
RISK FACTORS

An [REDACTED] in our H Shares involves various 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 H Shares. The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our H Shares could decline and you may lose all or part of your [REDACTED]. You should seek professional advice from your relevant advisors regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

We depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially affected.

All of our drug candidates are still in development. Our ability to generate revenue and realize profitability depends on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development, manufacturing and commercialization of our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to successful completion of preclinical and clinical studies, obtaining positive results in our clinical trials, and receipt of relevant regulatory approvals.

Some of our drug candidates employ novel therapeutic approaches which carry inherent development risks and may result in delays or failures in clinical development, regulatory approval, or commercialization. Modifications to clinical protocols or regulatory requirements relating to safety or efficacy may delay our programs and could require us to supplement, modify, withdraw or refile regulatory applications. We may fail to obtain full approval in a timely manner, and any conditional approval granted may be revoked if we do not satisfy post-marketing requirements. As of the Latest Practicable Date, all of our drug candidates were in clinical or pre-clinical stages and none had reached the NDA/BLA stage, and we have no prior experience obtaining regulatory approval. As a result, securing regulatory approval may involve greater uncertainty, longer timelines and higher costs than for companies with established approval experience.

We may not succeed in identifying, discovering, or developing new drug candidates, or in identifying additional opportunities for our existing candidates, which could limit the expansion or maintenance of our product pipeline.

There is no assurance that our internal research programs will enable us to identify new drug candidates, uncover additional therapeutic opportunities for existing candidates, or develop suitable drug candidates. Oncolytic immunotherapy that we intend to identify could also be technically challenging to develop and manufacture. Although our research programs may initially show promise in identifying potential indications or drug candidates, they may ultimately fail to advance to development for various reasons, including, but not limited to, unsuccessful research methodologies and nontransferable experimental results obtained from cell or animal studies.

We devote substantial resources to research and development to create, improve, or adapt to new technologies and methodologies, but these efforts may not always succeed.

To remain competitive in the rapidly evolving global biopharmaceutical markets, we must continuously adapt to new technologies and methodologies, which requires continuous investment of human and financial resources. Our research and development expenses were RMB102.8 million in 2024 and RMB84.3 million in 2025. Nevertheless, there is no assurance that we will succeed in

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developing, enhancing, or adapting to new technologies and methodologies. Failure to effectively adopt or accelerate such technologies in our R&D of novel therapies could lead to significant waste of human and financial resources.

We operate in a highly competitive industry, and competitors may discover, develop, or commercialize products more quickly or successfully than we do, which could adversely affect our ability to bring our drug candidates to market.

Major pharmaceutical companies, established biotechnology firms, specialty pharmaceutical companies, and research institutions have already commercialized, are commercializing, or are developing drugs that compete with our candidates. For example, several biopharmaceutical companies have successfully obtained NMPA and/or FDA approval for oncolytic immunotherapy drugs. Many of our competitors may benefit from greater financial, technical, and human resources, more established commercialization infrastructure, and a broader pipeline of late-stage drug candidates. They may obtain approvals sooner or achieve stronger market acceptance in the same therapeutic areas, thereby undermining our position. Furthermore, mergers and acquisitions, collaborations with larger, established players, disruptive technologies and medical breakthroughs could intensify competition and render our drug candidates obsolete or noncompetitive.

The process of clinical development is time-consuming, expensive, and inherently uncertain, and we may experience unanticipated challenges in executing clinical trials or timely commercializing our drug candidates.

Clinical trials are costly, challenging to design and execute, and their outcomes remain highly uncertain. Unexpected events may arise during, or as a result of, our clinical trials, and these could delay or prevent us from obtaining the regulatory approvals necessary to develop and commercialize our drug candidates, including, among others, situations where we or our investigators may be required to initiate a trial or to conduct it at an unplanned site, or the patient enrollment may be insufficient or slower than we anticipate for a number of reasons including but not limited to the trial design and the eligibility criteria set out in the trial protocol.

Furthermore, regulatory approval, once granted, does not guarantee permanence: our drugs could be withdrawn from the market, we may be required to conduct additional post-marketing studies, and regulators could impose restrictions on how our drugs are distributed or used.

Clinical trial and other regulatory delays can substantially increase the costs of drug development. Prolonged delays could shorten the period of market exclusivity for our drug candidates, enable competitors to launch their products earlier, and ultimately impair our ability to commercialize our candidates, with a material adverse effect on our business and operating results.

Our clinical development activities may face delays or other adverse effects if we are unable to enroll patients in our trials as planned.

Patient recruitment can be particularly challenging in clinical trials involving late-line treatments for advanced cancers. In addition, regulatory authorities may define patient eligibility more narrowly than the criteria we use in our trials, which could further reduce the pool of patients eligible for our drug candidates and exacerbate recruitment difficulties. Our clinical trials may also face competition from other studies in the same therapeutic areas, as patients may choose to participate in a competitor’s trial rather than ours, thereby reducing both the number and diversity of patients available to us. Because the pool of qualified clinical investigators and trial sites is limited, we may need to conduct trials at the same sites used by competitors. Even if we ultimately enroll a sufficient number of participants, delays in enrollment can increase trial costs, affect trial timelines or outcomes, and potentially delay or prevent the completion of our studies, which could materially and adversely impact the advancement of our drug candidates.

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

We plan to develop certain of our drug candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. If the regulatory agency revokes its approval of any therapy we use in combination with our drug candidates, we will not be able to market our drug candidates in combination. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we 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 drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

Our clinical development of BS001, our Core Product, involves combination therapies with a specific PD-1 inhibitor. We currently use pucotenlimab for the combination therapy development in advanced solid tumors, including CRC, STS and BTC. If any circumstance arises to require us to substitute an alternative PD-1 inhibitor, we may not be able to locate such alternative PD-1 inhibitors within a reasonable period of time, if not at all. Even if we are able to find such substitution, the alternative PD-1 inhibitors could materially affect the safety and efficacy outcomes, and regulatory pathway of existing combination therapies. In particular, the NMPA, FDA or other regulatory authorities may require additional preclinical or clinical studies to demonstrate comparability. In addition, if we cannot source a sufficient amount of the alternative PD-1 inhibitors, or we experience any supply shortage of such alternative PD-1 inhibitors, the clinical development of our combination therapies in relevant indications may be disrupted. Furthermore, differences in pharmacodynamics, pharmacokinetics or manufacturing standards between different PD-1 inhibitors may introduce uncertainties regarding patient safety and therapeutic effectiveness. Any such disruption could result in increased development costs, extended timelines, or failure to achieve regulatory approval, which may adversely affect our business, financial condition and prospects.

Side effects or adverse events associated with our drug candidates may disrupt clinical trials, hinder or delay regulatory approvals, narrow product labeling, or create serious post-approval consequences.

Undesirable side effects and adverse events arising from the use of our drug candidates, whether alone or in combination with other therapies, could result in serious negative consequences, including but not limited to interruption or delay of clinical trials of our drug candidates and suspension of further development, which may prevent a drug candidate from obtaining or maintaining market acceptance and materially harm our business, financial condition, results of operations, and growth prospects.

The outcomes observed in our early-stage clinical trials may not necessarily predict the results of later-stage trials.

