
RISK FACTORS

An [REDACTED] 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 [REDACTED] in our Shares. 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, results of operations and prospects. In any such case, the [REDACTED] of our Shares could decline, and you may lose all or part of your [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours, which may cause you to lose all or part of your [REDACTED].

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, business operations, intellectual property rights and financial prospects; (ii) other risks relating to our business; (iii) other risks relating to our financial position and need for additional capital; (iv) other risks relating to our operations; (v) risks relating to doing business in the jurisdictions where we operate; and (vi) risks relating to the [REDACTED]. Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

KEY RISKS RELATING TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY RIGHTS AND FINANCIAL PROSPECTS

We depend substantially on the success of our product candidates.

All of our product candidates are still in development. Ifebemtinib (IN10018), our Core Product and most clinically advanced product candidate, is undergoing multiple clinical development programs as combination therapy. Our ability to generate revenue and realize profitability depends on our ability to successfully complete the development of our product candidates and manufacture and commercialize our product candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates, and we expect to continue to incur substantial and increasing expenditures for the development, manufacturing and commercialization of our product candidates. The success of our product candidates will depend on several factors, including but not limited to: successful completion of pre-clinical and clinical studies; obtaining positive results in our clinical trials; continued compliance with, and retention of, third-party licenses to patents and other intellectual property critical to our programs; successful identification of potential product candidates; sufficient resources to discover or acquire additional product candidates; establishing sufficient commercial manufacturing capabilities; successful collaboration on the development and commercialization efforts; the performance by CRO service providers or other third parties we may retain; continued acceptable safety profile of our product candidates following regulatory approval; obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; obtaining and maintaining favorable governmental and private reimbursement; and competition with other drug products.

If we fail to achieve product development milestones as disclosed in this document, our business prospects could be adversely affected. Our costs will also increase if we experience delays in the development of product candidates or in obtaining regulatory approvals, which could result in us having to delay or suspend the trial until sufficient funding is procured, or we would have to abandon developing of the product candidate completely.

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Clinical development involves a lengthy, costly, and inherently uncertain process, wherein pre-clinical and early-phase clinical trial results may not predict future outcomes.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. If the results of clinical trials of our product candidates are not positive or only modestly positive for proposed indications or if they raise safety concerns, we may (i) be subject to substantial liabilities, (ii) be delayed in or even prevented from obtaining regulatory approval for our product candidates, (iii) obtain approval for indications that are not as broad as intended, (iv) have the product removed from the market after obtaining regulatory approval, (v) be subject to additional post-marketing testing requirements, (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for use of the product. Any of such events could materially and adversely affect our ability to commercialize the subject products and generate revenue. A major risk we face is the possibility that we may be prevented or delayed in obtaining marketing approval for such product candidates if the results of our ongoing or future pre-clinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates.

If the results of our trials reveal a high and unacceptable severity and prevalence of these or other side effects associated with our product candidates, our trials could be suspended or terminated and the regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications, and we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any disruptions, changes and delays in completing our clinical trials due to the above-mentioned reasons may increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenue for that product candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

Other than our core product, ifebemtinib, for which we own the intellectual property, we rely on third-party licenses to certain patents and other IP that are critical to the development, manufacture, or commercialization of some product candidates, “Business — Material Agreements” for more details. These licenses may not grant exclusive rights in all fields or territories, limiting our ability to develop or sell products outside the licensed scope and preventing us from blocking competitors in those regions. We generally lack control over the prosecution, maintenance, enforcement, or defense of licensed patents. If licensors fail to protect or lose rights to these patents, our ability to research, develop, and commercialize affected products could be impaired. License agreements also impose obligations related to clinical development, commercialization, milestone payments, and royalties. Their complex terms may be subject to differing interpretations, and disputes could restrict our rights or increase our obligations. Failure to comply, including missing milestones, could allow counterparties to terminate agreements, resulting in loss of product rights, financial penalties, or operational disruption. If licensors face financial distress, bankruptcy, or shifts in business focus, our licensed rights may be jeopardized. For details, see “Business — Material Agreements”. Any such events could materially and adversely affect our competitive position, business, financial condition, results of operations, and prospects.

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Our business and prospects are dependent on the successful development and commercialization of our Core Product, ifebemtinib.

Ifebemtinib is our Core Product and currently our only product candidate in late clinical development stage. We expect that development activities for ifebemtinib, including its indication expansion programs, will continue to account for a majority of our research and development expenditures in the foreseeable future. Our other product candidate, IN30778, is in the preclinical development stage. Advancing these candidates toward commercialization will require significant time, further development, and substantial capital investment. As a result, our ability to generate revenue in the near term is primarily dependent on the successful clinical development, regulatory approval, and commercial launch of ifebemtinib. Any significant delays, negative clinical trial results, or a failure to obtain regulatory approval for ifebemtinib for any of its targeted indications could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If safety, efficacy, or other issues arise with any pharmaceutical products or product candidates that are used in combination with our product candidates, we may be unable to market such product candidates or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We are developing certain product candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single-agent development, due to the greater risk of combined drug toxicity, potentially reduced efficacy resulting from drug-drug interactions, and toxicity limitations on efficacy. The risk of development failure is even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety, including the requirement for separate combination IND review, and the trial designs are also more complex and require closer monitoring. If the NMPA, FDA, or other regulatory agencies revoke approval of any therapy we use in combination with our product candidates, we will not be able to market our product candidates in combination. If safety or efficacy issues arise with these or other therapies that we seek to combine with our product candidates in the future, we may experience significant regulatory delays and may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination product candidates, we may not be able to complete clinical development of our product candidates on our current timeline, or at all.

If we are unable to compete effectively against our competitors, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We operate in a highly competitive environment, and we expect competition to intensify further. While our principal focus is to develop product candidates with the potential to become highly differentiated drugs, we face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We may not be able to outperform a competing product in the future for various reasons, including, without limitation, that the competing product is more popular, cheaper or more effective. In addition, the technologies used by us and our competitors are evolving rapidly, and new developments frequently result in price competition and product obsolescence. Significant pre-clinical study or clinical trial delays could also allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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We have no track record in launching and marketing approved product candidates, and we may not be able to successfully create or increase market awareness of our products or sell our products, if and when approved.

Our financial performance depends on the successful launch and marketing of our clinical-stage and pre-clinical product candidates. Since all are still in development, we have not yet demonstrated commercialization capability. Commercializing approved products may involve greater risk, time, and cost than for companies with prior experience. We plan to build commercialization and distribution capabilities to maximize sales and market acceptance, if approved. However, we must compete with other companies to recruit and retain marketing and sales staff, and there is no assurance we can establish or maintain effective in-house capabilities. Failure to do so could prevent us from generating planned revenue. If we do not develop internal sales and distribution, we will likely rely on collaborative arrangements. Yet there is no assurance we can establish or maintain such partnerships, or that they will provide effective sales forces. Revenue would depend on third-party efforts, over which we would have limited control, and may be lower than if we commercialized independently. Competition for such partners further increases risk.

We have incurred losses from operations since inception and there is no assurance that we will generate revenues or become profitable in the future.

