 31, 2025 as compared with December 31, 2024 was primarily due to the accounting treatment for our Preferred Shares, which are classified as convertible redeemable preferred shares under liabilities. See “—Any change in fair value of our Preferred Shares could materially affect

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our financial positions and performance” below. We may have net liabilities and net current liabilities for the foreseeable future. If we have any difficulties or fail to meet our liquidity needs as and when needed, we may default in our payment obligations and may not be able to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

**We will need to obtain additional financing to fund our operations and, if financing is not available on terms acceptable to us, or at all, we may be unable to complete the development and commercialization of our drug candidates.**

Our drug candidates will require substantial investment for clinical development, regulatory approval, manufacturing and commercialization before generating revenue. We may also expand our existing R&D programs or plan to invest in new programs. These and other activities will require us to expend significant amounts.

We will require further funding through public or private equity offerings, debt financing, collaboration and licensing arrangements or other sources to support our business operations. Adequate additional funding may be unavailable on acceptable terms, or at all. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our R&D programs or future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

**We have incurred and expect to continue to incur significant share-based payments in connection with equity grants to our Directors, senior management and employees. Such share-based compensation may also dilute your shareholding if new shares are offered under equity awards or option plans.**

To incentivize and retain our Directors, senior management and employees, we have made and expect to continue to make equity awards under the RSU Scheme. The granting of such share-based compensation would increase our share-based expenses and thus may adversely affect our financial performance. In 2024 and 2025, our equity-settled share-based payment expenses totaled RMB2.5 million and RMB3.3 million, respectively. We expect to continue to grant share-based payments to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations. Meanwhile, if new shares are offered under equity awards or option plans, your shareholding will be diluted.

**We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.**

We are a biotech company with a relatively short operating history. Our operations to date have focused on business planning, raising capital, establishing our drug portfolio and conducting clinical trials of our drug candidates. A majority of our drug portfolio remain in development and have not been commercialized. Our limited operating history may make it difficult to evaluate our current business and reliably predict our future performance. Our future financial performance will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential investors to lose substantially all of their investment in us.

**Any change in fair value of our Preferred Shares could materially affect our financial positions and performance.**

As of December 31, 2025, we had entered into various investment agreements with independent investors pursuant to which we issued Preferred Shares to the investors. We recorded these financial instruments as financial liabilities at fair value through profit or loss. The fair value of the financial instruments is established by using valuation techniques, which include back-solve method and equity allocation model involving various parameters and inputs. Management

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## RISK FACTORS

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estimates and assumptions are reviewed periodically and are adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the financial liabilities at fair value through profit or loss which may be charged into the profit or loss of the financial statements.

Although our Preferred Shares will be automatically converted to Shares upon the [REDACTED], any change in fair value of these Preferred Shares could materially affect our financial positions and performance. We recorded fair value losses on convertible redeemable preferred shares of RMB79.5 million and RMB9.7 million in 2024 and 2025, respectively. After the automatic conversion of all Preferred Shares into Shares upon the [REDACTED], we do not expect to recognize any further losses on fair value change from Preferred Shares in the future.

**We may fail to maintain and predict inventory levels in line with demand for our products, which could cause us to face the risk of obsolescence for our inventories or lose sales.**

Our inventories primarily consist of raw materials, finished goods and low-value consumables. In 2024 and 2025, write-down on inventories of RMB34.9 million and RMB54.0 million, respectively, was recorded mainly in relation to the raw materials held by us considering our future consumption.

As our business expands, our inventory level may increase and our inventory obsolescence risk may also increase accordingly. We cannot guarantee that we will always be able to maintain proper inventory levels. We maintain our inventory levels based on our internal demand forecasts. If our forecast demand is higher than actual demand, we may be exposed to increased inventory risks due to the accumulation of excess inventory. Excess inventory levels may increase our inventory holding costs, risk of inventory obsolescence or write-offs. Conversely, we may not be able to maintain an adequate inventory level and may lose sales and market share to our competitors. Therefore, our business prospects, financial condition and results of operations may be materially and adversely affected.

**Any significant impairment losses for intangible assets may adversely affect our results of operations.**

Our intangible assets include intellectual property we acquired, trademark and software. Our intangible assets decreased by 13.7% from RMB137.5 million as of December 31, 2024 to RMB118.7 million as of December 31, 2025, primarily due to the amortization charged during the year. Our non-financial assets (including the property, plant and equipment, right-of-use assets and intangible assets) are subject to impairment testing as at the end of each year end in the Track Record Period. We did not record impairment loss for intangible assets in the Track Record Period. If the carrying amount of our intangible assets is considered to exceed its recoverable amount and is therefore determined to be impaired in the future, we would be required to write down the carrying value or record a provision of impairment loss for these intangible assets in our financial statements during the period in which our intangible assets are determined to be impaired. For more details, please refer to Note 15 to the Accountants' Report set out in Appendix I to this document. Impairment losses for intangible assets would adversely affect our results of operations and our financial condition.