Early clinical trial results are not always indicative of outcomes in later-stage trials, and favorable initial or interim findings may not translate into positive final results. Even if our drug candidates advance through preclinical studies and early-stage clinical trials, they may still fail in later phases to demonstrate the expected safety or efficacy. Safety and efficacy outcomes for the same drug candidate can vary substantially across different clinical trials, resulting from numerous factors, including but not limited to changes in trial procedures specified in the protocols, differences in patient population size and demographics, levels of patient adherence to dosing regimens, other protocol-related elements, and participant dropout rates. Even if efficacy results appear favorable,

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not all patients may respond to treatment. In such circumstances, we may have already invested substantial capital to advance the relevant candidates without generating any revenue from them if regulatory approval is ultimately denied due to unsatisfactory clinical results. These unrecoverable expenditures could materially and adversely impact our business, financial condition, results of operations, and prospects.

Our drug candidates may not demonstrate the safety and efficacy required by regulatory authorities or otherwise fail to generate positive results, which could result in additional costs, significant delays, or the inability to complete their development and commercialization.

Negative or only modestly positive results yielded from clinical trials of our drug candidates for the proposed indications could result in, among others, delay or denial of regulatory approvals for our drug candidates or requiring additional clinical trials or other testing of our drug candidates, rendering our previous capital commitment futile.

The occurrence of any of these events may prevent an approved drug candidate from achieving or maintaining market acceptance, which could in turn materially harm our business, financial position, operating results, and future prospects.

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

As we have limited financial and managerial resources, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development platform and drug candidates for specific indications may not yield any commercially viable products. If we cannot accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

If the data or information generated through our research and development efforts is inaccurate or incomplete, our business, reputation, financial position, and results of operations could be materially harmed.

We collect, aggregate, process, and analyze data from our preclinical studies and clinical trials, as well as from additional information-gathering activities once a promising drug candidate is identified, which is often fragmented in origin, inconsistent in format, and incomplete. Mistakes in capturing, entering, or analyzing such data could materially impair our ability to advance the development of our drug candidates and could adversely affect our business, reputation, and prospects. Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a patient, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous, which may exceed our insurance coverage for clinical trials.

We are currently conducting and may in the future conduct certain clinical trials for our drug candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND with very limited and strict exceptions. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application

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on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA’s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in drug candidates that we may develop not receiving approval for commercialization in the applicable jurisdictions.

In the course of discovering, developing, and commercializing drugs, we are exposed to potential liabilities, particularly product liability claims or lawsuits, which could result in significant financial exposure.

Product liability claims could have wide-ranging negative effects, including reduced demand for our drug candidates, damage to our reputation, loss of clinical trial participants, and an inability to continue ongoing trials. They may also trigger regulatory investigations, increase litigation defense costs, and divert management’s attention and company resources. In addition, such claims could result in substantial damages awarded to trial participants or patients, product recalls or withdrawals, restrictions on labeling, marketing, or promotion, loss of revenue, depletion of available insurance coverage and capital resources, an inability to commercialize any approved drug candidate, and a decline in the market price of our H Shares. 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. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have limited experience in commercial-scale manufacturing of biopharmaceutical products

We cannot guarantee that manufacturing-related issues with our drug candidates will not arise in the future. The manufacturing of our drug candidates is subject to potential complications, which may arise from, among other things: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, and (iii) problems with raw materials. If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded and it may cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If manufacturing problems are not identified prior to the release of products to the market, we may face additional costs related to product recalls and product liability.

We may face damage to, destruction of or interruption of production at our facilities, which could impede the development plans for any subsequent commercialization efforts towards our drug candidates.

We have established commercial scale, GMP compliant facilities in Ezhou, China to support both the clinical development and future commercialization of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities and failure to catch up with advances in manufacturing techniques in the industry could result in our inability to satisfy the demands of our clinical trials or future commercialization. There can be no assurance that our existing manufacturing facilities will produce products in sufficient volumes in the event of any significant change in market demand. Manufacturing of our products depends on the continued service of qualified manufacturing personnel. We may experience unique difficulties attracting and

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retaining qualified manufacturing personnel in the future. If we are unable to maintain a sufficient number of qualified manufacturing personnel to support our products manufacture, production capacity may be adversely affected.

Our planned construction of new facilities in Wuhan and Shaoxing requires prior and ongoing review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements, which may be costly and time-consuming and could delay or halt the launch of our products. The new facilities will also be subject to pre-approval inspection. In addition, we have to demonstrate that the products made at the new facilities are equivalent to the products made at the former facilities by physical and chemical methods, which are costly and time consuming. Regulatory authorities may also require clinical testing as a way to prove equivalency, which would result in additional costs and delay. In the event we fail to increase our production capacity or develop the new manufacturing facilities, we may not capture the expected growth in demand for our products, or to successfully commercialize new products, each of which could materially and adversely affect our business prospects.

There is a risk that we may not be able to sustain effective quality control measures for our drug products, which could adversely affect their safety, efficacy, and marketability.

We cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. In addition, our internal management may result in ineffective implementation of quality control measures. Any of the above could make our drug products unsuitable for use, create deficiencies in process audits, and damage our reputation and business relationships and materially and adversely affect our business, financial condition, and results of operations.

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

Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates may prove to be incorrect and subject to further changes due to new studies. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates. Furthermore, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are aiming for. While we may seek approval for our drug 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 drug 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 drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, hospitals, patients, third-party payers and others in the medical community that would be necessary for their commercial success, and the actual market size of our drug candidates might be smaller than expected.

If our drug candidates (once approved and upon commercialization) do not achieve an adequate level of acceptance, the sales of our future drug products will be adversely affected, and we may fail to effectively market our drug candidates (once approved and upon commercialization). The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to the clinical indications for which our drug candidates are approved and efficacy and safety of our drug candidates.

Even if our future approved drug candidates 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 drug candidates, are more cost-effective or render our drug

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candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

Given our limited experience in commercializing drugs, there is a possibility that, if we cannot establish and manage sales networks or ensure sufficient sales and marketing capabilities, either internally or through third parties, we may fail to generate market awareness or achieve product sales, materially impacting our ability to derive revenue from our products.

We have not yet proven our ability to successfully launch or commercialize any of our drug candidates. Our commercialization abilities may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates. We may be unable to build and retain adequate in-house sales, marketing and distribution capabilities and face competition for qualified personnel. Alternatively, we may rely on third-party collaborators, but we may be unable to establish or maintain such arrangements on acceptable terms, if at all, or ensure their effectiveness. We also compete for access to third-party sales and distribution resources, which may be limited. Any revenue from collaborations would depend on third parties over whom we have limited control and may be lower than if we commercialized products ourselves. If we fail to develop sufficient commercialization capabilities internally or through collaborators, we may be unable to successfully commercialize any approved product or generate product sales revenue.

Counterfeit biopharmaceutical products and the illegal and/or parallel import of competing drugs may reduce demand for our drug candidates and compromise reputation, which could adversely affect our business.

The illegal importation of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in the PRC and other countries where we commercialize our products. Unauthorized foreign imports of prescription drugs are illegal under the current laws of the PRC. However, illegal imports have occurred and may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products.

Our drug candidates may be adversely affected by guidelines, recommendations, or studies published by medical, scientific, or regulatory organizations that do not support their use.

Publications of guidelines, recommendations, or studies by government agencies, professional associations, practice management groups, private foundations, or disease-focused organizations may influence the acceptance of our drug candidates as well as those of competitors. Any unfavorable content regarding our drug candidates, directly or indirectly, could diminish their use, sales, and revenues. Moreover, our efforts to inform and educate healthcare providers and patients about our drug candidates may be rendered ineffective by such third-party publications.