We have incurred substantial R&D expenses to date, and expect to continue to incur significant expenses related to clinical and pre-clinical studies. We cannot assure you that our product candidates will obtain regulatory approvals and/or become commercially viable. Even if we obtain regulatory approval to market our product candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our product candidates, and our ability to achieve sufficient market acceptance. We incurred losses from operations of RMB142.6 million and RMB185.1 million for the years ended December 31, 2024 and 2025, respectively, which primarily resulted from expenses in relation to our R&D activities and administrative activities. We expect to continue to incur significant expenses for the foreseeable future, as we continue to advance our pre-clinical, clinical, regulatory activities and our business operations. In addition, our expenses could increase beyond expectations if we are required by the NMPA, the FDA or other similar authorities to perform studies in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the product candidates. Even if we are able to generate revenue from the sale of our approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us.

We seek to protect the product candidates and technology that we consider commercially important by filing patent applications, relying on patent rights, trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. For further information on our patent portfolio, see “Business — Intellectual Property.” The patent process is costly, lengthy, and complex, and we may not be able to file, prosecute, maintain, defend, enforce, or license all necessary patents in a timely or affordable manner across all jurisdictions. Consequently, we may be unable to block competitors from developing or commercializing rival products. Failure to obtain or maintain adequate IP protection could materially harm our business, financial condition, results, and prospects. Patentability standards vary by jurisdiction, and compulsory licensing or limits on enforceability against governments may reduce patent value. If forced to grant licenses, our competitive position could be impaired.

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Patent applications may be denied or invalidated due to prior art, deficiencies, or lack of novelty, and we may fail to identify patentable aspects of R&D in time. Breaches by employees, collaborators, or contractors could disclose inventions prematurely, jeopardizing protection. Because publications and patent applications are often delayed, we cannot assure that we were first to invent or file. Under the “first-to-file” system in China and the U.S., third parties may secure patents on technologies we developed. The issuance, scope, validity, and enforceability of patents are highly uncertain. Coverage may narrow before or after issuance, and adverse rulings could invalidate rights, enable competitors, or block our commercialization. Even issued patents may not provide meaningful protection or advantage. Patent disputes in biopharma are frequent and unpredictable. Patent life is limited, and approved products may face generic or biosimilar competition after expiration. Such manufacturers may challenge our patents, and we may fail to enforce them, reducing exclusivity and sales. Our patents expire on various dates (see “Business — Intellectual Property”), after which we cannot assert rights against competitors.

OTHER RISKS RELATING TO OUR BUSINESS

Risks Relating to the Development of Our Product Candidates

If we encounter delays or difficulties enrolling subjects in our clinical trials, our clinical development progress could be delayed or otherwise adversely affected.

The timely completion of clinical trials depends on, among others, our ability to enroll a sufficient number of subjects who will remain in the clinical trials until their conclusion. If we are unable to locate and enroll a sufficient number of eligible subjects, or if there are delays in the enrollment of eligible subjects, we may not be able to initiate or continue clinical trials for our product candidates. We may encounter challenges with enrolling subjects in our clinical trials for various reasons beyond our control, such as the difficulties with recruiting a sufficient number of subjects that possess the traits and characteristics we seek; the resources we have to facilitate timely subject enrollment in our clinical trials; the efforts made by trial executing personnel to screen and recruit eligible subjects; and the proximity and availability of clinical trial sites for prospective subjects. Our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients available to us as some patients might choose to enroll in a trial being conducted by one of our competitors instead of ours. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance our pipeline.

We may allocate our limited resources to pursue a particular product candidate or indication and, as a result, fail to capitalize on product 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 product pipeline on research programs and product candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

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AEs or undesirable side effects caused by our product candidates could interrupt or suspend clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

AEs and undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or suspend clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval, or a significant change in our clinical protocol or even our development plan. Results of our trials may reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, our trials could be suspended or terminated and regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. AEs related to our product candidates may affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Additionally, if we or others identify undesirable side effects caused by those of our other product candidates after having received regulatory approval, this may lead to potentially significant negative consequences which include, but are not limited to, the following: we may suspend marketing of the product candidate; regulatory authorities may withdraw their approvals of or revoke the licenses for the product candidate or require additional warnings on the label; the FDA may require the establishment of a Risk Evaluation and Mitigation Strategy (“REMS”) or the NMPA or a comparable regulatory authority may require the establishment of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us.

The data and information we gather or otherwise rely on in our research and development process could be inaccurate or incomplete, which could harm our trial results, reputation and prospect.

We collect and analyze data from pre-clinical and clinical programs, and conduct extensive information gathering for promising candidates. Because pharmaceutical data is fragmented, inconsistent, and often incomplete, its quality is frequently challenged, and errors may arise during monitoring and auditing. Mistakes in data capture, input, or analysis could materially harm product development and damage our business, prospects, and reputation. We also manage and submit data to regulators for approvals, subject to complex validation rules. Interim or preliminary trial data may change as more patient information becomes available and undergoes audit, potentially exposing us to liability if submissions are deemed wrongful or erroneous. Even unsuccessful claims could result in significant costs and diversion of management resources, and uninsured claims could harm our financial condition. In addition, we rely on CROs and other third parties to manage data for certain studies, while controlling only parts of their activities. If they fail to meet standards of accuracy or completeness, study data may be compromised. Reliance on third parties does not relieve us of regulatory responsibilities, and failures could materially harm our ability to obtain approvals or commercialize product candidates. For a detailed discussion, see “— Risks Relating to our Reliance on Third Parties — We rely on third parties to monitor, support and/or conduct clinical trials and pre-clinical studies of our product candidates.” If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, and our business could be materially harmed.

We invest substantial human and capital resources in research and development in order to develop our product candidates and enhance our technologies, but we cannot guarantee that such efforts will lead to successful outcomes.

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For 2024 and 2025, we incurred research and development expenses of RMB100.0 million and RMB100.9 million, respectively. We intend to continue to strengthen our technical capabilities in the development of our product candidates, which requires substantial capital and time. We cannot assure you that we

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will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner.

Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data becomes 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 publicly disclose preliminary or top-line data from our pre-clinical studies and clinical trials, which is based on a preliminary analysis of then available data, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. We may also disclose interim data from our pre-clinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with participant enrollment where more participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile prices of our Shares after the [REDACTED]. Moreover, others may not accept or agree with our assumptions, estimates, calculations, conclusions analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidates.

Risks Relating to the Manufacturing and Commercialization of Our Product Candidates

We have limited experience in manufacturing therapeutic products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future products.

We have limited experience in large-scale manufacturing of our products for commercial use, if and when approved. To date, we have not engaged in the manufacture of any products ourselves. While we currently intend to rely on third-party manufacturers to produce our products, problems may arise during manufacturing for a variety of reasons, including but not limited to equipment malfunction; failure to follow specific protocols and procedures; changes in product specification; low quality or insufficient supply of materials; delays in the construction of new manufacturing facilities as a result of our ability to identify a suitable site and limits to manufacturing capacity due to regulatory requirements and other factors. Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products.

We deal with potentially harmful biological materials and other hazardous materials that may cause environmental contamination or injury to others.

