

RISK FACTORS

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

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

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to the Development of Our Drug Candidates

We depend substantially on the success of our drug candidates, almost all of which are undergoing preclinical or clinical development. If we are unable to successfully complete preclinical programs or clinical development of our drug candidates, obtain regulatory approvals or achieve commercialization for our drug candidates, or experience significant delays or cost overruns in doing any of the foregoing, our business prospects will be significantly impacted.

Our business will depend on the successful development of our existing and new drug candidates that we may identify and develop. We cannot guarantee that we can successfully complete the preclinical and clinical development of any of our existing drug candidates in a timely manner, or at all. Almost all of our drug candidates will require further preclinical and/or clinical development before they could obtain regulatory approval in China and potentially other jurisdictions.

A substantial portion of our drug candidates are biologic drugs indicated for the treatment of assisted reproductive and ophthalmology. Developing these drugs is a complex and challenging process that faces many challenges.

Therefore, we have significantly invested in the discovery and development of our drug candidates. We expect to continue to incur substantial expenditures as we develop and commercialize our drug candidates.

In this process, we may experience significant delays or cost overruns in completing or be unable to complete the development of our drug candidates, resulting in our inability to obtain regulatory approval for our drug candidate. As a result, we may fail to generate sufficient revenue or cash flow from product sales to continue our operations.

Clinical development involves a lengthy and expensive process with no assured outcome.

Clinical trials are expensive and difficult to design and implement and can take many years to complete with no assured outcome. As of the Latest Practicable Date, we had a pipeline of eight drug candidates in various phases of preclinical or clinical development. Expenditure on clinical trials recorded in our consolidated statements of profit or loss constituted a significant portion of our R&D expenditure during the Track Record Period.

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Commencement of clinical trials and subsequent marketing approval by the NMPA or other regulatory authorities are contingent on finalizing trial design and successful completion of trials. We cannot assure you as to when the clinical trials for our drug candidates which have not yet commenced pre-clinical or clinical trials will begin, if at all.

As a result, we may not be able to control the timing and expenses related to completing our clinical trials or obtaining regulatory approval. Unfavorable clinical trial results may force us to restructure our clinical trials, increase our drug development cost and delay our receipt of regulatory approval for our drug candidates. Therefore, it may take us longer to begin commercializing our drug candidates and navigate the path to profitability, potentially endangering our competitive advantage.

Delays or difficulties in enrolling patients for clinical trials may impede the progress of these trials and hinder our acquisition of regulatory approvals.

Our ability to initiate or continue clinical trials is dependent on enrolling a sufficient number of eligible patients as required by the NMPA or other relevant regulatory authorities.

This enrollment can be difficult, and its interruption or failure would result in significant delays, increased drug development costs and could even require us to abandon one or more clinical trials altogether. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Even with sufficient patient enrollment, external events like COVID-19 pandemic can cause delays. Such delays may increase costs, affect clinical trial timing or outcomes, prevent timely completion, and hinder our ability to advance drug candidate development, regulatory approval, and commercialization.

We may not achieve favorable results for our drug candidates in clinical trials and cannot give any assurance that any of our drug candidates currently in development will receive regulatory approval for further development or commercialization, which could hinder or delay their development.

Our drug candidates were in different stages of development as of the Latest Practicable Date. Our ability to generate revenue is dependent on obtaining regulatory approval for and successfully commercializing our drug candidates, which may never occur. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly, with no assured outcome.

In China, where almost all of our drug candidate development activities are presently located, we must first obtain regulatory approval from the NMPA before we can proceed to commercialize our drug candidates. Similarly, we cannot commercialize drug candidates in the United States, the European Union or other jurisdictions outside of China without obtaining regulatory approval from the FDA, the EMA or other relevant foreign regulatory authorities. The review procedures are comprehensive, stringent, expensive, and time-consuming, varying significantly based on the drug's nature.

Unfavorable findings, such as drug candidates being unsafe or ineffective, could halt development and prevent regulatory approval. The lengthy approval process is vulnerable to changes in regulations or policies, potentially delaying or rejecting applications. Such setbacks would make it difficult to recover invested time and cost, damaging financial prospects and reputation.