Evolving reimbursement practices and pricing policies at national, provincial, or third-party levels may impact our business.

Government agencies and third-party payers may restrict coverage, impose pricing controls, require predetermined discounts, mandate rebates or otherwise limit reimbursement levels to control costs, which may adversely impact the commercialization of our drug candidates. In China, inclusion in national, provincial or local medical insurance catalogs and reimbursement lists is subject to periodic review and update. There is no assurance that any of our approved drugs will be included, and such catalogs historically favor generic and essential medicines over innovative therapies. Unfavorable pricing or reimbursement determinations could limit our ability to recover development investments. In the United States, reimbursement policies vary by payer, and obtaining coverage is time-consuming and costly, requiring payer-by-payer submission of supporting clinical and

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cost-effectiveness data, with no assurance of approval or adequate reimbursement to achieve profitability. Interim payments may not become permanent or fully cover costs, payment rates may vary by clinical setting, be benchmarked against lower-cost alternatives, bundled with other services, or reduced by mandatory rebates. Because certain of our drug candidates may involve higher manufacturing costs and long-term follow-up requirements, the risk of inadequate reimbursement may be greater. If timely and sufficient coverage and reimbursement at profitable levels are not secured, demand for our products may be reduced and our business, operating results and financial condition could be materially and adversely affected.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we fail to obtain or maintain adequate patent and other intellectual property protection for our drug candidates in key markets worldwide, or if the scope of rights granted is too narrow, third parties may develop and commercialize drug candidates or technologies that are identical or similar to ours. Such competition could materially and adversely affect our ability to develop and commercialize our drug candidates or technologies.

Our success depends on our ability to obtain, maintain, defend and enforce adequate patent and other intellectual property protection for our drug candidates and technologies. We rely on patents, trade secrets, regulatory exclusivity and confidentiality agreements, but such protection is costly, time-consuming and inherently uncertain. Patent applications may be denied, and issued patents may be narrowed, invalidated, held unenforceable or subject to compulsory licensing or co-ownership limitations. We may fail to identify or timely protect patentable subject matter, may not have been first to file under applicable first-to-file systems, and may face post-grant challenges, inventorship disputes or prior art issues. Any loss, limitation or inability to enforce our intellectual property rights could permit competitors to develop and commercialize identical or similar products and materially harm our competitive position.

In addition, global patent protection is expensive and may be unavailable or weaker in certain jurisdictions, where enforcement standards, remedies and protection against government use or infringement may be limited. Competitors may design around our patents, exploit jurisdictions where we lack protection, or export competing products into markets where we hold rights. Enforcement proceedings may be costly, time-consuming, divert management resources, expose our patents to counterclaims or invalidation, and may not result in commercially meaningful remedies. If we fail to secure or effectively enforce adequate intellectual property protection worldwide, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Even where we are able to secure patent protection for our drug candidates, such protection is of limited duration. Once our patent rights expire, third parties could develop and commercialize products or technologies identical or similar to ours and compete directly with us, which would materially and adversely impact our ability to successfully commercialize any such product or technology.

Because the development, testing, and regulatory review of new drug candidates require significant time, the patents protecting such candidates may expire before or soon after commercialization. Although certain extensions may be available depending on the jurisdiction, the duration of a patent and the protection it provides are inherently limited. The actual term or scope of patent protection may be less than anticipated. If we fail to obtain a patent term extension, or if the extension is shorter than sought, competitors could secure approval of rival products once our patents expire, which could materially and adversely impact our business. Consequently, our patents and applications may not provide adequate rights to prevent others from commercializing products that are identical or substantially similar to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to

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grant extensions to our patents, or may grant more limited extensions than we request. In case of the occurrence of the foregoing events, our competitive position, business, financial conditions, results of operations and prospects may be materially and adversely affected.

We may need to initiate or defend lawsuits to protect or enforce our intellectual property rights, and such proceedings could be costly, protracted, and ultimately unsuccessful.

Third parties may dispute the ownership, validity or enforceability of our patents, or allege that we infringe, misappropriate or otherwise violate their intellectual property rights, requiring us to initiate or defend litigation to protect our interests. Such proceedings are costly, time-consuming and unpredictable, may divert management and technical resources, expose confidential information through discovery, and may not result in commercially meaningful remedies. We may not prevail, and the burden of successfully challenging third-party intellectual property rights may be high. If we are found to infringe or otherwise violate third-party rights, we could be subject to damages, licensing obligations, or injunctive or other equitable relief that could prevent or delay the development or commercialization of our drug candidates. Adverse outcomes could also invalidate, narrow or render unenforceable our patents, allowing competitors to commercialize competing products without compensation to us. Regardless of outcome, such proceedings may generate adverse publicity and harm our reputation and brand value.

We may also face inventorship or ownership disputes with former employees, collaborators or other third parties, and competitors with greater resources may be better positioned to pursue or defend intellectual property claims. Even if we succeed, litigation may involve substantial expense and disruption. If our intellectual property rights are successfully challenged, inadequately enforced, or otherwise compromised, we could lose exclusivity, diminish our ability to partner or commercialize our drug candidates, and suffer material adverse effects on our competitive position, business, financial condition, results of operations and prospects.

If we do not obtain adequate protection for our trademarks and trade names, our ability to establish brand recognition in our target markets may be impaired, which could adversely affect our business.

Our trademark registrations and applications may face objections, refusals, opposition or cancellation proceedings by governmental authorities or third parties, and we cannot assure that our pending or future applications will be approved or maintained. Our registered or unregistered trademarks and trade names may also be challenged, infringed, circumvented, declared generic, or determined to infringe third-party rights. Competitors or other third parties may adopt marks similar to ours, causing market confusion and hindering our ability to build and maintain brand identity and recognition among customers and partners. If we are unable to secure or effectively enforce trademark protection, or if we are required to change our brand names, our ability to compete effectively and our business could be materially and adversely affected.

If we fail to protect the confidentiality of our trade secrets, our business and competitive position could be adversely affected. In addition, we may face claims alleging that our employees, consultants, or advisors have improperly used or disclosed trade secrets belonging to former employers, or claims asserting ownership of intellectual property that we consider to be our own.

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates.

Despite confidentiality and assignment agreements, we may be unable to prevent unauthorized disclosure, misuse, independent development, or lawful acquisition of our trade secrets, and monitoring and enforcing our rights can be difficult, costly, time-consuming, and unpredictable. We may also fail to secure effective confidentiality or intellectual property assignment agreements with all relevant parties, or such agreements may be breached, ineffective, or subject to competing third-party obligations, resulting in disputes over ownership of intellectual property we consider our own. Moreover, current or former employees, consultants, or advisors may be subject to prior

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obligations to other employers, and we may face claims alleging misappropriation of third-party trade secrets or other proprietary rights. Any such disputes or litigation, regardless of outcome, could result in significant costs, diversion of management and scientific personnel, monetary damages, or loss of valuable intellectual property rights, and could materially and adversely affect our business and competitive position.

Because intellectual property laws and regulations continue to evolve, future changes could adversely affect the value of our intellectual property and limit the scope of protection for our drug candidates, thereby impairing our competitive position.