Our manufacturing operations and R&D activities involve the controlled use of potentially harmful biological materials and other hazardous materials. In particular, the risk of accidental contamination to the environment or injury to our employees or others from the use, manufacture, storage, handling or disposal of these materials may not be completely eliminated. In the event of

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contamination or injury, we could be held liable for any resulting damages, which could exceed any applicable insurance coverage we may have. Furthermore, governmental agencies could initiate investigations against us, which may result in fines, sanctions, revocations of operating permits, suspension of our operations, closure of our facilities or other penalties. Laws and regulations regarding handling of harmful biological materials and other hazardous materials, or more stringent environmental regulations that may be adopted in the future, may mandate additional protective and other measures against potential contamination or injury caused by these materials, compliance with which could be costly, and our financial condition may be affected as a result.

The size of the potential market for our current or future product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our current or future product candidates may be smaller than our estimates.

Our projections of the number of patients who have the potential to benefit from treatment with our product candidates are based on our beliefs and estimates. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our product candidates may be smaller than our estimates. Furthermore, there is no guarantee that any of our product candidates, even if approved, would be approved for the line of therapy we are aiming for. While we may seek approval for our product candidates as an early-line therapy for certain indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our product candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

Our product candidates, if and when approved, may fail to achieve the degree of market acceptance, and the actual market size of our product candidates might be smaller than expected.

The commercial success of our product candidates, upon regulatory approval, depends upon the degree of market acceptance each of such products achieves. Our product candidates, if and when approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other products to ours. If our approved product candidates do not achieve an adequate level of acceptance, the sales of our future products will be adversely affected, and we may fail to effectively market our product candidates. If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our future approved products achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our product candidates, are more cost-effective or render our product candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved products would materially adversely affect our business and prospects.

Guidelines, policies, recommendations and studies published by various organizations could disfavor our product 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 product candidates. Any such guidelines, recommendations or studies that reflect negatively on our three product candidates, either directly or relative to our competitive product candidates, could result in potential decreased use, sales of, and revenues from one or more of our product candidates. Additionally, our success depends in part on our and our collaboration partner’s ability to educate healthcare providers and patients about our product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties’ guidelines, recommendations or studies.

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

The illegal importation of competing products from countries where governmental price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved product candidates and, in turn, may adversely affect our sales and profitability in regions where we commercialize our products in the future. Illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. In addition, governmental authorities may expand consumers’ ability to import lower priced versions of our future approved products or competing products. Cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future products and exert commercial pressure on our product pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower priced medicines could have a material adverse effect on our business.

Furthermore, certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits could quickly erode the demand for our product candidates approved in the future. A patient who receives a counterfeit or unauthorized pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences.

Negative results from off-label use of our future marketed products could harm our reputation, product brand, business operations and financial condition and expose us to liability.

Off-label drug use is the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. There remains a 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 or AEs. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, business operations and financial conditions. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our product candidates.

Risks Relating to Our Reliance on Third Parties

We rely on third parties to monitor, support and/or conduct clinical trials and pre-clinical studies of our product candidates.

We work with third-party collaborators, such as CROs, to conduct pre-clinical studies and clinical trials, but control only certain aspects of their activities. While collaboration does not relieve us of regulatory responsibilities, we remain accountable for compliance with protocols, laws, and scientific standards. We and our CROs must follow GCP requirements enforced by the NMPA, FDA, and other regulators. Failure to comply could render trial data unreliable, require additional or repeated trials, and delay approvals. If relationships with CROs end, we may struggle to secure replacements on reasonable terms. CROs are not our employees, and we cannot ensure they devote sufficient resources. If they fail to meet obligations, deadlines, or quality standards, or

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if data accuracy is compromised, trials may be delayed, extended, or terminated, harming commercialization prospects, increasing costs, and delaying revenue. Switching or adding CROs also adds cost and delays, which may materially affect development timelines. We may also engage third parties to perform specification tests on product candidates. If tests are inadequate or data unreliable, patients could face serious risks and regulators could impose restrictions until deficiencies are corrected.

We may form or seek additional collaborations or strategic alliances or enter into licensing arrangements in the future. We may not realize any or all benefits of such alliances or collaboration arrangements, and disputes may arise between us and our collaboration partners.

Developing and commercializing our product candidates will require significant capital. We have existing agreements with Boehringer Ingelheim for our Core Product and Oncomatrix Biopharma for OMTX705, please refer to “Business — Material Agreements” for details, and may pursue additional partnerships, licenses, or collaborations to support R&D and commercialization. Such arrangements could increase expenses, dilute shares, disrupt operations, or expose us to liabilities and integration risks, potentially delaying timelines or harming our business. Competition for strategic partners is intense, negotiations are complex, and potential collaborators may view our candidates as too early-stage or lacking sufficient potential. Even if collaborations are formed, we may relinquish control over product success, face restrictions under license agreements, or encounter partners who prioritize other opportunities. Collaborations also carry risks: partners may control the level of effort and resources applied, discontinue development due to strategic shifts or funding issues, delay or repeat trials, demand new formulations, or develop competing products. They may fail to protect our intellectual property, misuse proprietary information, or engage in disputes that cause delays, litigation, or arbitration. In some cases, collaborators may co-own resulting intellectual property, limiting our exclusivity. We cannot guarantee collaborations will yield expected benefits. Failure to secure suitable partners could force us to scale back, delay, or self-fund development and commercialization, requiring additional expertise and capital that may not be available, materially harming our business, financial condition, results, and prospects.

We had a limited number of suppliers during the Track Record Period and the loss of one or more key suppliers could disrupt our operations.

For each year during the Track Record Period, purchases from our five largest suppliers, calculated on the group level, for 2024 and 2025 accounted for 27.2% and 28.9% of our total purchase cost for the respective period. Our suppliers primarily include CRO service providers and suppliers of the materials and equipment to support the R&D, clinical trial and manufacturing of our product candidates. We expect to continue our cooperation with these suppliers as we fund the continuing development activities of our product candidates in our pipeline. We believe that we have long and stable relationships with our existing large third-party suppliers. However, if any of our large suppliers terminates business relationship with us, we may encounter difficulty in finding a replacement that can provide services or materials of equal quality at a similar price.

We rely in part on third parties to manufacture our products. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product.

To date, we have relied on third-party CDMOs to manufacture our products. Our reliance on these third-party CDMOs exposes us to certain risks, including, but not limited to, the following: we may be unable to identify CDMOs that may meet some or all acceptable terms; our CDMOs may have limited capacity or limited manufacturing slots; we do not have full control over our CDMOs’ compliance with these regulations and requirements; our CDMOs might be unable to timely manufacture our products or produce the quantity and quality required to meet our commercial needs, if any; our CDMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed; our

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CDMOs may violate the intellectual property rights of third parties; our CDMOs could terminate their agreements with us; and our CDMOs and their suppliers may be subject to inclement weather, as well as natural or man-made disasters, which may lead to interruption of supply. Any disruption in the production or the inability of our CDMOs to deliver our products or meet our business needs on a timely basis may have a material and adverse effect on our business.

Our Directors, employees, principal investigators, consultants, commercial partners and independent contractors may engage in misconduct or other improper activities. We may be unable to detect, deter and prevent all instances.