In addition, clinical trials accepted in one jurisdiction may not be recognized elsewhere due to differing requirements, population characteristics, or statistical methods. Therefore, approval in one region does not guarantee or facilitate approval in another, as processes vary globally and often require additional testing and review. Even successful clinical trials do not assure success in other

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jurisdictions. Furthermore, safety issues or product recalls in one market could negatively impact approval prospects in others. Failure to secure widespread regulatory approval, or approval with significant limitations, could severely impede funding and revenue, jeopardizing the continued development of current and future drug candidates.

Even after regulatory approval, authorities can revoke it, grant approval for limited indications, require post-marketing trials, or impose narrow labeling. They possess significant discretion, potentially rejecting applications or demanding additional studies if data is deemed insufficient.

Successful results in preclinical studies and early-stage clinical trials are not necessarily predictive of future trial results.

Even if our drug candidates demonstrate favorable results in pre-clinical studies and clinical trials, we cannot assure you that the results of clinical trials will be favorable enough to support the continued development of our drug candidates. In addition, the outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

Data interpretations vary, and many companies with promising early results still face significant delays, setbacks, or failures in all development stages, including regulatory approval. We cannot assure that our drug candidates, despite favorable early results, will achieve similar success in later clinical or post-clinical trials.

Later stage clinical trial results can vary and even if pre-clinical and clinical trial data show a satisfactory safety and efficacy profile, these results might not be sufficient to secure regulatory approval from authorities for marketing and distribution. If additional clinical trials or testing are required, or if trials are unsuccessful, yield insufficiently positive results, or if safety concerns emerge, we could face delays or outright failure in obtaining regulatory approval. This might lead to approval for narrower indications or patient populations, impose post-marketing testing requirements, create difficulties in securing drug reimbursement, and result in restrictions on distribution and commercialization, or even the market removal of approved drugs. Any of these developments could have a material adverse effect on our business, financial condition, and results of operations.

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

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events, which could affect patient recruitment or the ability of enrolled subjects to complete the trial, and result in potential product liability claims. In addition, our clinical trials may be shown to lack meaningful clinical response or possess other unexpected characteristics.

If the clinical trial results for our drug candidates are not positive, only modestly positive for proposed indications, or raise safety concerns, we may face delays or outright failure in obtaining regulatory approval. This could necessitate additional trials or testing, result in mandatory labeling such as "boxed" warnings or contraindications, and require patient medication guides. Furthermore, we might need to develop risk management plans, including restricted distribution or patient registries, and could receive approval for fewer proposed indications or face restrictions on drug distribution or use. Such outcomes could also lead to liability for injuries and an inability to obtain reimbursement for the drug. Moreover, if our drug candidates fail to demonstrate safety and efficacy to regulatory authorities' satisfaction or do not produce positive results in future clinical trials, we may be unable to recover significant previous investments, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

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Adverse events or undesirable side effects caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial prospects of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events (“AEs”) and undesirable side effects from our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, a delay or denial of regulatory approval, or a significant change in our clinical protocol or even our development plan. High severity or prevalence of AEs in trials, conducted by us or our licensing partners, could result in trial suspension or termination, and regulatory authorities could order a halt to development or deny approval for targeted indications. AEs may also hinder subject recruitment, affect trial completion, or lead to liability claims. Any such outcome could significantly harm our reputation, business, financial condition, and prospects.

If undesirable side effects are identified after a drug candidate receives regulatory approval: (i) regulatory authorities may withdraw approvals or licenses, or require marketing suspension; (ii) additional warnings on labels, Risk Evaluation and Mitigation Strategies restricting distribution, or changes in drug administration and mandatory post-marketing studies could be imposed; (iii) we could face litigation and liability for patient harm; and (iv) our reputation could suffer.

We may be unable to successfully develop or market our drug candidates or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates. Additionally, any such use of pharmaceutical product or medical treatment may cause AEs, which in some cases could be exacerbated compared with AEs from monotherapies.

If regulatory authorities revoke approvals of the pharmaceutical products or medical treatments we intend to use in combination with our drug candidates, we may not be able to develop or market our drug candidates as a combination therapy as planned. In addition, safety or efficacy issues with these combination components could also cause significant regulatory delays, requiring re-design or termination of clinical trials. Moreover, manufacturing or supply shortages of any component in our combination therapies could prevent us from completing clinical development within our target timetable, budget, or at all.