In the pharmaceutical industry, securing and enforcing patents is a technologically and legally complex process that is costly, time-consuming, and inherently uncertain. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the applicable authorities, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

Patent protection is contingent on compliance with numerous procedural, regulatory, and other requirements, and failure to meet these obligations could result in the reduction or loss of our patent rights.

The governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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.

Intellectual property rights do not necessarily protect us from all potential threats.

The intellectual property legal systems vary across different countries and regions, introducing uncertainty to the protection of corporate intellectual property. The intellectual property protection in various countries has its limitations, which may be insufficient to fully safeguard our business or enable us to maintain a competitive edge. The limitations of the intellectual property protection system include but not limited to that others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that are not covered by the claims of the patents that we own or license now or in the future; or we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future.

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

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RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are a clinical-stage biopharmaceutical company, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage biopharmaceutical company with a relatively short operating history. Our operations to date have focused on business planning, raising capital, establishing our drug portfolio and conducting clinical trials of our drug candidates. All of our drug candidates were still at various stages of development and we had not commercialized any of our drug candidates as of the Latest Practicable Date. Our limited operating history, particularly in the rapidly evolving biopharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. Our future financial performance will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential [REDACTED] to lose substantially all of their [REDACTED] in us.

We have experienced net losses since our inception and expect to continue incurring net losses for the foreseeable future. We may be unable to generate sufficient revenue to achieve or sustain profitability.

[REDACTED] in biopharmaceuticals is highly unpredictable in terms of commercial success. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We incurred losses and net operating cash outflows in each period since our inception. In 2024 and 2025, we recorded loss for the year of RMB113.1 million and RMB120.9 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from administrative expenses associated with our operations. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our research and development of our product and drug candidates, as well as to enhance our sales and marketing efforts.

In 2024 and 2025, we recorded net cash used in operating activities of RMB98.9 million and RMB96.0 million, respectively. For a detailed operating cash flow analysis, please see “Financial Information—Liquidity and Capital Resources—Cash Flows—Net Cash Used in Operating Activities.” Negative operating cash flow may require us to obtain additional financing to meet our financing needs and obligations and support our expansion plans. We cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities, we will incur additional financing costs, and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, which may materially and adversely affect our liquidity and financial condition and we may not be able to expand our business as expected. If we encounter long-term and continuous net operating cash outflow in the future, we may not have sufficient working capital to cover our operating costs, and our business, financial condition and results of operations may be materially and adversely affected.

We have historically received government grants, subsidies and other preferential policies for our R&D and other activities and enjoyed preferential tax treatment during the Track Record Period. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

We have historically benefited from government grants, subsidies and other preferential policies as incentives for our R&D and other activities. We recorded government grants of RMB7.5 million and RMB5.4 million in 2024 and 2025, respectively. Please refer to the paragraphs headed “Financial Information—Description of Selected Components of Consolidated Statements of Loss

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and Other Comprehensive Expense—Other Income and Gains” in this document for further details. The government grants and preferential income tax treatment are subject to the discretion of the central government or relevant local government authorities, which could determine whether to eliminate, suspend or reduce these financial incentives or our eligibility for the preferential income tax treatment, generally with prospective effect. Since our receipt of the government grants and eligibility for the preferential income tax treatment are subject to periodic time lags, as long as we continue to receive these government grants and enjoy the preferential income tax treatment, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these government grants or preferential income tax policies in addition to any business or operational factors that we may otherwise experience. There is no assurance that we will continue to receive such government grants, receive similar level of government grants, or at all, or be eligible to enjoy the preferential income tax treatment in the future, which could have an adverse effect on our business, financial condition and results of operations.

We are subject to credit risks arising from prepayments, other receivables and other assets.

As of December 31, 2024 and 2025, we recorded prepayments, other receivables and other assets of RMB36.0 million and RMB52.7 million, respectively. We may be exposed to credit risk with our counterparties and may not be able to collect all of such receivables due to a variety of factors that are outside of our control. If the relationship between us and any of our counterparties is terminated or deteriorated, or if our counterparties experience financial or operational difficulties, the recoverability of our receives may be negatively affected, which may have an adverse effect on our business, financial condition and results of operations.

Our financial performance and results of operations may be adversely affected by fair value changes of our financial assets at FVTPL.

As of December 31, 2024 and 2025, we recorded financial assets at FVTPL of RMB113.0 million and RMB79.2 million, respectively. Our financial assets at FVTPL represented investments in structured deposits and wealth management products. As these wealth management products were not traded in active market, their fair values were determined based on the expected rate of return on our investment. The valuation involves the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs. As a result, such treatment of carrying amounts of our financial assets measured at FVTPL may cause significant volatility in or materially and adversely affect our period-to-period earnings, financial condition and results of operations.

Share-based payments may impact our financial performance and cause shareholding dilution to our existing Shareholders.

We operate the Employee Incentive Scheme for the benefit of our Directors, senior management and core employees as remuneration for their services provided to us and to incentivize and reward the eligible persons who have contributed to the success of our Company. For further details, see “Appendix V—Statutory and General Information—D. Employee Incentive Scheme.” We recorded share-based payments of RMB10.0 million and RMB14.4 million in 2024 and 2025, respectively.

Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.

Valuations of our properties as of January 31, 2026 prepared by Cushman & Wakefield are set forth in the report set out in Appendix III to this Document. The valuations are made based on assumptions which, by their nature, are subjective and uncertain and may differ from actual results. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the valuation of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value.

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Fluctuations in exchange rates could result in foreign currency exchange losses.

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably due to changes in political and economic conditions and by foreign exchange policies, among other things, making it difficult to predict. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future, which may result in the decrease in the value of our [REDACTED] from the [REDACTED] which will be received in Hong Kong dollars. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the State Administration of Foreign Exchange of the PRC (the “SAFE”) before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors including, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others, which may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms. In addition, natural disasters, health epidemics, acts of war or 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, which may materially and adversely impact our business.

RISKS RELATING TO OUR OPERATIONS

Our reputation, business, operating results, and future prospects could be materially and adversely affected if we fail to comply with regulatory requirements and industry standards, or if we are unable to obtain or renew necessary approvals, licenses, and permits.

Numerous governmental agencies and industry regulatory bodies in the PRC, the U.S., and other relevant jurisdictions impose stringent rules, regulations, and industry standards on biopharmaceutical research and development activities, all of which are applicable to us. Our or our CROs’ failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business, failure of which may result in enforcement actions thereunder, including being required to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations.

Our business could be materially and adversely affected if we lose any key members of our senior management team or are unable to recruit and retain the highly skilled scientists, and clinical personnel necessary to support our operations.

As a biotechnology company, our success is highly dependent on the expertise, leadership and vision of a limited number of key research and development personnel, in particular our founder and chairperson of our Board, Dr. Liu brings over 30 years of specialized expertise in tumor immunology and oncolytic virology, including his role as a core member of the original R&D team for IMLYGIC® (talimogene laherparepvec, or T-VEC), the first oncolytic virus drug ever approved by the FDA. See “Business—Our Competitive Strengths—Top-tier Management Team with Global Vision and Deep Medical Expertise, Supported by Prominent Investors”, “Business—Research and Development—Our In-house R&D Team” and “Directors and Senior Management” for more details. His expertise in the technical challenges, development strategies, and regulatory pathways

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specific to oncolytic virus therapies is highly difficult to replicate. Under Dr. Liu’s leadership, our R&D team has built our proprietary oncolytic HSV-2 platform and successfully executed multiple national scientific programs. Dr. Liu has played, and is expected to continue to play pivotal roles in shaping our research and development strategies, driving scientific innovation and overseeing the execution of our core business initiatives. His deep industry knowledge, technical expertise and extensive experience have been instrumental to our achievements during the Track Record Period, and we expect his continued involvement to be critical to our future prospects. Should Dr. Liu leave the Company, our research and development capabilities, strategic plans, clinical development timelines, and business operations could be materially and adversely affected. The loss of his leadership and technical guidance could result in significant delays to our programs and negatively impact our ability to execute our business strategy.