We are exposed to risks of fraud, bribery, misconduct or other illegal activity by our Directors, employees, principal investigators, consultants, commercial partners and independent contractors that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. If we obtain approval for any of our product candidates and begin commercializing those drugs, our potential exposure under relevant laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our clinical trials, and our use of information obtained in the course of patient recruitment for clinical trials, as well as proposed and future sales and marketing programs. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

Additionally, we could be liable for actions taken by them that violate anti-bribery, anti-corruption and other related laws and regulations in China, the United States or other jurisdictions. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees or commercial partners. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our Shares could be adversely affected if we are associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our Directors, employees or commercial partners. We cannot assure you that there will not be any instances of fraud, bribery, or other misconduct involving our Directors, employees and other third parties that had any material and adverse impact on our business and results of operations in future, and we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

We depend on a stable and adequate supply of quality materials, devices and equipment from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require materials such as active pharmaceutical ingredients, reagents and consumables, devices and equipment. Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the R&D of our product candidates. However, there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our product candidates or our ability to timely meet market demand for our commercialized products. Our suppliers may not be able to cater to our growing demand or may reduce or cease their supply of materials at any time. Even if our suppliers have adequate capacity to meet our demand, they may fail to deliver the materials in a timely manner due to logistics difficulties or other reasons beyond their control.

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We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

Risks Relating to Our Intellectual Property Rights

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (“CNIPA”), United States Patent and Trademark Office (“USPTO”) and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant 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 any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business. As of the Latest Practicable Date, we did not own any issued patent related to one of our clinical stage products, OMTX705, and we only had exclusive licensed rights in issued patents from license-in arrangements.

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

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the CNIPA, USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. Even if we conduct our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the

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defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activities and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future product candidates. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

If our patent terms expire before or soon after our product candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed.

Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the United States. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. 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, as a result, 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. Upon the expiration of our issued patents or patents that may issue from our patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and in-licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Moreover, the applicable time period or the scope of patent protection afforded could be less than what we request. If we are unable to obtain a patent term extension or the term of any such extension is less than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed.

In addition, some of our patents have been co-owned and may in the future be co-owned with third parties. The patent application relating to the combination of ifebemtinib with D1553 will, upon approval, be co-owned by us and an independent third party pursuant to an agreement between the parties. In addition, all rights to inventions and discoveries made in connection with the combination of ifebemtinib and Cobimetinib will be co-owned by the Company and Roche pursuant to a Clinical Supply Agreement between the parties, and all inventions arising from the combination of ifebemtinib and RNK08954 will be co-owned by the Company and Ranok pursuant to a Cooperation Agreement between the parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. Besides this, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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We may from time to time be involved in legal proceedings and disputes.

Our intellectual property rights (including those transferred or licensed from third parties, if any) could be challenged or invalidated. For example, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. On the other hand, competitors or other third parties may infringe or misappropriate our patents and other intellectual property rights. In the event of any potential infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. 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. In addition, if the breadth or strength of protection provided by our patents and other intellectual property rights is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future product candidates. Any loss of intellectual property protection could have a material adverse impact on one or more of our product candidates and our business.

An adverse result in any litigation or defense proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or investors perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our Shares. There is no assurance that our product candidates will not be subject to the same risks.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisers have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or including such undertakings in agreements with parties that have access to them, such as our employees, consultants, and other third-party corporate partners. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

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Furthermore, certain of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees might have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individuals’ former employer, and in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. In the event that our trademarks or trade names are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and cause substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Changes in patent and other intellectual property laws of China, the United States or other jurisdictions could diminish the value of our patents in general.

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the United States or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

Risks Relating to Government Regulations

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with relevant laws, regulations and industry standards or any adverse actions by the regulatory authorities against us could negatively impact our reputation and our business.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to implement a global development strategy, with a focus on China and the United States, the major pharmaceutical markets in the world. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ a broad range of strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

We are required to obtain and maintain certain licenses and permits for conducting our business. The process of obtaining regulatory approvals and compliance with appropriate laws, regulations and guidance requires the expenditure of substantial time and financial resources. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or

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permits or promulgates new laws and regulations that require additional approvals or licenses or imposes additional restrictions on the operation of any part of our business, it has the power, among other things, to levy fines, confiscate our income, revoke our business licenses, and require us to discontinue our relevant business or impose restrictions on the affected portion of our business. In particular, failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an approval, license revocation; clinical hold, voluntary or mandatory product recalls, product seizures; total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution and disgorgement, or other civil or criminal penalties. Failure to comply with these laws, regulations and guidance could have a material and adverse effect on our business and prospects.

In many countries or regions where a product is intended to be ultimately sold, including without limitation, China and the United States, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such product, as well as strict rules, regulations and industry standards on how we develop such product. For example, we may need to obtain clearance from the NMPA, the FDA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our products, 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 laws, 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.

If we are unable to obtain without undue delay any regulatory approvals for our product candidates in our target markets, our business may be subject to actual or perceived harm.

The time required to obtain the approval of the NMPA, the FDA and other comparable regulatory authorities is uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take years to be obtained following the commencement of pre-clinical studies and clinical trials. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. We cannot guarantee that we will be able to obtain regulatory approvals for our other existing product candidates or any product candidates we may discover, in-license or acquire and seek to develop in the future. Our product candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including but not limited to failure of our clinical trials to demonstrate safety and efficacy, or to meet the level of statistical significance required for approval.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a product candidate with an indication that is not desirable for the successful commercialization of that product candidate. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

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If we are able to commercialize our product candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. We intend to seek approval to market our product candidates in China, the United States, and other jurisdictions. In China, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved product candidates successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the National Healthcare Security Administration of China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the “NRDL”), or provincial or local medical insurance catalogues for the National Medical Insurance Program (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. There can be no assurance that any of our future approved product candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our product candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to the affordability of the government’s Basis Medical Insurance.

In the United States, there is no uniform policy of medical insurance coverage and reimbursement for drugs. In China, the average period for innovative drugs to be included in the NRDL or the PRDL has shortened from five to two years. Obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

We cannot be sure that reimbursement will be available for any approved product candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved product candidates that we commercialize. There may be significant delays in obtaining reimbursement for approved product candidates, and coverage may be more limited than the purposes for which the product candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payers for any future approved product candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

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Even after we obtain regulatory approval, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses.

If any of our product candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information, including requirements of regulatory authorities in China, the United States and other jurisdictions. These requirements also include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacture Practices (the “cGMP”) and Good Clinical Practice (the “GCP”) for any clinical trials that we conduct post-approval.

Any approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, which could adversely affect the product’s commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidates. The NMPA, the FDA or a comparable regulatory authority may also require a REMS program as a condition of approval of our product candidates or following approval.

Once a product is approved by the NMPA, the FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the product, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products, it may result in, among other things: restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory recalls; fines, warning letters or holds on our clinical trials; refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; refusal by the NMPA, the FDA or comparable regulatory authorities to accept any of our other IND approvals and NDAs; product seizure or detention, or refusal to permit the import or export of products; and injunctions or the imposition of civil, administrative or criminal penalties. In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China, the United States or other jurisdictions, where the regulatory environment is constantly evolving. If we are unable to maintain regulatory compliance, or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained, and we may not achieve or sustain profitability.