**We are subject to credit risks and may incur impairment losses for trade receivables, prepayments and other receivables and other assets.**

Our trade receivables as of December 31, 2024 primarily represented outstanding sales-based royalties due from Fosun Pharmaceutical Industrial; and that as of December 31, 2025 represented our trade receivables from our distributors. Subsequent to the termination of our collaboration with Fosun Pharmaceutical Industrial, we expect our customers will primarily comprise our distributors. Our prepayments, other receivables and other assets consist of, among others, (i) prepayments, representing the fees prepaid for research and development services and raw materials; (ii) value-added tax recoverable, representing value-added taxes paid with respect to our procurement that can be credited against future value-added tax payables; and (iii) other receivables, representing mainly (a) the amount for prepayment for the office and laboratory refurbishment project, which had been impaired as of December 31, 2024 and partially recovered as of December 31, 2025, (b) petty cash held by our employees for business development purposes and (c) other

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miscellaneous deposits; (iv) deferred [REDACTED] expenses, representing capitalized [REDACTED] costs; and (v) receivables due from shareholders, representing the amount we prepaid for registered capital. See “Financial Information — Discussion of Certain Key Balance Sheet Items — Prepayments, Other Receivables and Other Assets.”

There is no guarantee that our customers, suppliers, service providers and other counterparties will perform their obligations in a timely manner and we are subject to credit risk in relation to trade receivables, prepayments and other receivables and other assets. The assessment of impairment losses involves a significant degree of management judgments as well as estimates in determining the key assumptions, and unpredictable adverse changes in the future may also result in decreases in the value of our trade receivables, prepayments and other receivables and other assets. Therefore, we cannot ensure that these assumptions and estimates would not result in outcomes that require a material adjustment to the carrying amounts of our trade receivables, prepayments and other receivables and other assets in the future, which may in turn result in impairment losses. Any significant impairment losses of trade receivables, prepayments and other receivables and other assets in the future could have an adverse effect on our business, financial condition and results of operations.

**The discontinuation of any of the government grants currently available to us could adversely affect our business, financial condition, results of operations and prospects.**

We receive government grants from the PRC government which are generally non-recurring. Our income from the government grants may vary from time to time. In 2024 and 2025, our government grants amounted to RMB21.7 million and RMB5.8 million, respectively. We cannot assure you that we will continue to be eligible to receive such government subsidies or that the amount of such subsidies will not be reduced in the future.

Our ability to continue to enjoy government grants is subject to changes in policies and our own situation to satisfy the requirements for such government grants, which may be impacted by factors beyond our control. Any decrease in or termination of such government grants in the future may have an adverse effect on our financial condition, results of operations and prospects.

**Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.**

Unless and until we can generate a substantial amount of revenue from our drug candidates, we expect to fund our future cash needs through public or private equity offerings, debt financing and other sources. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in us will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party, on unfavorable terms, our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves, or possibly reserve for future potential arrangements, when we might be able to achieve more favorable terms.

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### RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATION

**All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing laws, regulations and industry standards or any adverse actions by the drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.**

We intend to primarily focus our activities on the Chinese market and ultimately expect to extend our activities to overseas markets. These geopolitical areas all strictly regulate the biotech and pharmaceutical industries, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, marketing, sales and distribution of products. However, there are differences in the regulatory regimes, which make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in each of these markets.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator's non-approval, refusal or withdrawal, license revocation and total or partial suspension of clinical trials, production or distribution. Failure to comply with these regulations could have a material adverse effect on our business.

We cannot assure you that we will be able to pass all the inspections and obtain clearance in relation to discovery, development and manufacturing, as applicable, from the applicable regulatory authorities in all material respects. Any failure to comply with existing regulations and industry standards could result in fines or other punitive actions against us and the disqualification of data for submission to regulatory authorities, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and adversely affect our reputation and financial results.

**The regulatory approval processes of the NMPA and other comparable regulatory authorities are time-consuming and inherently unpredictable. If we are ultimately unable to obtain, or are substantially delayed in obtaining, regulatory approval for our drug candidates, our business will be substantially harmed.**

The time required to obtain approval by the NMPA and other comparable regulatory authorities is unpredictable but can take up to five to ten years following the commencement of clinical trials and depends on numerous factors.

While we have and may continue to leverage trial networks with hospitals to expedite development of our drug candidates, there is no guarantee that any of our drug candidates will be approved for inclusion in the studies by regulatory authorities and/or hospitals. Even if approved, a drug candidate could be dropped from the study, or additional studies, modifications or curtailment of our development efforts could be required.

Our drug candidates could fail to receive regulatory approval for many reasons, including but not limited to (1) failure to begin or complete clinical trials for various reasons, including disagreements with regulatory authorities; (2) failure to demonstrate that a drug candidate is safe and effective or, if it is a biologic, that it is safe, pure, and potent for its proposed indication; (3) failure of clinical trial results to meet the level of statistical significance required for approval; (4) data integrity issues related to our clinical trials; (5) disagreement with our interpretation of data from preclinical studies or clinical trials; (6) changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval and require us to amend our clinical trial protocols; (7) regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products; (8) our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and (9) clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.



## RISK FACTORS

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If we experience delays in the completion of a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed, and may harm our business, financial condition and prospects significantly.

**Our failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.**

Pursuant to relevant laws and regulations, we are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder and capital expenditure or remedial actions, which could materially and adversely affect our business, financial condition and results of operations. There is also no assurance that the relevant authorities would not take any enforcement action against us, and our business operations could be materially and adversely disrupted.