The data we gather in our research and development may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of our clinical results or analyses.

We analyze data when we identify a promising drug candidate and while conducting preclinical studies and clinical trials. During the process, the overall quality of data collected or accessed may be affected by many factors that are unrelated to the tested drug candidates and out of our control. Additionally, we cannot guarantee that all of our employees or staff of our CROs would strictly comply with the GCP standards or other related guidelines and regulations when collecting or accessing preclinical and/or clinical data. We may not be able to discover every data issue and error when monitoring and auditing our data.

Such factors may negatively affect the reliability of our trial results and analyses, and regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications. Significant issues related to data integrity could also subject us to questions or claims from relevant authorities, and may expose us to liability relating to our storage, handling, submission, delivery or display of clinical data. Our insurance coverage for clinical trials may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Any such claims or proceedings brought against us may negatively impact our business, prospects and reputation.

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We may not be successful in our efforts to identify, discover or license-in new drug candidates to build or maintain our drug pipeline.

We may fail to identify, discover or license-in new drug candidates for clinical development because our research methodology might be unsuccessful, or identified candidates could have harmful side effects, be unmarketable, or unlikely to receive regulatory approval. Despite requiring substantial technical, financial, and human resources, our R&D efforts, whether in-house or licensed, might initially seem promising but ultimately fail. This could be due to candidates later exhibiting harmful adverse effects or insufficient efficacy, or because the necessary human and financial resources to identify new therapeutic opportunities or develop candidates through internal programs exceed our capacity, thereby limiting portfolio diversification and expansion.

Accordingly, there can be no assurance that we will identify additional therapeutic opportunities, develop suitable in-house drug candidates, or successfully license new ones on favorable terms. Even if we identify or license drug candidates, successful commercialization is not guaranteed, and we risk misallocating resources to unsuccessful programs. Furthermore, licensed agreements carry risks. Licensors may breach or claim our breach, leading to termination and halting development and commercialization of critical drug candidates.

We may allocate our limited resources to pursue a particular drug candidate or indication 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 human and financial resources, we must limit our research and development programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Such developments could have a material adverse effect on our business, financial condition and results of operations.

We have entered into license and collaboration agreements with third parties in the development of our drug candidates and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. See “Business — Commercialization, Sales, Marketing and Distribution” for details on our ongoing collaboration efforts. License and collaboration agreements for our drug candidates carry various risks, including that: (i) these agreements can be terminated on short notice, due to non-compliance by us or our partners, or if partners change strategic focus, acquire competing drugs, or face funding issues, necessitating additional capital for development; (ii) milestone payments and royalties are conditional and not guaranteed; (iii) our partners have significant discretion over the efforts and resources they commit and might independently develop drugs that compete with ours; (iv) partners may not properly maintain or may misuse our intellectual property (IP), or co-own IP developed under the agreement, potentially leading to litigation, IP invalidation, or loss of exclusivity; and (v) disputes with partners could delay or terminate research, development, or commercialization, or result in costly litigation, diverting resources and management attention.

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We rely on third parties to conduct certain aspects of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. If our relationships with our third parties are damaged, our product or drug development efforts could be delayed.

As is common practice in our industry, we have engaged and plan to continue to engage third-party CROs, PIs and hospitals to monitor and manage data for some of our ongoing pre-clinical and clinical programs. In particular, we engaged CROs to conduct preclinical studies and specific phases of clinical trials of our drug candidates.

This outsourcing inherently carries risks as these third parties may not meet our performance standards, deliver timely results, or perform their duties at all. Furthermore, this reliance necessitates disclosing our proprietary information, increasing the risk of its misappropriation. For more information on our terms with CROs, see “Business — Our Research and Development — Engagement of Third Parties in Research and Development.”