We may be directly or indirectly subject to applicable healthcare and security laws and regulations in China and other jurisdictions, which could expose us to sanctions, penalties, damages, and diminished profits and future earnings.

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our product candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法), the PRC Criminal Law (中華人民共和國刑法), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, HIPAA, and the U.S. Physician Payments Sunshine Act.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Government authorities could conclude that our business practices may not comply with current or future statutes, regulations or

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case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business. Furthermore, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to environmental protection, health and safety laws and regulations.

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment, the use of toxic and hazardous chemicals in the process of our business operations and fire prevention. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of our product candidates. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. We may also be forced to close or suspend operations at certain of our affected facilities temporarily or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. In terms of the construction of our R&D, manufacturing or other facilities, they can be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety examine and approve such facilities. We cannot assure you that we will be able to obtain all regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all such requisite regulatory approvals may affect our abilities to develop, manufacture and commercialize our product candidates as we plan.

We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

We and the CRO service providers we engage may routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or potentially sensitive information. As such, we are subject to the relevant local, state or provincial, national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal information in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance including, for example, substantial operational costs associated with changes

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to our data processing practices. Failure to comply with any of these laws could result in enforcement action against us, including and without limitation to fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material and adverse effect on our business, financial condition, and results of operations or prospects.

The personal information of patients or subjects which might be involved in our clinical trials could be highly sensitive and we are subject to strict requirements under the applicable privacy protection regulations in the relevant jurisdictions. Our security policies and measures to protect our proprietary data and patients’ privacy might not satisfy all the requirements in every respect under the applicable laws and regulations. Data leakage and abuse and other misconduct related to data and personal information protection might not be completely avoided, due to hacking activities, human error, employee misconduct or negligence or system breakdown, among other reasons. We also cooperate with hospitals, CRO service providers and other business partners, licensees, contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with data/privacy policies or data/privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personal information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

Changes in laws and regulations relating to the pharmaceutical industry may result in additional compliance risks and costs.

In China, the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the pharmaceutical industry and the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, see “— If we are able to commercialize our product candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business” for more details. These legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our product candidates in the future. Moreover, these laws and regulations may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

We may face risks from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “Scientific Data Measures”), which provided a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, if the provision of scientific data involving “state secrets” is required in foreign exchanges and cooperation, Chinese enterprises should clarify the type, scope and purpose of the data to be used, and report to the competent authority for approval in accordance with relevant procedures of confidentiality management regulations. When publishing a paper in a foreign academic journal requires the author to submit the relevant scientific data, the author should, prior to the publication, submit such scientific data to the belonged institution for unified management if such scientific data are generated with the government funding. Given the term “state secret” is not clearly defined in the Measures for the Management of Scientific Data, we cannot assure you that we can always obtain relevant approvals for sending scientific data, such as the results of our pre-clinical studies or clinical trials conducted within the PRC, abroad or to our foreign partners in the PRC. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of product candidates may be hindered, which could

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materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to rectification and other administrative penalties imposed by those government authorities.

OTHER RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net cash outflows from our operating activities during the Track Record Period, and we may need to obtain additional financing to fund our operations.

Our net cash used in operating activities was RMB120.2 million and RMB172.3 million for the years ended December 31, 2024 and 2025, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may experience net cash outflows from operating activities for the foreseeable future. Our product candidates require substantial investments for the completion of clinical development, regulatory review, manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We will need to expend substantial resources on the R&D and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to, the progress of our clinical trials, regulatory process, manufacturing and commercialization plans, and our business growth in general. If the financial resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

We had net liabilities of RMB980.9 million as of December 31, 2025, and we recorded net current liabilities of RMB994.2 million as of December 31, 2025. While we believe we have sufficient working capital to fund our current operations, we may have net liabilities and/or net current liabilities for the foreseeable future. Net liabilities and/or net current liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Fair value changes in our financial instruments issued to [REDACTED] and related valuation uncertainty may materially affect our financial condition and results of operations.

We recorded fair value loss on financial liabilities at FVTPL of RMB46.1 million and RMB70.5 million for 2024 and 2025, respectively. We designated the Preferred Shares as financial liabilities at fair value through profit or loss, which may directly affect our financial performance and results of operations. The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect the actual fair value of these financial liabilities and result in significant fluctuations in profit or loss from year to year, which could materially and adversely affect our financial performance and results of operations. The financial liabilities of such Preferred Shares will be derecognized and credit to equity as a result of the automatic conversion into Shares upon the [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the Preferred Shares.

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The discontinuation of any government grants or preferential tax treatment currently available to us may adversely affect our business, financial condition and results of operations.

We benefited from government grants and preferential tax treatment during the Track Record Period. We recorded government grants of RMB3.3 million and RMB1.6 million for 2024 and 2025, respectively. Such government grants included a variety of subsidies in support of our research and development activities. We cannot assure you that we will continue to receive government grants or preferential tax treatment at the existing levels, or at all. The relevant authorities may issue administrative decisions or modify government policies that reduce the amount of government grants and preferential tax treatment that has been available to us, or end our eligibility to receive such financial subsidies. The discontinuation of government grants or preferential tax treatment currently available to us may adversely affect our results of operations and prospects. Further, prospective [REDACTED] should note that should there be any changes in the amounts of our government grants and preferential tax treatment in a given year, our financial performance for that period may not be directly comparable to our historical financial results.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

The RMB has fluctuated against Hong Kong dollar and the U.S. dollar at times significantly and unpredictably. We incurred net foreign exchange losses of RMB0.9 million and RMB0.4 million for 2024 and 2025, respectively. We cannot assure you that RMB will not appreciate or depreciate significantly in value against Hong Kong dollar or the U.S. dollar in the future. It is difficult to predict how market forces may impact the exchange rate between RMB and foreign currencies in the future. Significant revaluation of RMB may have a material and adverse effect on your [REDACTED]. For example, to the extent that we need to convert Hong Kong dollars we receive from this [REDACTED] into RMB for our operations, appreciation of RMB against Hong Kong dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB into Hong Kong dollars for the purpose of making payments for dividends on our Shares or for other business purposes, appreciation of Hong Kong dollar against RMB would have a negative effect on the Hong Kong dollar amount available to us. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure or at all. As a result, fluctuations in exchange rates may have a material adverse effect on your [REDACTED].

The impairment of our prepayments and other receivables may affect our business operations.

During the Track Record Period, our prepayments, primarily included service and material and prepaid expenses, were RMB3.8 million, and RMB5.1 million as of December 31, 2024 and 2025, respectively; our other receivables, primarily included deposits, were RMB1.7 million, and RMB1.8 million as of December 31, 2024 and 2025, respectively. For details, see Notes 15 and 16 to the Accountants’ Report set out in Appendix I to this document. We conduct assessments on the recoverability of prepayments and other receivables based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate, or any precautions we take to prevent an impairment will be effective, as we are not in control of all the underlying factors affecting such prepayments and other receivables. If we are not able to recover the prepayments and other receivables as scheduled, our financial position and results of operations may be adversely affected.