Furthermore, the interpretation or implementation of existing laws and regulations may change and we may need to obtain additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, which we cannot assure you that we will successfully obtain. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and prospects.

**Our drug candidates will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.**

Our drug candidates will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, marketing, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and, accordingly, manufacturers and manufacturers' facilities are required to comply with extensive NMPA and other regulatory authority requirements to ensure quality control and conformity to GMP regulations. We and our CMOs must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed, or to the conditions of approval, which could adversely affect the drug's commercial potential. The NMPA or other regulatory authorities may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or as a condition following approval. In addition, if the NMPA or any other regulatory authority approves our drug candidates, we will have to comply with requirements.

In addition, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, 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 any of our drug candidates, it may result in (1) restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls; (2) fines, warning letters or holds on clinical trials; (3) regulatory refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals; (4) drug seizure or detention, or refusal to permit the import or export of drugs; and (5) 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.

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## RISK FACTORS

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**Adverse drug reactions and negative results from off-label use of our products could materially harm our business reputation, product brand name, financial condition and expose us to liability.**

Products distributed or sold in the biotech and pharmaceutical markets may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that have not been approved by the relevant authorities. Even though the NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

**The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.**

The illegal importation of competing products from jurisdictions where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and may adversely affect our sales and profitability. Unapproved imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' possibility to import lower priced versions of our future approved products, which could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be deliberately or fraudulently mislabeled and referred to as counterfeit pharmaceutical products. The control and enforcement system may not be at an adequate level to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our brand name.

### **RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS**

**We may not be able to generate sufficient revenue from acquired technology to meet our objectives in undertaking the acquisition or even to offset the associated costs.**

We have acquired intellectual property rights in azvudine from Zhengzhou University and intellectual property rights in certain patents from Meitaibao, a company controlled by Dr. Du, relating to pipeline products including CL-197, dosimertinib and MTB-1806 for which Dr. Du is one of the inventors, and certain technical secrets from the National Institute of Pathogen Biology, Chinese Academy of Medical Sciences. Please see "Business—Our Technology Transfer Arrangements and Collaborations" in this document for detailed information on the terms and payment schedules of technology transfer arrangements. However, we may be unable to successfully develop and/or commercialize the relevant drug candidates nor generate sufficient revenue from acquired technology to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and development costs. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

## RISK FACTORS

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**Our acquired patents and other intellectual property may be subject to priority disputes or inventorship disputes and similar proceedings.**

We or our transferors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patents or other intellectual property. If we or our transferors are unsuccessful in any interference proceedings or other priority or validity disputes, we may lose valuable intellectual property rights, or our owned patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our transferors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights. If we or our transferors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain acquisitions or licenses from third parties. If we are unable to obtain and maintain the intellectual property rights we owned, we may need to cease the development, manufacture, and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our owned patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

**We may be unable to establish, protect or enforce our intellectual property rights adequately and, may be adversely affected.**

We seek to protect our drug candidates and technology that we consider commercially important by (i) filing patent applications in China and other jurisdictions; (ii) relying on trade secrets or pharmaceutical regulatory protection; or (iii) employing a combination of these methods.

The application for or issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and does not guarantee that we will receive similar protections in other jurisdictions. Further, under the first-to-file system, third parties may be granted a patent relating to a technology which we invented. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

We may fail to identify patentable aspects of our inventions in time to obtain patent protection. We may incorporate terms of non-disclosure and confidentiality in agreements or enter into separate non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our R&D output; however, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, patent rights that we may own currently or may own or in-license in the future may be subject to a reservation of rights by one or more third parties.

The life of a patent, and the protection it affords, is limited. Even if we successfully obtain patent protection for a drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized.

Patent protection are expensive, time-consuming and complex and we may not be able to protect our inventions at a reasonable cost or in a timely manner in all desirable jurisdictions. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Any failure to adequately protect our intellectual property, including due to the foregoing, could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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## RISK FACTORS

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**If we are sued for infringing, or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.**

We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

Third parties might allege that we are infringing their patent rights or trade secrets, or that we are otherwise violating their intellectual property rights, which might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties, which may not be available on acceptable terms, or at all, and may be nonexclusive. Ultimately, if, as a result of any actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms, we could be prevented from commercializing a future approved drug, or be forced, by court order or otherwise, to cease some or all aspects of our business operations. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement, including treble damages and attorneys' fees if we are found to willfully infringe a third party's patent.

Intellectual property litigations could be costly and time-consuming, and some of our confidential information could be compromised by disclosure during this type of litigation. Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain future approved drug, and may lead to unfavorable publicity which may harm our reputation or have a substantial adverse effect on the market price of our Shares. Such litigations 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 be successful in obtaining necessary rights for our development pipeline through acquisitions and licenses in the future.**

R&D programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and/or in-license other rights to use these proprietary rights. We may be unable to acquire or in-license these intellectual property rights from third parties that we identify, and therefor may have to abandon development of the relevant R&D program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

**Issued patents covering one or more of our drug candidates could be found invalid or unenforceable if challenged in court.**

Our intellectual property rights could be challenged, invalidated or found unenforceable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose patent protection on a drug candidate. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties.