Although we engage third-party CROs, PIs, and hospitals for our pre-clinical and clinical programs, we cannot control their allocation of time and resources. Crucially, we remain responsible for ensuring these studies comply with applicable protocols and legal, regulatory, and scientific standards like GCP and GLP, as enforced by regulatory authorities. Failure by us or our third parties to meet these requirements could render data unreliable, necessitating additional studies and delaying the regulatory approval process. If CROs, PIs, or hospitals do not fulfill their contractual obligations, miss deadlines, or compromise data quality, our studies could be extended, delayed, or terminated. This would significantly hinder our ability to obtain regulatory approval or commercialize our drug candidates, leading to a material adverse effect on our business, financial condition, and results of operations.

Switching or adding third-party service providers incurs additional costs and management time. These providers can terminate agreements for material breach. Identifying, qualifying, and managing new providers is challenging, time-consuming, and can delay R&D programs. Furthermore, new providers require a transition period and may not offer the same service quality. If any of our relationships with our third-party service providers is terminated, finding alternative providers promptly or on commercially reasonable terms may be difficult, potentially disrupting our clinical development timelines.

Our future performance relies heavily on effective collaboration to develop, secure regulatory approval for, and commercialize our drug candidates. We depend on collaborators for R&D, pre-clinical or clinical trials, regulatory filings, and commercialization efforts. Since we do not control these third parties, we cannot guarantee their adequate or timely performance. Their failure to successfully complete studies could delay, adversely affect, or prevent regulatory approval. We cannot assure satisfactory performance from any collaborator, and their breach or termination of agreements would significantly impact us.

We may not be successful in adapting to new technologies and methodologies during our development process.

Our continued competitiveness depends on our ability to adapt to evolving technological developments and methodologies in the biotech and pharmaceutical industry. However, adapting to the latest technological developments and methodologies may require us to invest significant resources to enhance our own research and development, testing and manufacturing capabilities. There is no assurance that we will be able to secure such resources, or that we will succeed in making the necessary improvements. We also cannot guarantee that we will be successful in our attempts to adapt our drug candidates to emerging technologies and methodologies in a way that will gain market acceptance. Should we fail to respond in a timely or effective manner, we may be unable to improve and maintain our competitive position and materially and adversely affect our business and prospects.

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Risks Relating to the Commercialization of Our Drug Candidates

Our drug candidates will be subject to intense competition with biologic drugs and other drugs for assisted reproduction and ophthalmology after commercialization and may fail to compete effectively against competitors.

The pharmaceutical industry is subject to intense competition. As a result, we will face intense competition with respect to the drug candidates we are developing presently and any drug candidates that we may seek to develop or commercialize in the future.

Many of our drug candidates will face competition from biologic drugs developed by major international and domestic pharmaceutical companies with the same targets as ours. Some of our competitors’ drug candidates are in the same or more advanced development stages than our drugs. Various other treatment options and drugs, such as assisted reproductive technology procedures and chemical drugs, may also compete with our drug candidates.

Our ability to compete with other drugs targeting the same conditions and to gain market share depends on factors like regulatory approval timing, our drug candidates’ efficacy and safety profile, dosing convenience, pricing, and sales/distribution reach. However, we cannot guarantee successful competition against major pharmaceutical companies that possess superior medical, technological, financial, marketing, and brand recognition resources. Furthermore, demand for assisted reproduction products, particularly in China, is vulnerable to social and economic factors beyond our control. Rising average age at first marriage, increased singlehood, high child-rearing costs, and evolving lifestyle preferences may reduce the willingness to reproduce and the treatment-seeking population size. Such reductions could limit market uptake of our assisted reproduction products, materially and adversely affecting our business, results of operations, and prospects.

Certain of our biosimilar candidates may not be as advanced in development as some of the equivalent biosimilar candidates being developed by our competitors.