Although we have not historically experienced difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the pharmaceutical industry is intense, and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced senior management or key scientific and clinical personnel in the future. The departure of one or more of our senior management or key scientific and clinical personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material adverse effect on our business and results of operations. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. 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 as well as difficulty to recruit new employees due to the reputational damage caused by labor disputes.

If we are unable to effectively manage our anticipated growth or to successfully implement our growth strategies, our business, financial condition, results of operations, and prospects could be adversely affected.

Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global and Chinese pharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

Since our inception, we have significantly expanded the size and capabilities of our organization, which may lead to challenges in effectively managing our 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 personnel management and development of advanced technology.

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We are subject to risks associated with our owned or leased properties.

We have facilities under development in Wuhan and Shaoxing, and expect to obtain the relevant building ownership certificate upon completion of construction and inspection. See “Business—Properties—Owned Land and Properties.” However, we cannot guarantee that our construction project will be completed or that the relevant certificates will be obtained as planned, or at all. There can be no assurance that we will not be subject to any punishment, challenges, lawsuits or other actions taken against us with respect to these properties. In addition, failure to file lease agreements with relevant authorities for record and obtain property leasing filing certificate may result in fines from RMB1,000 to RMB10,000 for each unregistered agreement under the relevant PRC laws and regulations. See “Business—Properties.” As of the Latest Practicable Date, we were not aware of any notice or allegation of penalty from PRC government authorities for our failure on the registration of lease agreements.

We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to increased operating expenses and cash requirements and the assumption of additional indebtedness or contingent or unforeseen liabilities. Such acquisitions may also subject us to investigations and requirements under 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》).

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

We plan to explore market opportunities overseas, where we believe there is substantial demand for our drug candidates, and we intend to identify and collaborate with reputable companies that have proven track record to maximize the global value of our drug candidates. We will also continue to seek licensing and co-development opportunities with global partners, and expand our global clinical programs. For more details, see “Business—Our Strategies.” 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 increasing expenses and diversion of our management’s attention from the development of drug candidates.

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

We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

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, CROs 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.

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We are subject to environmental protection, health and safety laws and regulations, and if we or our CROs and other business partners fail to comply with these laws and regulations, we could be subject to fines, penalties, or other adverse consequences or incur costs that could have a material adverse effect on our business.

We and certain third parties we work with, such as our CROs and other business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities.

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

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, principal investigators, consultants and commercial partners.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, 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.

Our information technology systems, or those used by our CROs and partners, other independent contractors or consultants, may fail or suffer security breaches, which may require us to expend additional resources to protect our information technology systems and could materially and adversely affect our business, financial condition, results of operations and prospects.

Despite the implementation of security measures, our information technology systems and those of our CROs, 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. 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 drug candidates could be delayed.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.

Any negative publicity concerning us, 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. 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

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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].

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. These third parties are also required to comply with applicable regulatory requirements. If these third parties do not successfully carry out their contractual duties, fail to comply with regulatory requirements, or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have relied on and plan to continue to rely on third-party CROs and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs, while remaining responsible for ensuring compliance with applicable protocols and regulatory standards, including GCP, GLP and cGMP requirements enforced by the NMPA, the FDA and other comparable authorities. If these third parties fail to perform to our standards, comply with regulatory requirements, devote sufficient resources, adhere to protocols, or meet expected timelines, the quality or integrity of our data may be compromised, our trials may be delayed, suspended or terminated, and regulatory authorities may require additional studies or decline to approve our marketing applications.

Our dependence on third parties also limits our direct control and internal capacity, and requires us to share proprietary and confidential information, increasing risks of misappropriation. If existing relationships terminate, we may be unable to engage alternative providers on a timely or commercially reasonable basis, and switching providers could result in additional costs and delays. Any such performance failures, compliance issues, disruptions, or delays could materially and adversely affect our development timelines, regulatory approvals, financial condition and business prospects.

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

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Some of these are important to the business and performance of our Group. See “Business—Collaboration Agreements.” Any of these relationships may require us to incur nonrecurring and other charges, increase our near-and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

The expected revenue, cost synergies, or other benefits from these collaborations are uncertain and may be offset by additional costs, operating losses, or other challenges. Termination, expiration, or non-renewal of any collaboration or license agreement could result in loss of development or commercialization opportunities, delays in clinical programs, or increased costs, and there is no assurance that anticipated benefits will be achieved. We face competition in securing collaborators, and managing relationships across territories can be complex. In collaborations, we may relinquish control over drug candidates, and for in-licensed candidates, we may face competition from larger companies. Disputes may arise over development priorities, payments, territorial rights, or competitive activities, potentially leading to delays, termination of collaborations, or costly litigation or arbitration. Failure to manage these risks, individually or collectively, could materially and adversely affect our business, financial condition, results of operations, and growth prospects, including our ability to expand into global markets.

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If our business partners fail to maintain the necessary licenses for the development, manufacturing and commercialization of our products, our business could be materially affected.

Our business partners, such as CROs and other suppliers, on whom we may rely on to develop, manufacture, market, sell and distribute our drug candidates, may be subject to requirement of obtaining and maintaining necessary permits, licenses and certificates in their operations. If our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Any changes in the standards used by governmental authorities in considering whether to renew or reassess our business partners’ licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business partners’ operations, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our business, financial condition and results of operations.

We have only limited customers during the Track Record Period.

We are a clinical-stage biotechnology company and have not commercialized any of our drug candidates during the Track Record Period. As a result, we had a limited number of customers, and our revenue was derived from (i) provision of research and development services, (ii) sales of reagents and consumables for R&D purposes, and (iii) other revenue generated from leasing of equipment. Please refer to the section headed “Business—Customers” for more details.

If we cannot maintain or develop clinical collaborations and relationships with principal investigators, physicians and other industry experts, our results of operations and prospects could be adversely affected.

Our relationships with principal investigators, physicians and other industry experts play an important role in our research and development and marketing activities. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products. Situations including, but not limited to, cease of their roles or their collaboration with us, inaccuracy of their market insights and perceptions, and change of their business or practice focus may adversely affect our business, financial condition and results of operations.

RISKS RELATING TO GOVERNMENT REGULATIONS

The research, development, and commercialization of pharmaceutical products are extensively regulated across all material aspects of the industry. Any failure to comply with existing or evolving regulatory requirements and industry standards, or any unfavorable action taken by drug approval authorities, could adversely affect our reputation and materially harm our business, financial condition, results of operations, and prospects.