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**If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.**

The life of a patent, and the protection it affords, is limited. Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after commercialization, which may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we are unable to obtain patent term extension or the term of any such extension 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 our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.**

We rely on our trademarks to differentiate us from our competitors. However, we may not be able to obtain trademark protection in jurisdictions that we consider of significant importance to us. In addition, any of our trademarks or trade names may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest and our compete effectively and our business may be adversely affected.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, documentation, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Failure to comply with procedural, documentary, fee payment and other similar provisions during the patent application process can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the respective jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In addition, under the PRC law, certain filing procedures need to be conducted with relevant procedures with respect to license agreements for patents and technology, otherwise the terms of the license agreements may not be enforceable against a good faith third party. Any of the above events may harm our patent protection or rights under the license agreements, which would have a material adverse effect on our business.

**Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.**

Laws and regulations governing patents may be amended from time to time, which will affect our ability to obtain new patents or enforce existing and potentially future patents. There may be a potential impact on our existing patents and future patent applications. These changes may affect the value of our patent rights or other intellectual property rights. Changes in either the patent laws or their interpretation in various countries, which in turn may increase the cost of patent litigation, may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.



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### **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 (1) others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future; (2) we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future; (3) we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; (4) others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights; (5) it is possible that our pending internally developed patent applications or those that we may own in the future will not lead to issued patents; (6) patents that may be issued from our pending patent applications that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; (7) our competitors might conduct R&D activities in jurisdictions 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; (8) we may not develop additional proprietary technologies that are patentable; (9) the patents of others may harm our business; and (10) we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

### **RISKS RELATING TO OUR RELATIONSHIP WITH THIRD PARTIES**

**We engage third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. 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 drug candidates and our business could be substantially harmed. If we lose our relationships with our third parties, especially our CROs, our product or drug development efforts could be delayed.**

We have engaged, and plan to continue to engage third-party CROs for the execution of our preclinical studies and clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our relationship with the CROs does not relieve us of our regulatory responsibilities.

Switching or adding additional CROs involves additional cost and requires management's time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our R&D programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as our original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs timely or to do so on commercially reasonable terms, or to meet our desired clinical development timelines.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. Our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates if (i) CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines; (ii) they need to be replaced; or (iii) the quality or accuracy of the clinical data that they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons. For example, the third parties on which we rely to assist are required to conduct our preclinical studies in accordance with GLP and the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》). We, our CROs for our clinical programs, and our

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## RISK FACTORS

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clinical investigators are also required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other regulatory authorities, for our drugs in clinical development. Our pivotal clinical trials must be conducted with product produced under GMP regulations. If we or any of our CROs or clinical investigators fail to comply with these regulations, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications, which would delay the regulatory approval process. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that such information will be misappropriated.

To the extent that we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

**We engage third parties to manufacture our clinical and initial commercial drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.**

We engage third parties for our manufacturing process and for the clinical supply of our drug candidates. During the Track Record Period, we engaged seven drug manufacturers in China, all of which are Independent Third Parties, to manufacture azvudine. Engagement of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA or other regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the NMPA, and, if applicable, other regulatory authorities. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- manufacturers may terminate or may not renew our manufacturing agreement in a manner or at a time that is costly or damaging to us, including due to the time and expense related to transferring information to a replacement;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, pandemics, as well as natural or man-made disasters.

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Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, and result in higher costs or adversely impact commercialization of our products. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

### **Third-party manufacturers may fail to comply with manufacturing regulations.**

Commercial manufacturing of our drug candidates is subject to regulatory inspections and must pass national or international regulatory inspections in a cost effective manner in order for us to maintain or obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the NMPA or other regulatory authorities and/or fail to comply with GMPs, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure could require prior review by the NMPA or other regulatory authorities and/or approval of the manufacturing process and procedures in accordance with the NMPA or comparable requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre-approval inspection.

Any failure by our third-party manufacturers to comply with GMP or failure to scale up manufacturing processes could lead to a delay in, or failure to maintain or obtain, regulatory approval of any of our drug candidates, or result in inability to meet our commercial or clinical trial demand. In addition, such failure could be the basis for the regulatory authorities to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action.

### **We have entered into collaborations, partnerships and technology transfer agreements, and may form or seek other collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not fully realize the benefits of such alliances or licensing arrangements.**

We have engaged in and may continue to explore a number of collaborative R&D programs with universities and research institutions in China for R&D collaboration. 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.

We face significant competition in seeking appropriate strategic partners and the negotiation process, which is time-consuming and complex and we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotech companies with more abundant resources or better capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Further, we may not be able to fully realize the benefit of or choose to exercise any options under current or future collaborations, strategic partnerships or the acquisition or license of our third-party drugs 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

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business. We also cannot be certain that we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay our R&D program or one or more of our other R&D programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

**We cannot guarantee we can achieve the expected sales goal through our collaboration with CSOs.**

We have engaged external partners such as CSOs to leverage their sales and marketing expertise and various networks and resources. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from such product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

### RISKS RELATING TO OUR INDUSTRY AND BUSINESS OPERATIONS

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

Our business is subject to constantly changing international economic, regulatory, social and political conditions and local conditions in foreign jurisdictions and regions. There can be no assurance that potential collaboration partners in those foreign jurisdictions and regions will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between various countries. For example, the military conflicts in Eastern Europe have led to significant volatility in the global capital markets and on the global economy. The impact of such geo-political conflicts on the global economy is still unclear. Our business, results of operations, financial condition and prospects may be materially and adversely affected by such geo-political conflicts and changes in global macro-economic environment.