Our biosimilar drug candidates face strong competition from other marketed drugs or drug candidates in the development stage. These competitor candidates may ultimately be approved and commercialized before our candidates, which may enable them to capture significant first-entrant advantages in establishing market presence and brand awareness. This in turn could place our drug candidates at a major commercial disadvantage at the time of launch, from which we may not be able to recover. In particular, under the Prescription Management Regulation (處方管理辦法) PRC hospitals may not procure more than two drugs of the same generic name (two injectable and two oral dosage forms), which in practice means that for each generic drug, a hospital will only procure the reference drug and one biosimilar. Unlike new or innovative drugs, biosimilar candidates are approved based on their bioequivalence to the reference drugs, and as such, biosimilars to the same reference drug as developed by different companies are generally not expected to have meaningful differences in efficacy or safety compared to each other. This policy may therefore limit our ability to place JZB30 (rhFSH) and JZB05 (aflibercept) on hospital formularies where the reference drug and an earlier-listed biosimilar are already procured. Consequently, it may be difficult for us to compete and gain market shares from the first-entrant products on those bases. We may instead seek to compete on pricing or product quality and reliability (perceived or otherwise), which we may not be able to do successfully. As a result, even assuming that we are able to obtain regulatory approvals for our drug candidates, we cannot assure you that they will be able to achieve commercial success, whether due to established first-entrants or otherwise. This in turn could have a material adverse effect on our business, financial condition and results of operations.

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The commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community.

Even if our drug candidates receive the requisite regulatory approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs and we may not become profitable. Market acceptance of our drug candidates will depend on numerous factors, including: (i) the specific clinical indications for which they are approved; (ii) physicians’ and patients’ perceptions of their safety and effectiveness, and their potential advantages over alternative treatments; (iii) the prevalence and severity of any side effects, along with product labeling, insert requirements, limitations, or warnings mandated by regulatory authorities like the NMPA or FDA; (iv) the timing of market introduction relative to competing drugs; (v) the cost of treatment compared to alternatives; (vi) the upfront costs or training required for physicians to administer our drug candidates; (vii) the availability of adequate government coverage and reimbursement, as well as patients’ willingness to pay out-of-pocket; (viii) the relative convenience and ease of administration; and (ix) the effectiveness of our sales and marketing efforts.

Even if our drugs achieve market acceptance once commercialized, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

We have no track record in commercializing drug candidates and may not be able to successfully commercialize our Core Products and key products. Our collaboration with companies in the pharmaceuticals industry to market our drug candidates and our plan to establish in-house commercialization team may not materialize as we expected.

We do not have any track record of successfully launching and commercializing drugs. We intend to seek opportunities of strategic cooperation with well-known pharmaceutical companies with extensive experience in the sales and marketing of assisted reproductive and ophthalmic drugs in China.

We aim to commercialize approved drugs by collaborating with pharmaceutical companies to leverage their market access and sales/marketing networks, particularly in assisted reproductive areas. However, we cannot guarantee establishing or maintaining these collaborations, nor their expected success. Such arrangements would make our drug sales and marketing dependent on partners, over whom we have limited control, potentially resulting in lower revenue compared to self-commercialization. Collaborations involving our drug candidates are subject to various risks, for further discussion, see “— Risks Relating to the Development of Our Drug Candidates — We have entered into license and collaboration agreements with third parties in the development of our drug candidates and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected.”

We plan to build an in-house commercialization team for our assisted reproductive drug pipeline, initially targeting key hospitals and centers. However, this demands substantial expenditures, management resources, and time, and we anticipate competition for skilled sales and marketing personnel. Given the team’s likely small scale, we cannot guarantee sufficient sales coverage and market penetration across China, which could adversely affect our drug candidates’ commercial opportunities.

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We may fail to effectively manage our network of distributors after our drug candidates are commercially launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

We may rely in part on third-party distributors to distribute our drugs once they receive approvals. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely and effective delivery of our products to the relevant markets. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach the distribution agreements and the policies and measures we have in place to manage their distribution.

If our distributors breach agreements, fail to maintain necessary licenses, or violate anti-corruption, anti-bribery, competition, or other applicable laws and regulations, we could face liabilities, monetary damages, decreased brand value, and negative public perception. Such issues would materially and adversely affect our business, financial condition, results of operations, and prospects.

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect demand for our drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to drugs offered by our competitors, could diminish demand for our drug candidates and adversely impact our future sales revenues. Furthermore, the sales of our future approved drugs depend in part on our ability to educate patients and members of the medical community (including healthcare providers) about our drugs and drug candidates. Our ability to convey our messages effectively may be negatively impacted by the publication of guidelines, recommendations or studies on our drug candidates.

The market opportunities for our drug candidates may be smaller than we originally anticipated, and our drug candidates may be ultimately unprofitable even if commercialized.