All jurisdictions in which we operate or intend to operate our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products in great depth and detail. Regulatory regimes cover product development and approval, manufacturing, marketing, sales, and distribution, and differences or changes in these regimes could increase compliance costs. We must obtain and maintain necessary licenses and approvals, and failure to comply with applicable laws, regulations, or guidance—at any stage of development, approval, or post-approval—could result in administrative or judicial sanctions, including fines, license revocation, clinical holds, product recalls or seizures, suspension of production or distribution, injunctions, or other civil or criminal penalties. Such failures could materially harm our business, financial condition, results of operations, and prospects. In the jurisdictions where our drugs are intended to be sold, including China, authorities impose strict standards on drug efficacy and on the development process. Noncompliance may lead to termination of ongoing research, disqualification of data, fines, bans on future sales, or other punitive actions. Even if we successfully defend against

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any regulatory action, we could incur substantial legal expenses, divert management attention, and suffer reputational damage, all of which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Failure to comply with relevant regulations relating to social insurance and housing provident fund may subject us to penalties and adversely affect our business, financial condition, results of operations and prospects.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to social insurance and housing provident funds for our employees. According to the Interpretation II of the Supreme People’s Court of Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) enacted by the Supreme People’s Court on July 31, 2025 and implemented on September 1, 2025, where the employer and the employee agree, or the employee promises the employer, that there is no need to make social insurance contributions, the people’s court shall determine that such agreement or promise is invalid. During the Track Record Period, we did not make full contributions to the social insurance and housing provident funds for certain employees in accordance with the relevant PRC laws and regulations. We have since rectified the housing provident fund contributions, and have been making full contributions in compliance with applicable requirements starting from February 2024.

Our Directors are of the view that the aforementioned failure to fully contribute to social insurance and housing provident funds would not have a material adverse effect on our business, financial condition or results of operations. As confirmed by our Directors, as of the Latest Practicable Date, no administrative action or penalty had been imposed by the relevant regulatory authorities with respect to our social insurance and housing provident funds, and we had not received any material complaint from any of our employees as a result of our arrangement with respect to social insurance and housing provident funds. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance or to pay any penalty related thereto.

Changes in laws, government regulations, policies, or in practices relating to the biopharmaceutical industry may affect our business.

Changes in laws, government regulations, policies, or practices relating to the biopharmaceutical industry may affect our business. Such changes may include, but are not limited to, marketing approval procedures, clinical trial requirements, manufacturing standards, intellectual property rights, data privacy, foreign investment restrictions, environmental standards, antitrust laws, and pricing and reimbursement policies. Changes in patent laws or their interpretation in China, the United States, or other jurisdictions may increase uncertainties and costs in prosecuting our patents, limit our ability to obtain, maintain, defend, and enforce intellectual property rights, and affect the value or scope of our patents. For example, the fourth Amendments to the PRC Patent Law (《中華人民共和國專利法第四次修正案》) and the third Amendments to Implementing Rules of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則第三次修訂稿》) introduced patent term extension and adjustment mechanisms, which may extend third-party patents and affect our ability to commercialize drug candidates without facing infringement risks. Any delay in commercialization could allow technological advances or new products to reduce the competitiveness of our drugs. Future changes to PRC intellectual property laws could further negatively impact our intellectual property protection.

We are also subject to evolving domestic and foreign investment laws and regulations, including the PRC Foreign Investment Law (《中華人民共和國外商投資法》) and related measures such as the Special Administrative Measures (Negative List) (《外商投資法特別管理措施(負面清單)》), as well as U.S. regulations like the final rule implementing Executive Order 14105 (Outbound

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Investment Rule). Changes to these laws may impose investment restrictions, additional filing requirements, and increased costs, limiting strategic transactions, financing, or investment activities. Further, new or amended laws and regulations may increase the difficulty and cost of obtaining regulatory approvals, commercializing our drug candidates, and achieving competitive pricing. Relaxations or tightening of regulatory requirements, or inspections of our facilities to monitor compliance, could materially and adversely affect our business, financial condition, results of operations, and prospects.

The regulatory approval processes relating to the marketing of our drug candidates are lengthy, time-consuming and can be changed. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.

Generally, approval from the NMPA and FDA take many years to obtain, following the commencement of preclinical 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 drug candidate’s clinical development and may vary among jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes. Our drug 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, disagreement with the design or implementation of our clinical trials and failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional preclinical 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 drug 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 drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

If we are unable to obtain or maintain approval from the NMPA, the FDA and other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may have implemented expedited review programs for drug candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies. The NMPA’s Breakthrough Therapy Designation, for example, is intended to facilitate and expedite the development and review of an investigational drug to treat a serious disease or condition when preliminary clinical evidence indicates that the drug has demonstrated substantial improvement over current therapies. Similarly, the FDA may facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address medical need for the condition.

As of the Latest Practicable Date, BS001, our Core Product, has received one Breakthrough Therapy Designation from the NMPA, two Fast Track Designations from the FDA, as well as two Orphan Drug Designations from the FDA. For details, see “Business—Our Pipeline.” There can be no assurance, however, that the regulatory authorities will consider granting Fast Track

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Designation, Breakthrough Therapy Designation or other expedited review programs for our other or future drug candidates, or that we will decide to pursue or submit any applications for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited development, review or approvals, even if we initially decide to do so. Furthermore, there can be no assurance that such a submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all. In addition, expedited registration pathways may contain certain conditions related to use restrictions for certain patient populations, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our drug candidates and/or any future changes to current policies and approvals with respect to the expedited registration pathways of our drug candidates could result in a longer period of time prior to the commercialization of such drug candidate, an increase in the development expenses for such drug candidate and an adverse impact on our competitive position in the market.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security in data storage and data transfer, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. We routinely receive, collect and store desensitized and deidentified codes of subjects enrolled in our clinical trials, and process, transmit and maintain medical data treatment records and other personal details of the subjects, along with other personal or sensitive information. As such, we are subject to the relevant local, state, 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 data in the jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. Currently, we are primarily subject to numerous PRC laws and U.S. federal and state laws governing data protection and privacy. For further details on applicable PRC laws and regulations, please refer to the section headed “Regulatory Overview.”

Numerous U.S. federal and state laws regulate the privacy and security of personal information. In particular, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related regulations impose standards on the use, disclosure, and safeguarding of protected health information, and violations may give rise to significant liability and penalties. Ensuring compliance can be complex and is subject to evolving interpretation. Our systems may be vulnerable to cyberattacks, employee misconduct, or inadvertent breaches. Any unauthorized access, use, or disclosure of information could result in legal proceedings, regulatory penalties, mandatory notifications to regulators and affected individuals, reputational harm, and a loss of competitiveness.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage,

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investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we participate in compassionate use programs, current regulatory discrepancies among competent authorities of different countries may lead to increased risk of adverse drug reactions and serious adverse events arising from the use of our products.

Compassionate use programs are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. Currently, there is no unified approach or standard practice to regulate compassionate use programs among competent authorities in different countries for access to investigational drugs. In China, currently there is no officially approved regulation to oversee compassionate use programs. In the U.S., compassionate use programs are limited to patients who have a life-threatening disease or serious disease or condition, who may gain access to an investigational pharmaceutical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. The regulatory discrepancy for compassionate use programs among competent authorities in different countries may lead to uneven patient entry criteria and protocols for compassionate use programs. This may create increased risk of serious adverse events because of enrolled patients’ advanced disease or comorbidities. In addition, because the products in compassionate use programs are investigational drugs, many of which are still in experimental stages and have not received marketing approval, patients in compassionate use programs may exhibit adverse drug reactions from using these products. If we participate in compassionate use programs, we may be subject to the risk of enrolled patients exhibiting adverse drug reactions or serious adverse events arising from the use of our products. These occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs.