**We face intense competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.**

We operate in a rapidly changing and time-sensitive environment, and the development and commercialization of innovative drugs is highly competitive. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates.

Some of our competitors have better resources and expertise than us. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. If more effective or easier to administer treatments are developed for the same indications as our products, or if there is a perception that our products do not provide incremental benefits over existing products, we may be unable to commercialize, or may not obtain satisfactory return in the sales of our drugs.

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**If we engage in acquisitions or strategic partnerships, such arrangements may increase our capital requirements, dilute our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.**

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, such as increased operating expenses and cash requirements and our inability to generate sufficient revenue from acquired technology and/or products to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

The implementation of our M&A activities is subject to applicable regulations and rules, and compliance with the requirements of the relevant regulations and rules could be time-consuming, and any required approval and filing processes may delay or inhibit our ability to complete such transactions. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

**We are subject to heightened sanction compliance risks as a result of our R&D activities in Russia.**

The United States and other jurisdictions or organizations, including the European Union, the United Nations and Australia, have, through executive order, passing of legislation or other governmental means, implemented measures that impose sanctions, including economic sanctions, against certain countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries. Russia, as well as certain industry sectors and other persons located in Russia, are subject to various sanctions programs administered by, among others, the United States and the European Union.

We authorized Beijing Union to submit an IND application to the Ministry of Health of the Russian Federation (Russian MoH) for initiating a Phase III clinical trial of azvudine for treating COVID-19 in Russia and received approval in January 2021. The Phase III clinical trial in Russia was completed in November 2022 and Beijing Union as the MAH received marketing authorization for azvudine from the Russian MoH in February 2023. We had not derived any revenue from Beijing Union under such collaborative arrangement from Russia and had not initiated and had no intention to initiate any clinical trials in Ukraine as of the Latest Practicable Date. We cannot assure you that our internal control measures would always be able to effectively eliminate all risk exposure to the international sanctions, sanctions laws and regulations. Sanctions laws and regulations are subject to change, new requirements or restrictions could come into effect which might increase the scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions. Our business and reputation could be adversely affected, and in particular we may be subject to penalties, if the authorities of United States, the European Union, the United Nations, Australia or any other jurisdictions were to determine that any future activities of our Group and/or our business partners, such as CROs, constitute a violation of the sanctions they impose or provides a basis for a sanction designation of our Group.

**We may out-license some of our commercialization rights and engage in other forms of collaboration worldwide, including conducting clinical trials abroad, we may be exposed to specific risks of conducting our business and operations in international markets.**

Global markets are an important component of our growth strategy. If we fail to obtain or grant licenses or enter into collaboration arrangements with third parties in other markets, or if an existing or future third-party collaboration is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including (1) efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales and marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates; (2) unexpected changes in laws and regulatory requirements and difficulty of effective enforcement of contractual provisions in local jurisdictions; (3) inadequate intellectual property protection; (4) unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements; (5) economic weakness,



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including inflation and currency fluctuations; (6) compliance with tax, employment, immigration and labor laws for employees traveling abroad; (7) the effects of applicable foreign tax structures and potentially adverse tax consequences; (8) workforce uncertainty and labor unrest; (9) business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics.

These and other risks may materially adversely affect our ability to conduct our business and operations in international markets.

**Our risk management and internal control systems, as well as the risk management tools available to us, may not fully protect us against various risks inherent in our business.**

Our risk management and internal control systems may not be fully effective in mitigating our risk exposure in all market environments or against all types of risks, including risks that are unidentified or unanticipated. As we will become a public company upon the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operations and reputation may be materially and adversely affected.

Effective implementation of our risk management and internal control policies and procedures also depends on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected.

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

Our internal computer systems and those of our CROs, CMOs, CSOs, collaboration partners and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access which can cause interruptions in our operations and result in a material disruption of our R&D programs and our business operations.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors. We are also reliant on our employees to protect information systems and networks and we provide training and implement security measures to mitigate such risks. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, 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 and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices, which could result in fines, increased costs or loss of revenue. We could incur liability, our competitive position could be harmed and the further development and commercialization of our drug candidates could be delayed.

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**Our future success depends in part on our ability to retain key executives and to attract, train, retain and motivate qualified and skilled personnel.**

We depend on the continued contributions of our directors, senior management (particularly the executive officers, listed in the section of this document headed “Directors and Senior Management”) and other key employees, many of whom may be difficult to replace. Replacing executives, scientific employees and other qualified personnel could be difficult and could take a long time because of the limited number of individuals in our industry with the skills and experience necessary to successfully develop, obtain regulatory approval for, and commercialize products similar to those we develop. The loss of any top executives or key employees could prevent us from achieving our research and development and commercialization goals.