We estimate target patient populations and market opportunities using third-party sources and internal analyses to guide our drug development strategy. However, these estimates may be inaccurate or based on imprecise data. The actual total addressable market will depend on medical community and patient acceptance, drug pricing, reimbursement, and the availability of alternative treatments. Consequently, the number of eligible patients may be lower than anticipated, they might not respond to our drugs, or identifying and accessing new patients could become increasingly difficult. New studies or technologies might alter disease incidence/prevalence, leading to a smaller than expected addressable patient population for our drug candidates.

In such cases, even with significant market share, we may not achieve profitability without regulatory approval for additional indications. Any of these unfavorable developments could materially and adversely affect our business, financial condition, and results of operations.

Medical insurance coverage or reimbursement schemes may be limited or unavailable in certain market segments for our drug candidates.

Successful sales of our future approved drugs partly depend on the availability of adequate insurance coverage and reimbursement from the government and commercial insurers, as patients often rely on such reimbursement for all or part of the costs associated with their medical treatment. Government authorities and commercial medical insurance providers determine drug coverage and reimbursement based on various factors that are not in our control. We cannot guarantee that reimbursement will be available for our future approved drugs and, if available, the level of

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reimbursement. In China, the amounts reimbursable to program participants for their drug purchases depend on the inclusion of the drugs in the NRDL or other government-sponsored medical insurance programs, as well as the tiers under which the drugs are classified in such programs. Even though the number of innovative drugs included in the NRDL is expected to increase in the future, there can be no assurance that any of our future approved drugs will be included in the NRDL or other government-sponsored medical insurance programs.

Even if medical insurance coverage or reimbursement schemes are available, we may need to significantly concede on prices for our future approved drugs in China.

Seeking inclusion in China’s NRDL may necessitate price negotiations with the NHSA, leading to potential price reductions. While NRDL inclusion could increase demand, our revenue and profitability might still decrease due to lower prices. Reimbursement eligibility does not guarantee full cost recovery. Furthermore, prices offered to the NHSA may become benchmarks for private hospitals, and the centralized tender process could create pricing pressure, negatively impacting our future approved drugs.

Our drug candidates may cause undesirable side effects unforeseeable or undetectable at time of development or have other properties that could have significant negative consequences on our ability to market and distribute our drug candidates or maintain market acceptance of such drugs if commercialized.

Our drug candidates, like most pharmaceutical products, carry the risk of side effects or adverse events that may emerge at any stage, including during clinical trials or after commercialization, even if unforeseeable or undetectable earlier. It is common for drugs showing early promise to later reveal side effects that halt development or lead to significant negative consequences post-market. Due to the limited patient population and exposure duration in clinical trials, rare and severe adverse events may only become apparent when a significantly larger number of patients are exposed after commercialization.

Our drug candidates may cause side effects like enlarged ovaries, abdominal bloating, eye swelling, and eye redness. However, a high and unacceptable severity or prevalence of these or other side effects during clinical trials could force us, or regulators like the NMPA, to conduct additional studies, delay, suspend, or terminate trials, or cease further development and withdraw the drug from targeted indications. Even if development continues, we cannot guarantee timely or satisfactory resolution of product-related adverse effects to regulatory bodies. Such side effects could also hinder patient recruitment or completion of clinical trials, and lead to potential liability claims.

If undesirable side effects are identified after a drug candidate receives marketing approval, significant negative consequences may arise.

Regulatory agencies may require cross-reporting of adverse medical events involving our drug candidates to other jurisdictions within a specified timeframe. Failure to timely comply with these reporting obligations could result in disciplinary actions, including criminal liability, civil penalties, product seizure, and delays in future drug candidate approvals or clearances.

Any of the above negative developments could prevent us from achieving or maintaining regulatory approval or market acceptance of the affected drug candidates, as well as substantially increase the costs of commercializing our drug candidates even if approved.

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

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

We may explore opportunities to commercialize our drugs globally, which may expose us to risks associated with conducting business in international markets.