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Unanticipated changes in our tax rates or trade policies that we are subject to, or imposition of any additional taxes and surcharges could adversely affect our business, financial condition, results of operations and prospects.

Our business is subject to a wide variety of complex domestic and international laws, rules and regulations, including trade policies and tax regimes. We may face evolving tax regimes in the countries or regions in which we operate, including interpretations by the courts and regulators, whether prompted by changes in government administrations or otherwise which could adversely affect our effective tax rate or exposure to additional tax liabilities. We strive to comply with applicable tax laws and regulations in each of the countries or regions in which we operate, but there can be no assurance that we will be successful in doing so, which could result in material adverse effects on our business, financial condition, results of operations and prospects. These laws, regulations and policies, and changes thereto, may result in restrictions or limitations to our current operational practices and could have a material adverse effect on our financial condition, results of operations and prospects.

OTHER RISKS RELATING TO OUR OPERATIONS

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Since our inception, we have made significant strides in expanding our organization and enhancing our operational capabilities. Our future financial performance and our ability to commercialize our product candidates 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. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on our management, including but not limited to, recruitment and management. If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially adversely affect our business, financial condition, results of operations and prospects.

The loss of any key members of our senior management team or our inability to attract, hire and retain highly skilled scientists, clinical and sales personnel could delay or prevent the successful development of our product candidates and result in material and adverse effects on our business and results of operations.

Our commercial success depends heavily on the continued service of senior management, for more details of our senior management, see “Directors and Senior Management”. Loss of any senior leader could materially harm our business. Employment agreements do not prevent executives from leaving at any time, and recruiting and retaining qualified scientific, technical, clinical, sales, and marketing personnel is critical. To retain staff, we provide equity incentives, but their value depends on share price performance and may not offset more attractive offers elsewhere. Loss of executives or key employees could impede R&D, commercialization, and strategic execution. Competition for talent in the pharmaceutical industry is intense, and the pool of qualified candidates is limited. Departures of senior or key personnel, whether or not they join competitors, could disrupt development and harm operations. Replacing executives or specialists is difficult and time-consuming due to the limited number of individuals with the necessary expertise. Intense

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competition may force us to offer higher compensation or benefits, adversely affecting our financial condition. We may also struggle to train staff to keep pace with technological and regulatory standards. Any inability to attract, retain, or train qualified personnel could materially harm our business, financial condition, results, cash flows, and prospects.

We may engage in acquisitions or strategic partnerships in the future, which may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities or 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, including: increased operating expenses and cash requirements; the assumption of additional indebtedness or contingent or unforeseen liabilities; the issuance of our equity securities; assimilation of operations, intellectual property and products of an acquired company; the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; risks and uncertainties associated with the other party to such a transaction; and our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. According to the Anti-Monopoly Law of PRC (《中華人民共和國反壟斷法》) and the Provisions of the State Council 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》), issued by the State Council, 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 filed in advance to the SAMR when the threshold is crossed and such concentration shall not be implemented without the clearance of prior filing.

We may be exposed to risks of conducting our business and operations in international markets.

International markets are an important component of our growth strategy. We plan to advance our comprehensive business model combining self-development and collaboration, and pursue and strengthen strategic partnership with pharmaceutical companies over the world. We actively seek to reach and expand strategic relationships with international and domestic reputable pharmaceutical companies to advance the global development and commercialization of our pipeline assets. However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to: efforts to enter into collaboration or licensing arrangements with third parties may increase our expenses or divert our management’s attention from the development of product candidates; changes in a specific country’s or region’s political and cultural climate or economic condition; differing regulatory requirements for product approvals and marketing internationally; difficulty of effective enforcement of contractual provisions in local jurisdictions; potentially reduced protection for intellectual property rights; unexpected changes in tariffs, trade barriers and regulatory requirements; compliance with tax, employment, immigration and labor laws for employees traveling abroad; and business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires. These and other risks may materially adversely affect our ability to attain or sustain revenue and profits from international markets.

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We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

From time to time, we may be involved in inspections, claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, privacy protection, environmental and safety matters, breach of contract, employment or labor disputes and intellectual property rights. Any inspections, claims, disputes or legal proceedings initiated by us or brought against us, our management or directors, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, inspections, claims, disputes or legal proceedings against us, our management or directors may be due to actions taken by our counterparties, such as our suppliers, CRO service providers and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings. Moreover, we may be subject to claims or legal proceedings arising from incidents or events that are not directly related to our operations or are beyond our control, and any such claims or proceedings could result in significant costs, diversion of management attention, and have a material adverse effect on our business, financial condition, results of operations and reputation.

We are subject to risks associated with our leased properties.

We have leased certain properties used as office premises, laboratories, and employee dormitories in the PRC. Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As at the Latest Practicable Date, we and the lessors had not filed 2 of our leases with the governmental authorities due to various reasons, including, without limitation, the failure or unwillingness of the lessors to provide relevant documents. The failure to file and obtain property leasing filing certificates for such leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed.

Any failure to comply with the PRC regulations regarding mandatory social insurance and housing provident fund contributions may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) which was last amended on December 29, 2018 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to open social insurance registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties. According to the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), as amended in 2002 and 2019, the relevant housing fund authority may order an enterprise to pay outstanding contributions within a prescribed time limit.

On July 31, 2025, the Supreme People’s Court of the People’s Republic of China promulgated the Interpretation of the Supreme People’s Court on the Application of Law in the Trial of Labor Dispute Cases (II) (Judicial Interpretation [2025] No. 12), which became effective on September 1, 2025. The interpretation provides that any agreement between an employer and an employee, or any unilateral undertaking by an employee to an employer, waiving the payment of social insurance premiums shall be invalid. Where an employer fails to pay social insurance premiums in accordance with applicable law, and the employee requests termination of the labor contract and payment of economic compensation pursuant to Article 38(3) of the Labor Contract Law, the people’s court shall grant such a request in accordance with the law. In circumstances described in the preceding

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paragraph, where the employer subsequently remedies the non-payment by making social insurance premium payments in accordance with the law, and requests that the employee return any social insurance compensation already paid, the people’s court shall grant such a request in accordance with the law. During the Track Record Period and up to the Latest Practicable Date, we had not entered into any such arrangements with our employees, nor had our employees made unilateral undertakings that social insurance premiums could be waived. During the Track Record Period, we made full contributions to social insurance and the housing provident fund for all of our employees in accordance with the relevant regulations, both directly and through third-party human resources agencies. During the Track Record Period, we engaged third-party human resources agencies to pay, on behalf of our Company, the relevant contributions to social insurance and housing provident funds for certain offsite employees. If the local governments determine the use of third-party agencies to pay social insurance and housing provident funds to be non-compliant or such human resource agencies fail to make such contributions for and on behalf of our employees as required by applicable PRC laws and regulations, we may be required to pay outstanding amount, late fees and/or fines imposed by the relevant PRC authorities for failing to discharge our obligations to pay social insurance and housing provident funds as an employer or be ordered to rectify.