To retain valuable employees, in addition to salary and cash incentives, we may provide share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our Shares that are beyond our control and may, at any time, be insufficient to counteract more lucrative offers from other companies. Any of our employees could leave our employment at any time, with or without notice. Should we fail to retain or motivate existing employees and attract qualified personnel, such failure could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

**We do not own any real property and may incur substantial relocation expenses if any lease for our offices is not renewed upon its expiration or is terminated.**

As of the Latest Practicable Date, we had leased five properties in China for daily business operations, R&D and in preparation of future in-house manufacturing. As of the same date, we had one leased property in Shenzhen where the actual use did not conform to the intended use as recorded in the property ownership certificate. During the Track Record Period and up to the Latest Practicable Date, we experienced certain incidents in relation to our leased properties where our lessor failed to complete certain relevant construction procedures prior to commencing operations, which may also expose us to the risks of relocation. Any dispute or claim in relation to the titles of the properties that we occupy, including any litigation involving allegations of illegal or unauthorized use of the properties, could cause the lease agreements to be terminated and require us to relocate our offices occupying these properties. If we cannot continue to use any of our leased property, we may need to seek an alternative location and incur substantial expenses related to such relocation.

Further, as of the Latest Practicable Date, two of our lease agreements were not registered with the relevant municipal land and real estate administration department in accordance with applicable PRC laws and regulations. As registration of the lease agreement will require the cooperation of the landlord, we cannot assure you that we can complete the registration of such lease agreement in a timely manner or at all. If we fail to complete the registration within the prescribed time frame as required by competent municipal land and real estate administration departments in the PRC, a maximum penalty of RMB10,000 may be imposed for each non-registered lease. Please see “Business—Properties and Facilities” in this document for details.

**Our employees, CROs, CMOs, CSOs, collaboration partners and others with whom we deal may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and applicable anti-bribery laws, which could harm our reputation and subject us to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.**

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, CROs, CMOs, CSOs, collaboration partners and others with whom we deal. If we obtain NMPA approval for any of our drug candidates and begin commercializing those drugs in China or other jurisdictions, our potential exposure under applicable laws will increase significantly and our costs associated with compliance with such laws are also likely to increase.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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We are subject to the anti-bribery laws of China and other jurisdictions. As our business expands, the applicability of the relevant anti-bribery laws to our operations will increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations and prospects.

**If we or our CROs, CMOs, CSOs or other contractors or consultants fail to comply with 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 the success of our business.**

We and third parties, such as our CROs, CMOs, CSOs or other contractors or consultants, are subject to numerous environmental, health and safety laws and regulations. Our operations involve the use of hazardous and flammable chemical materials and may also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

**Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.**

We are subject to PRC laws and regulations on data protection, privacy and human genetic resources, including the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), the Data Security Law of the PRC (《中華人民共和國數據安全法》), the Measures for Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) and the Regulation on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》). These regimes impose stringent requirements on the collection, use and cross-border transfer of data and biological materials, and may require filings or security assessments. Compliance with these and any other applicable laws and regulations may be costly and time-consuming and may require changes to our operations and data practices. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face proceedings against us by data protection authorities, governmental entities or others, which would subject us to significant awards, fines, penalties, judgments, negative publicity and reputational damage, and may otherwise materially and adversely affect our business, financial condition and results of operations.

**Failure to comply with PRC regulations regarding the registration requirements for employee stock incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.**

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Company (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules, which replaced the earlier rules promulgated by SAFE in March 2007 and January 2008. Under the Stock Option Rules, PRC residents who

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participate in stock incentive plans in an overseas publicly listed company are required, through a domestic companies of such overseas publicly listed company by collectively appointing a PRC agency institution, to register with SAFE and complete certain other procedures. Such participants must also retain a offshore institution to be responsible for the unified processing in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agent is required to amend SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes.

We and our PRC resident employees will be subject to the Stock Option Rules upon completion of the [REDACTED]. Failure of the PRC resident holders to complete their SAFE registrations may subject these PRC residents to fines and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to distribute dividends to us, or otherwise materially adversely affect our business.

**We face potential liabilities, in particular, product liability claims or lawsuits could cause us to incur substantial liabilities.**

We face an inherent risk of product liability as a result of the clinical trial and any future commercialization of our drug candidates inside and outside China, subject to limited immunity that we may seek in connection with some of our drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources.

**Any future litigation, legal disputes, claims or administrative proceedings against us could be costly and time-consuming to defend.**

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activities. Litigation to which we subsequently become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings that may initially not appear to be of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved.

**We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.**

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. We maintain different types of insurance policies. Our insurance coverage may be insufficient to cover any claim for product liability or damage to our fixed assets. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Our insurance might not adequately cover claims brought against us, or at all and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

**Our facilities and the facilities of our collaborators may be vulnerable to natural disasters or other unforeseen catastrophic events.**

Our operations, and those of our CROs, CMOs, CSOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics, and other natural or man-made disasters or business interruptions. The occurrence of any

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of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to develop our drug candidates could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions.