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

Our business operations and arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers are subject to broadly applicable healthcare, anti-fraud, and anti-bribery laws and regulations, including in China and under the U.S. Foreign Corrupt Practices Act. Compliance with these laws — including restrictions on marketing, sales, distribution, payments, and other financial arrangements — requires substantial costs and resources, and failure to comply could result in civil, criminal, or administrative penalties, fines, disgorgement, damages, exclusion from government programs, reputational harm, reduced profits, or curtailment of operations. Anti-bribery laws prohibit improper payments to government officials or other third parties to obtain business advantages, and violation could disrupt operations and result in severe penalties. As we expand globally, we may become subject to additional anti-fraud, anti-corruption, and healthcare compliance laws in other jurisdictions, and ambiguity in the scope or application of these laws may increase our risk exposure. Even if we successfully defend against enforcement actions, defending claims can be costly and time-consuming, and our business operations may still be materially and adversely affected.

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

A substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, 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. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. and international trade policies may cause significant disruptions to our drug candidate manufacturing and other operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions and local conditions in foreign countries and regions. China’s political relationships with foreign countries and regions may affect the prospects of our relationships with third parties, such as business partners, suppliers and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flow and prospects. Rising trade and political tensions could reduce levels of trade, investments, technological exchanges and other economic activities between China and other countries and regions, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

Recent changes in international trade policies, including the imposition or increase of tariffs, have created uncertainty in global markets. For example, the U.S. has implemented several new tariffs and increased existing tariffs, prompting retaliatory measures from other countries. These tariffs, or the threat of further tariffs, could increase the cost of importing raw materials essential for our operations and reduce the competitiveness of our future commercialized products in the U.S. market. Additionally, changes in trade policies may negatively impact companies reliant on international trade, including our potential collaborators and suppliers, thereby indirectly affecting our business. Trade policy changes within the life sciences sector can specifically harm our operations, such as creating non-tariff barriers that disrupt global clinical development or collaboration, and jeopardizing our specialized supply chains. Uncertainty surrounding future trade policies, tariffs, and regulations may also complicate our ability to plan for and manage costs, which could adversely affect our business operations and financial performance. Furthermore, retaliatory tariffs or other trade restrictions may impact our ability to effectively compete in certain markets, particularly the U.S., which could hinder our growth and long-term prospects.

Changes in geopolitical relationships, barriers to trade or escalation of trade disputes, including the imposition of trade restrictions and sanctions, could negatively affect demand for our products, and consequently could have a material adverse effect to our business, financial condition and results of operation.

Our global operations are subject to the risk of deterioration in the political and economic relations among countries and sanctions and export controls administered by the government authorities in the countries in which we operate, and other geopolitical challenges. We cannot predict whether the countries in which we operate, or may operate in the future, would become subject to new or additional trade restrictions and sanctions, including the type or effect of such restrictions and sanctions imposed by the United States or other governments. We cannot assure you that we, our research partners, our suppliers and customers, or the global value chains we serve will not be impacted in the future. Any impacts may result in our customers seeking other suppliers for

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the products that we offer, and we may be unable to recapture and/or replace such customers. We may also have to adjust or even terminate our collaborations with our research and other business partners, which could disrupt our research and development and commercialization strategies. Further, any increased customs restrictions and tariffs or quotas, or the imposition of additional duties and other charges on imports and exports could change the way we and our customers conduct business, increase our costs, or impede the timely delivery of our products. This could have a negative effect on our business, financial condition, results of operations and prospects.

In Particular, the United States government’s attitude towards Chinese service providers in pharmaceutical and biotechnology industries may directly or indirectly affect our business operations. Recently, members of the U.S. House of Representatives proposed pending legislation, namely the BIOSECURE Act (the “Act”). If the Act is enacted in its proposed form, it would prohibit U.S. federal executive agencies from: (1) procuring or obtaining any biotechnology equipment or service produced or provided by a “biotechnology company of concern”, (2) entering into or renewing a contract with an entity that uses such biotechnology equipment or enters into a contract requiring the use of such biotechnology equipment after the applicable effective date of the prohibition, or (3) providing loan or grant funds to perform either of these functions. For details, see “Regulatory Overview.”

Specifically, although the Act did not become law in the 118th Congress the House passed its version on September 9, 2024, and substantially similar provisions could be reintroduced in a subsequent Congress. If it is reintroduced and subsequently enacted in the proposed form, it could prohibit the U.S. government and recipients of federal funds from entering into contracts with us or with our customers if, in performing customer contracts, we supply equipment or services provided by a “biotechnology company of concern” under the Act. For example, such a law, if enacted in that form, could apply to some of the biotechnology equipment and services provided or produced we procure. As a result, continued use of these biotechnology equipment and services provided or produced could affect not only our ability to enter into contracts with the U.S. government, but also our customers’ ability to enter into contracts with, obtain loans or grants from, or participate in other assistance or joint research and development opportunities with the U.S. government.

Consequently, we may need to re-evaluate or adjust our established supply chains, should the Act or other similar legislation become law. The need to re-evaluate our supply chain contracts may impose additional costs and operational complexities on our business, including, among other things, an examination and potential modification to existing personnel and expertise, and examination of our existing contracts, and a re-assessment of our current suppliers in order to identify possible alternative sources of supply. We may not be able to identify alternative sources of supply with competitive prices and terms and satisfactory quality in a timely manner, and any disruption to our established supply chains may lead to delays in procurement, production, and delivery, all of which could have a material adverse effect to our business, financial condition and results of operation. Since the Act has not been enacted, its form, scope and context remain subject to changes, and such changes, if material, could also adversely affect our business, financial condition and results of operation.

Holders of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of H shares by such shareholders.

For non-PRC resident individuals, the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and its Implementation Regulations (《中華人民共和國個人所得稅法實施條例》), both effective January 1, 2019, impose a 20% tax on such dividends and gains, withheld by the withholding agent. Under the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion

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with respect to Taxes on Income (the “**Arrangements**”) (《關於內地與香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the PRC may levy taxes on dividends paid to Hong Kong residents, capped at 10% if the beneficial owner is not a company directly holding at least 25% of the payer.

For non-PRC resident enterprises, the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) and its Implementation Regulations (《中華人民共和國企業所得稅法實施條例》), effective December 29, 2018 and April 23, 2019 respectively, impose a 10% tax on income from China if the enterprise has no presence in China or the income is unconnected to such presence. Under the Arrangements, dividends paid to Hong Kong residents are taxed either in Hong Kong or under PRC law, with the tax capped at 5% for Hong Kong companies holding at least 25% of the PRC enterprise, or 10% otherwise. Accordingly, non-PRC resident holders of H Shares may be liable for PRC income tax on dividends and gains from their H Shares.

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 joint stock company incorporated in China. In addition, a majority of our Directors and senior management personnel reside within mainland China, and substantially all of their assets are located within the PRC, which may impede [REDACTED] ability to pursue claims. While the New Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters between the Courts of the Mainland and Hong Kong SAR, effective January 29, 2024, provides a framework for recognition and enforcement of certain judgments under choice of court agreements, it does not apply to all civil and commercial matters. In the absence of relevant treaties or arrangements, uncertainties remain regarding the enforceability of foreign judgments or arbitral awards in the PRC, which could limit [REDACTED] ability to recover claims. Therefore, it may be difficult for [REDACTED] to directly effect service of legal process upon us or our Directors and senior management personnel in the PRC.