As the laws and policies related to social insurance and housing provident fund may continue to evolve, we cannot assure you that our employment policies and practices will always be regarded as fully complying with the relevant laws and regulations in China, and we may face labor disputes or government investigations. The PRC government may strengthen its measures and requirements on social insurance and housing provident fund collection, which may lead to stricter law enforcement. Compliance with stricter regulatory requirements may increase our operating expenses, especially our staff costs. We cannot guarantee that the amount of social insurance contributions we would be required to pay will not increase, nor that we would not be required to pay any shortfall or be subject to any penalties or fines, any of which may have a material and adverse effect on our business and results of operations.

Increased labor costs could result in exceeding expenses, slow our growth and affect our profitability.

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused by labor disputes.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate globally and rely on suppliers outside the U.S., exposing us to risks from political, diplomatic, and security factors that may lead to trade restrictions or regulatory changes. The international trade environment is highly uncertain, with recent U.S. tariffs and foreign retaliatory measures creating a volatile landscape that could adversely affect our business, financial condition, and prospects. We depend on third parties to manufacture product candidates for clinical testing and, if approved, for commercialization. Current or future tariffs may raise R&D costs, disrupt supply chains, delay clinical timelines, and hinder cost-effective production, placing us at a competitive disadvantage and reducing [REDACTED] confidence. Tariffs and trade restrictions also increase compliance risks, potentially subjecting us or our partners to enforcement actions.

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Foreign governments may adopt non-tariff measures, reduce IP protection, delay approvals, or impose sanctions, further limiting our ability to compete internationally and attract investment. Trade disputes and political tensions may exacerbate inflation, currency volatility, market instability, and economic downturns. The ultimate impact of tariffs and restrictions remains uncertain but could materially harm our business, financing ability, operations, and prospects, while heightening risks described elsewhere in this document.

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 the PRC laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover AEs in our clinical trials. We maintain social welfare insurance for our employees in accordance with applicable laws and regulations. In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claims that we may have. 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, and may adversely impact our product development and overall operations.

Product liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

We face inherent risks related to product and professional liability as a result of the clinical testing and any future commercialization of our product candidates inside and outside China. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. 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 the claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulatory authorities; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance to cover AEs in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

Our internal information technology systems, or those used by our business partners, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CRO service providers, partners, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss

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of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our pipeline could be delayed.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation.

Any negative publicity concerning us, our affiliates, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could adversely affect our reputation and business prospects. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were in compliance with any laws or regulations or 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. In addition, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our [REDACTED].

We may be subject to natural disasters, acts of war or terrorism, epidemics or other factors beyond our control.

Natural disasters, acts of war, terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Our business could be adversely affected by the effects of epidemics. Any such occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories. In recent years, there have been outbreaks of epidemics globally.

Difficult conditions and turbulence in the global economic, political and financial environment may adversely affect our business.

The global macroeconomic environment is facing numerous challenges. In particular, there is significant uncertainty about the future relationship between the United States and its major trading partners, including China, with respect to trade policies, treaties, government regulations and tariffs. The growth rate of the Chinese economy has generally been slowing since 2012. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world’s leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa, which have resulted in market volatility. There have also been concerns on the relationship between the United States and certain Asian countries, which may potentially have economic effects. For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo entitled the “America First Investment Policy” (the “America First Memo”), outlining the ongoing review and consideration of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, directed energy, and other areas implicated by the PRC’s national military-civil fusion strategy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds,

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university endowments and other limited partner investors. Such political tensions and policy changes would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations and financial condition.

Our Single Largest Group of Shareholders may have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately following the completion of the [REDACTED], our Single Largest Group of Shareholders will hold in aggregate approximately [REDACTED]% of the voting power at general meetings of our Company, assuming the [REDACTED] and the [REDACTED] are not exercised. Our Single Largest Group of Shareholders will, through their voting power at the Shareholders meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Single Largest Group of Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Single Largest Group of Shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

RISKS RELATING TO DOING BUSINESS IN THE JURISDICTIONS WHERE WE OPERATE

Changes in social and economic policies, as well as the interpretation and implementation of the relevant laws, rules and regulations, may affect our business, financial condition, results of operations and prospects.

Our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, legal and social conditions in the jurisdictions where we operate. A substantial portion of our operations are based in China, our business, financial condition, results of operations and prospects may be affected by economic, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources. However, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations in relation to economic matters are promulgated from time to time, including those related to such as foreign investment, corporate organization and governance, commerce, taxation, finance, foreign exchange and trade, so as to develop a comprehensive system of commercial law. Furthermore, the interpretation and implementation of the laws and regulations relating to pharmaceutical industry also evolve from time to time. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

There might be uncertainties in effecting service of legal process, enforcing foreign judgments against us or our Directors and senior management personnel in the PRC.

We are a company registered by way of continuation in the BVI with substantially all of our assets located within China. Most of our Directors and senior management members reside in China and the majority of their assets are within China. It may be difficult or impossible for you to enforce a judgment between these jurisdictions if you have not agreed on sole jurisdiction with the other party. As a result, you may encounter difficulty in enforcing foreign judgments against us or our Directors or senior management members.

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Judgments of courts of another jurisdiction may be reciprocally recognized or enforced if the jurisdiction has a treaty on that with China. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《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》) (the “2006 Arrangement”), pursuant to which reciprocal recognition and enforcement of the judgment may be possible between these two jurisdictions provided that the judgment is rendered by a final court of these two jurisdictions and the parties have an expressly written choice of court.

On January 18, 2019, 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 (《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》) (the “2019 Arrangement”) was signed between the Supreme People’s Court of China and Hong Kong, and such arrangement came into effect on January 29, 2024. Compared with the 2006 Arrangement, the 2019 Arrangement seeks to establish a bilateral legal mechanism with greater clarity and certainty for reciprocal recognition and enforcement of judgments between Hong Kong and the PRC in civil and commercial matters under both Hong Kong and PRC laws. The 2019 Arrangement applies to judgments made by the courts of Hong Kong and the PRC on or after its commencement date. The 2006 Arrangement was superseded upon the effective date of the 2019 Arrangement. However, the 2006 Arrangement will remain applicable to a “choice of court agreement in writing” as defined in the 2006 Arrangement which is entered into before the 2019 Arrangement takes effect. As the 2019 Arrangement went effective relatively recently, its implementation and interpretation are still evolving.

Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of the PRC may limit our ability to pay dividends and other obligations and affect the value of your [REDACTED].

The remittance of currency in and out of China is subject to various laws and regulations. Our revenues and expenses are substantially denominated in Renminbi, and the [REDACTED] from the [REDACTED] and any dividends we pay on our Shares will be in Hong Kong dollars. Under China’s existing foreign exchange regulations, following the completion of the [REDACTED], we will be able to make current account foreign exchange transactions, including paying dividends in foreign currencies without prior approval from SAFE. However, in the future, the PRC government may take measures to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. If such measures are implemented, we may not be able to pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under our capital account are subject to significant foreign exchange controls and require SAFE’s approval. These limitations could affect our ability to obtain foreign exchange through offshore financing. Furthermore, the [REDACTED] from the [REDACTED] are expected to be deposited in currencies other than Renminbi until we obtain necessary approvals from relevant PRC regulatory authorities to convert these [REDACTED] into onshore Renminbi. If the [REDACTED] cannot be converted into onshore Renminbi in a timely manner, our ability to deploy these [REDACTED] efficiently may be affected as we will not be able to [REDACTED] these [REDACTED] on Renminbi-denominated assets onshore or deploy them in uses onshore where Renminbi is required. All of these factors could materially and adversely affect our business, financial condition and results of operations.