**Negative publicity with respect to us, our Shareholders, our management, employees, business partners, affiliates, or our industry, may adversely affect our reputation, business and growth prospect.**

We, our Shareholders, our management, employees, business partners, affiliates, or our industry may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, our management, employees, business partners and affiliates were in compliance with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

**Any failure to comply housing provident fund or the mandatory social insurance may subject us to fines and other legal or administrative sanctions.**

According to the Social Insurance Law (《中華人民共和國社會保險法》) implemented on December 29, 2018, the Administrative Regulations on the Housing Provident Fund (《住房公積金管理條例》) implemented on March 24, 2019 and other applicable PRC regulations, any employer operating in China must apply for registration for payment and deposit of the social insurance and housing provident fund, and contribute social insurance premium and pay housing provident contribution for its employees. Any failure to make timely registration of social insurance premium or housing provident fund for its employees may trigger an order of correction from competent authority requiring the employer to register within a specified period of time and may impose fines if the employer fails to do so. As of December 31, 2024 and 2025, we engaged third-party agents to make the payment of social insurance and housing provident fund on behalf of us for 16 and 28 employees, respectively. As of the Latest Practicable Date, we had not received any order of correction from the competent authority and also had not received any complaint or labor arbitration application from any of our employees, in each case as a result of any such arrangement. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance or to pay any penalty related thereto.

**The interpretation and enforcement of PRC laws, rules and regulations need to be determined in accordance with the relevant laws and regulations in effect at that time.**

A substantial portion of our operations are conducted in China through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China, and the interpretation and enforcement of these laws, rules and regulations subject to adjustments and refinements.

The Foreign Investment Law came into effect January 1, 2020. The Foreign Investment Law may materially impact our current corporate governance practices and business operations in many aspects and may increase our compliance costs. For instance, the Foreign Investment Law imposes foreign investment information report requirements on foreign investors and the applicable foreign invested entities.

Additionally, the NMPA's recent reforms of the drug approval system. The timing and full impact of such reforms will need to be determined in accordance with the relevant laws and regulations in effect at that time, and we may not be able to commercialize our drug candidates in a timely manner.

Any administrative and court proceedings may be protracted, resulting in substantial costs and diversion of resources and management attention. These factors may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.



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**System of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay us from making loans or additional contributions to our PRC subsidiaries, which could impact our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.**

The PRC has regulations governing the conversion of foreign currencies into Renminbi. Under China's existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to normative management. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the Ministry of Commerce or its local counterparts.

We are subject to foreign exchange regulations in the PRC, including SAFE Circular 19 (《國家外匯局關於改革外商投資企業外匯資本金結匯管理方式的通知》), SAFE Circular 16 (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) and SAFE Circular 28 (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which impose restrictions on the use of RMB converted from foreign capital, including limitations on loans and investment activities. The interpretation and implementation of these regulations remain uncertain and subject to regulatory discretion. Any non-compliance or adverse interpretation may restrict our ability to use capital efficiently and adversely affect our business, financial condition and results of operations. We cannot assure you that we will be able to complete the necessary registrations or obtain the approvals on a timely basis, if at all, with respect to future loans or capital contributions to our PRC subsidiaries and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

**Any failure by the Shareholders or beneficial owners of our Shares who are PRC residents to comply with certain PRC Foreign Exchange Regulations relating to offshore investment activities by such PRC residents could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.**

We are subject to PRC foreign exchange regulations, including SAFE Circular 37 (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) and SAFE Circular 13 (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), which require PRC residents to register and update offshore investment structures. Failure by our shareholders to comply with such requirements may restrict our PRC subsidiaries' ability to distribute profits or conduct capital transactions, and may subject them to regulatory penalties. We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and regulations, however, we may not always be able to compel our Shareholders to comply with SAFE Circular 37 or other related regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such Shareholders to comply with SAFE Circular 37 may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident to penalties under the PRC foreign exchange administration regulations.

**It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.**

Our operating subsidiaries are incorporated in China. Some of our management reside in China from time to time. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China.

On July 14, 2006, Hong Kong and Chinese Mainland entered into the Arrangement of the Supreme People's Court between the Mainland and the HKSAR on Reciprocal Recognition and Enforcement of the Decisions of Civil and Commercial Cases under Consensual Jurisdiction. Pursuant to Choice of Court Agreements Between Parties Concerned (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the

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Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in Chinese Mainland. Similarly, a party with a final judgment rendered by a Chinese Mainland court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. The Supreme People's Court and the Hong Kong government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), or the New Arrangement, effective in January 2024, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the Chinese Mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement.

Furthermore, 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, or most other western jurisdictions or Japan. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

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

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

People's Bank of China, or PBOC, and the SAFE promulgated a series of measures, including strict vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. More restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

**Any future dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.**

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), or the EIT Law and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.

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Pursuant to the Arrangement between Chinese Mainland and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, or the Hong Kong Tax Treaty (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is the beneficial owner of the PRC-sourced income and we have obtained the approval of the competent tax authority. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), or Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available.

**We face possible changes to PRC laws and regulations relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.**

On February 3, 2015, the PRC State Administration of Taxation issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Circular 7, amended on December 29, 2017, which provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets.

Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors are not subject to the PRC enterprise income tax pursuant to Circular 7 where such shares were acquired in a transaction through a public stock exchange. However, the sale of ordinary shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Circular 7.