RISKS RELATING TO THE [REDACTED]

We are subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with overseas [REDACTED] and future capital raising activities, including this [REDACTED].

On February 17, 2023, the China Securities Regulatory Commission (“CSRC”) promulgated the Trial Administrative Measures of 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》) (“**Overseas Listing Trial Measures**”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures have comprehensively improved and reformed the existing regulatory regime for overseas [REDACTED] and [REDACTED] of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities. For further details, please refer to the section headed “Regulatory Overview”.

We will file with the CSRC within the specific time limit as required by the Overseas Listing Trial Measures. In addition, it is uncertain whether we can or how long it will take us to complete the CSRC filing. Any failure to complete the CSRC filing may impede the [REDACTED] and may subject us to sanctions by the CSRC. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

No public market currently exists for our H Shares, and an active [REDACTED] market for our H Shares may not develop, especially taking into account that certain of our existing shareholders may be subject to a lock-up period.

No public market currently exists for our H Shares. The initial [REDACTED] for our H Shares to the public will be the result of our negotiations with the [REDACTED] (for themselves and on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the market price

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of the H Shares following the [REDACTED]. We have applied to the Stock Exchange for [REDACTED] of, and permission to deal in, our [REDACTED]. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the H Shares will not decline following the [REDACTED].

In particular, certain part of the H Shares in issue as of the date of this document will be subject to a lock-up period from the [REDACTED], which may significantly affect the liquidity and trade volume of our H Shares in the short term following the [REDACTED]. A [REDACTED] on the Stock Exchange does not guarantee that an active and liquid [REDACTED] market for our H Shares will develop, especially during the period when certain portion of our H Shares may be subjected to lock-up, or if it does develop, that it will sustained following the [REDACTED], or that market price of the H Shares will rise following the [REDACTED].

The interests of our Single Largest Shareholder Group may not necessarily be aligned with the interests of our other Shareholders.

The interests of our Single Largest Shareholder Group may differ from the interests of our other Shareholders. They could through their shareholding interest in our Company exert influence in determining the outcome of any corporate transaction or other matter submitted to our Shareholders for approval, including mergers, consolidations, the sale of all or substantially all of our assets, election of Directors, and other significant corporate actions. This as a result, may discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for their H Shares in a sale of our Company or may reduce the market price of our H Shares. In addition, to the extent the interests of our Single Largest Shareholder Group conflict with the interests of other Shareholders, the interests of other Shareholders may be disadvantaged or harmed

The price and [REDACTED] volume of our H Shares may be volatile, which could lead to substantial losses to [REDACTED].

The price and [REDACTED] volume of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and [REDACTED] volume of our H Shares. In addition to market and industry factors, the price and [REDACTED] volume of our H Shares may be highly volatile for specific business reasons, including but not limited to the results of clinical trials of our drug candidates and the results of our applications for regulatory approvals of our drug candidates. Moreover, shares of other companies [REDACTED] on the Stock Exchange have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

Future sales or perceived sales of our H Shares in the public market by major Shareholders following the [REDACTED] could materially and adversely affect the price of our H Shares.

Prior to the [REDACTED], there has not been a public market for our H Shares. Future sales or perceived sales by our existing Shareholders of our H Shares after the [REDACTED] could result in a significant decrease in the prevailing market price of our H Shares. Only a limited number of the H 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 H Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing market price of our H Shares and our ability to raise equity capital in the future.

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Should the [REDACTED] be higher than the net tangible book value per H Share, subject to pricing, you may experience an immediate dilution in the book value of the [REDACTED] you purchased in the [REDACTED].

Potential [REDACTED] will pay a price per H Share in the [REDACTED] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of December 31, 2025. Therefore, purchasers of our H Shares in the [REDACTED] will experience a substantial immediate dilution in [REDACTED] net tangible assets, and our existing Shareholders will receive an increase in the [REDACTED] adjusted net tangible assets per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [REDACTED] potential [REDACTED] would receive less than the amount they paid for their H Shares. For more details, please refer to “Appendix II—Unaudited [REDACTED] Financial Information” to this document.

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

We may finance our future cash needs through equity offerings, licensing arrangements or other collaborations, government funding arrangements, debt financings, or any combination thereof. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our H Shares to decline.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our H 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 drug 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 H Shares as a source for any future dividend income. Our Board has complete discretion 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 H Shares will likely depend entirely upon any future price appreciation of our H Shares. You may not realize a return on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

We may allocate the net [REDACTED] from this [REDACTED] in ways that you and other Shareholders may not agree.

Our management will have broad discretion in the application of the net [REDACTED] from this [REDACTED], including for any of the purposes described in the section titled “Future Plans and Use of [REDACTED].” Because of the number and variability of factors that will determine our use of the net [REDACTED] from this [REDACTED], their ultimate use may vary substantially from their currently intended use. Our management might not apply the net [REDACTED] in ways that ultimately increase the value of your [REDACTED], and the failure by our management to apply these funds effectively could harm our business. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results

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of operation. You will not have the opportunity, as part of your [REDACTED] decision, to assess whether [REDACTED] are being used appropriately. You must rely on the judgment of our management regarding the application of the net [REDACTED] of this [REDACTED].

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 convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency into and out of China are subject to PRC foreign exchange regulations. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations. Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. If we cannot obtain sufficient foreign currencies under the current foreign exchange control system to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

Any possible conversion of our Unlisted Shares into H Shares in the future could increase the number of our H Shares in the market and negatively impact the market price of our H Shares.

Potential conversion of Unlisted Shares into H Shares may result in an increase in the number of our H Shares available in the market, which could, in turn, affect the price of our H Shares. The PRC Company Law provides that in relation to the [REDACTED] of a company, the shares of that company which are issued prior to the [REDACTED] shall not be transferred within one year from the date of [REDACTED] of the [REDACTED]. Therefore, upon completing the requisite filing, our Unlisted Shares may be traded, after the conversion, in the form of H Shares on the Stock Exchange one year after this [REDACTED], which at that time could further increase the number of our H Shares available in the market and may negatively impact the market price of our H Shares.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On April 30, 2018, the Stock Exchange adopted rules under Chapter 18A of its Rules Governing the Listing of Securities on the Stock Exchange. Under these rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

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Facts, forecasts and statistics obtained from various government sources in this document relating to the pharmaceutical industry may not be fully reliable since we have not independently verify them.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources, comprising information provided or published by government agencies, and we can guarantee neither the quality nor reliability of such source materials. However, neither we, the Joint Sponsors, the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisors have verified information and statistics obtained from official government sources. Therefore, we make no representation as to the accuracy of such information and statistics. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate, and you should not place undue reliance on it. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon. The foregoing representation does not limit responsibilities of our Directors and the Sponsors on information sourced from expert reports.

Forward-looking information in this document is subject to risks and uncertainties.

This document contains certain statements and information that are forward-looking and uses forward-looking terminology such as “believe,” “expect,” “estimate,” “predict,” “aim,” “intend,” “will,” “may,” “plan,” “consider,” “anticipate,” “seek,” “should,” “could,” “would,” “continue,” and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations or warranties by us that our plans and objectives will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

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

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.