The interpretation and implementation of the PRC Foreign Investment Law may evolve from time to time, which may impose new burdens on us.

The PRC Foreign Investment Law (the “FIL”) was enacted by the National People’s Congress of the PRC on March 15, 2019, and became effective on January 1, 2020. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, the changes in interpretation and implementation of the FIL and its Implementation Rules may increase our compliance costs or set higher standards

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on our corporate governance practice. For instance, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

Failure by our Shareholders or beneficial owners who are PRC residents to make required applications and filings pursuant to regulations relating to offshore investment activities by PRC residents may prevent us from distributing dividends and could expose us and our Shareholders who are PRC residents to liability under Chinese laws.

In 2014, the SAFE promulgated the Circular of the State Administration of Foreign Exchange on Relevant Issues concerning Foreign Exchange Control on Domestic Residents’ Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《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》) (“SAFE Circular 37”). SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents’ legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a “special purpose vehicle.” If the shareholders of the offshore holding company who are PRC residents do not complete their registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries.

We may not be fully informed of the identities of all our Shareholders or beneficial owners who are the PRC residents, and therefore, we may not be able to identify all our Shareholders or beneficial owners who are PRC residents to ensure their compliance with SAFE Circular 37 or other outbound investment related rules. The failure or inability of our PRC resident Shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, restrict our cross-border investment activities, and limit the ability of our PRC subsidiaries to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into the PRC subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operation and our ability to distribute profits to you could be materially and adversely affected.

We may 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 as an exempted company in the BVI, 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 incurs 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. In addition, the ability of our PRC subsidiaries to make payments to us is subject to any changes in the laws and regulations relating to the currency conversion, capital outflow management and cross-border transactions.

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Any failure to comply with PRC regulations regarding the registration requirements for employee stock incentive plans of overseas publicly listed companies may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, the SAFE promulgated the Notices of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Domestic Individuals’ Participation in Equity Incentive Plans of Overseas Listed Companies (《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》). In accordance with these rules and other relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. Any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our PRC subsidiaries to distribute dividends to us.

Dividends paid by our PRC subsidiaries to us may be subject to PRC withholding taxes.

The PRC Enterprise Income Tax Law (“Enterprise Income Tax 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 [REDACTED] jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to the PRC withholding tax at a rate of 10%. Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, 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 a Hong Kong tax resident as well as the beneficial owner of our PRC-sourced income, and it directly holds 25% or more interests in our PRC subsidiaries. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement, also known as Circular 9, which provides guidance for determining whether a resident of a contracting state or region 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 to any of our Hong Kong subsidiaries.

We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law and become subject to tax liabilities.

Under the Enterprise Income Tax Law, an enterprise established outside the PRC with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for the PRC enterprise income tax (“EIT”) purposes. The implementing rules of the Enterprise Income Tax 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, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (“Circular 82”) specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and

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departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. State Administration of Taxation of the PRC has subsequently provided further guidance on the implementation of Circular 82.

If the PRC tax authorities determine that our BVI holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC EIT purposes, a number of tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. Second, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax. Finally, dividends paid by us to our non-PRC shareholders, and any gain realized from the transfer of our Shares by our non-PRC shareholders, may be treated as income derived from sources within China. As a result, dividends paid to our non-PRC resident enterprise shareholders may be subject to PRC withholding tax and gains realized by our non-PRC resident enterprise shareholders from the transfer of our Shares may be subject to PRC tax. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

Filing with the CSRC may be required in connection with our future offerings, and we cannot predict whether we will be able to complete such filing.

On February 17, 2023, the CSRC released Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理 試行辦法》) (the “Overseas Listing Trial Measures”) and five relevant guidelines, which became effective on March 31, 2023. Pursuant to the Overseas Listing Trial Measures, PRC domestic companies which, after the overseas offering and listing, offers subsequent securities in the same overseas market or conducts offering and listing in other overseas markets (the “Future Offerings”), shall complete the filing procedures of, and report relevant information to, the CSRC. See “Regulatory Overview — Principal Regulatory Laws and Regulations — Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies.” Based on the foregoing, for the Future Offerings after the proposed [REDACTED], we are required to comply with the filing procedures of the CSRC. It is uncertain whether we can, or how long it will take us to, complete filings procedures in connection with the Future Offerings. We may be subject to approval, filing or other requirements by other PRC government authorities under the PRC laws in the future. Any failure to complete the relevant procedures may have an adverse effect on Future Offerings.

RISKS RELATING TO THE [REDACTED]

No [REDACTED] currently exists for our Shares, and an active [REDACTED] for our Shares may not develop and the [REDACTED] for our Shares may decline or become volatile.

Prior to this [REDACTED], there has been no [REDACTED] for our Shares. The [REDACTED] for our [REDACTED] was the result of negotiations among us and the [REDACTED] (on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the [REDACTED] for our Shares following this [REDACTED]. We have [REDACTED] for [REDACTED] of and permission to [REDACTED] our [REDACTED] on the Stock Exchange. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for the Shares will develop, especially during the period when a certain portion of our Shares may be subject to lock-up, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED]. In addition, the [REDACTED] price and [REDACTED] volume of the Shares may be subject to significant volatility in responses 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 [REDACTED] of the shares of other companies engaging in similar business may affect the price and [REDACTED] volume of our Shares. In addition to market and industry factors, the price and [REDACTED] volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates,

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the results of our applications for approval of our product candidates, regulatory developments affecting the pharmaceutical markets, 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 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.

Future sales or perceived sales of a substantial number of our Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the price of our Shares and our ability to raise additional capital in the future and may result in dilution of your [REDACTED].

Prior to the [REDACTED], there has not been a [REDACTED] for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the [REDACTED] or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our Shares and our ability to raise equity capital in the future.

As the [REDACTED] of our [REDACTED] is higher than our net tangible book value per share, [REDACTED] of our Shares in the [REDACTED] may experience immediate dilution upon such purchases. [REDACTED] of Shares may also experience further [REDACTED] in shareholdings if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the [REDACTED] in the [REDACTED] will experience an immediate [REDACTED] in [REDACTED] net tangible asset value, and our existing Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible assets per Share of their Shares. In order to expand our business, we may consider offering and issuing additional Shares in the future. [REDACTED] of the [REDACTED] may also 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.

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

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] 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 received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] in our Shares will likely 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 [REDACTED]. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

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We cannot guarantee the accuracy of facts, forecasts and other statistics obtained from official government sources or other publicly available sources, representing the information and statistics from official government sources that have not been independently verified, contained in this document.

Facts, forecasts and statistics in this document relating to the biopharmaceutical industry in and outside China are obtained from various sources including official government publications that we believe are reliable. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, we cannot guarantee the quality or reliability of these sources. The information from official government sources has not been independently verified by us, the Joint Sponsors, [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

You should read this entire document carefully and should not consider or rely on any particular statements in published media reports without carefully considering the risks and other information contained in this document.

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information. You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your [REDACTED] 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 [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] 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.