The application of Circular 7 will be determined in accordance with the applicable laws and regulations in force at the time. Circular 7 may be determined by the tax authorities to be applicable to the sale of the shares of our offshore subsidiaries or investments where PRC Taxable Assets are involved. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Circular 7 or to establish that we and our non-resident enterprises should not be taxed under Circular 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have an adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Circular 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Circular 7, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

**Under China’s Enterprise Income Tax Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.**

Under the EIT Law, an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise”, meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Under the Circular on Issues Relating to Identification of PRC-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the De Facto Standards of Organizational Management (《國家稅務總局關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》), issued and amended by the PRC State Administration of Taxation on April 22, 2009 and December 29, 2017, respectively, or Circular 82, dividends and other distributions paid by resident enterprises will be considered to be PRC source income, subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. The

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implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management operation; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and archives of minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the PRC State Administration of Taxation issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011 and was amended on June 15, 2018, to further clarify certain issues related to determining PRC resident enterprise status, including which the competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Currently, some of the members of our management team as well as the management team of some of our offshore holding companies are located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. Without further issuing the detailed implementation regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the SAT may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45, dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, the EIT Law and its implementing rules issued by PRC tax authorities provide that dividends paid by us to our non-PRC shareholders and, while less clear, capital gains recognized by them with respect to the sale of our Shares may be subject to tax of 10% for non-PRC resident enterprise shareholders and 20% for non-PRC resident individual shareholders. In the case of dividend payments, such PRC tax may be withheld at the source.

### **Certain regulations may make it more difficult for us to pursue growth through acquisitions.**

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, adopted by six PRC regulatory agencies in 2006 and amended in 2009, established additional procedures and requirements that could make merger and acquisition activities by foreign investors time-consuming and complex. Such regulation requires, among other things, that the Ministry of Commerce, or MOFCOM, be notified in advance of any change of control transaction in which a foreign investor acquires control of a PRC domestic enterprise and involves any of the following circumstances: (i) any important industry is concerned; (ii) such transaction involves factors that impact or may impact national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, pursuant to the Anti-Monopoly Law of the PRC (《中華人民共和國反壟斷法》) promulgated by the Standing



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Committee of NPC which became effective in 2008 and was amended on June 24, 2022 and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《國務院關於經營者集中申報標準的規定》) promulgated by the State Council which became effective in 2008 and was recently amended in January 2024, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the applicable threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《商務部實施外國投資者併購境內企業安全審查制度的規定》), or the Security Review Rules, issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to such security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially adversely affected.

### RISKS RELATING TO THE [REDACTED]

**No public market currently exists for our Shares; an active trading market for our Shares may not develop and the market price for our Shares may decline or become volatile.**

No public market currently exists for our Shares. The [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will not decline following the [REDACTED].

**The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.**

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the biotech and pharmaceutical industries, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past and it is possible that our Shares may be subject to changes in price not directly related to our performance.



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**The interests of our Controlling Shareholders may differ from your interests and they may exercise their vote to the disadvantage of our minority Shareholders.**

Immediately following the completion of the [REDACTED] and the [REDACTED], our Controlling Shareholders will control approximately [REDACTED] of the total issued share capital (without taking into account any Shares which may be issued pursuant to the exercise of the [REDACTED]). Accordingly, our Controlling Shareholders will, for the foreseeable future, through their voting rights control, be able to exercise substantial influence over our operations and business strategy, such as matters related to the composition of our Board of Directors, selection of our senior management, amount and timing of dividends and other distributions, our overall strategic and investment decisions, issuance of securities and adjustment to our capital structure, amendment to our Memorandum and Articles of Association, and other corporate actions requiring approval of our Shareholders, including merger, consolidation or sale of our assets, or any other change of control event that may affect our other Shareholders generally. Such voting rights control may discourage certain types of transactions, including those involving an actual or potential change of control of our Company. In the event that there is a divergence of our strategic and other interests from those of our Controlling Shareholders in the future, our Controlling Shareholders may exercise control over our Company in ways that conflict with the interests of our other Shareholders, and minority Shareholders could be disadvantaged.

**You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future, including pursuant to the Share Incentive Schemes.**

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value. In order to expand our business, we may consider [REDACTED] and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price that is lower than the net tangible asset value per Share at that time. The total number of Shares issuable under any share scheme of our Group shall not in aggregate exceed 10% of the total number of Shares in issue immediately following completion of the [REDACTED].

**Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.**

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate to pay cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Directors. Accordingly, the return on your investment in our Shares likely will depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

**We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.**

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Islands Companies Act and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary

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responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority Shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority shareholders may be located. See “Appendix III—Summary of the Constitution of the Company and Cayman Islands Company Law” to this document.

As a result of all of the above, minority Shareholders when protecting their interests through actions against our management, Directors or controlling Shareholders under the laws of the Cayman Islands will have different remedies available to them under Cayman law when compared to the laws of the jurisdiction which such Shareholders are located in.

### **Facts, forecasts and statistics in this document relating to the biotech and pharmaceutical industries may not be fully reliable.**

Facts, forecasts and statistics in this document, particularly the sections headed “Business” and “Industry Overview,” contain certain information relating to the biotech and pharmaceutical industries, the market and current events in and outside China are obtained from various sources that we believe are reliable, including official government publications, third-party reports, other publicly available sources, as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of this information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any material fact has been omitted that would render such information false or misleading. Neither we, the Sole Sponsor, [REDACTED] or any of the [REDACTED] nor our, its or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the biotech and pharmaceutical industries, the respective markets and current events in and outside China may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risks and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

### **You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].**

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your investment decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to invest in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].