As we grow our business, we may cooperate with pharmaceutical companies with established local sales networks to conduct clinical trials and/or sell our drugs outside of China. We currently plan to pursue overseas opportunities through partners and regional distribution partnerships. Should we succeed in doing so, our business is subject to risks associated with doing business globally, including (i) changes in a country or region’s political and cultural climate or general economic conditions, (ii) unexpected changes in or high costs associated with complying with laws and regulatory requirements, (iii) difficulties with enforcing contractual provisions in unfamiliar jurisdictions, (iv) potential disputes with foreign partners that may be protracted or more difficult to resolve due to distance and time differences, (v) exposure to litigation or third-party product liability claims outside of China, (vi) concerns voiced by local governments and regulators on arrangements pertaining to our research and clinical trial sites, (vii) inadequate intellectual property protection in other countries, (viii) the possibility of economic sanctions, trade restrictions, discrimination, protectionism or unfavorable policies against foreign drug companies, including those from China, (ix) the effects of applicable local tax regimes, royalties and other payment obligations owed to local governments, and (x) fluctuations in local currency exchange rates. Any of such occurrences could negatively affect our expansion plan.

Risks Relating to the Manufacturing of Our Drug Candidates

We have relatively limited experience in manufacturing drugs on a large commercial scale, which is a highly exacting and complex process.

Our experience in large-scale commercial manufacturing is limited, as we have not commercialized any product as of the Latest Practicable Date. Moreover, the manufacture of biological products is a highly exacting and complex process, due in part to strict regulatory requirements. If problems arise in the course of producing a batch of product, that batch may need to be discarded, which would result in additional expenses and may also lead to product shortages.

Undiscovered product issues reaching the market may lead to recall and product liability costs. Production challenges include longer lead times, insufficient work orders for full capacity utilization, supply shortages, excess expiring supplies, and low success rates in meeting regulatory or quality standards. We cannot assure timely and cost-effective resolution of these issues.

Our drug candidates and products must meet GMP standards enforced by the NMPA and other regulatory authorities. Failure to achieve or maintain these standards, even due to factors beyond our control, can trigger severe regulatory actions, including: (i) warnings, approval withdrawals, product recalls or seizures, production suspensions, refusal to approve applications, and civil or criminal penalties; and (ii) regulators may also withdraw approvals for unexpected problems like severe adverse events, leading to revised labeling, additional safety studies, or other restrictions. Any such negative developments could materially and adversely affect our business, financial condition, and results of operations.

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Scarcity of available raw materials or increases in our raw material costs may negatively impact our manufacturing progress, financial condition and results of operations.

Our drug development relies on raw materials from a limited number of suppliers. If these suppliers suspend production, raise prices, or fail to supply due to logistical issues or non-compliance with regulations/licensing, we may be unable to secure suitable alternative materials. Such disruptions could lead to raw material shortages, delays in clinical trials and regulatory filings, product recalls, potential product liability claims, non-compliance with regulatory requirements, and significant costs, thereby materially and adversely affecting our business, financial condition, and results of operations.

As our business expands and drug candidates advance, our demand for raw materials and comparison drugs will increase. Delays in obtaining these in required quantity and quality could disrupt preclinical studies, clinical trials, regulatory approval, or manufacturing of approved drugs. Moreover, raw material prices are subject to volatility from external factors that we do not control. The need to find replacement suppliers or materials could also reduce production, delay operations, divert resources, and materially harm our business, financial condition, results of operations, and prospects.

Failure to obtain, maintain and renew regulatory approvals for our manufacturing facilities, delays in the construction of our new manufacturing facilities, or any disruption or suspension of manufacturing activities may affect our business and results of operations.

As of the Latest Practicable Date, our manufacturing activities were primarily limited to supporting our drug development process. For more details, see “Business — Manufacturing.”

Failure to obtain or maintain regulatory approvals for our manufacturing facilities, or delays in new facility construction/approval, could hinder our ability to produce sufficient drug candidates, limiting development, commercialization, and growth, and potentially incurring cost overruns. Our facilities must comply with NMPA regulatory requirements and GMP standards, undergoing periodic inspections. We cannot guarantee adherence, and remediating deficiencies is costly and time-consuming. Failure to maintain these approvals would materially affect R&D and manufacturing, seriously delaying clinical trials and commercialization. Operational challenges, such as failing to meet product standards, controlling costs, equipment issues, personnel/material shortages, or facility damage, could force us to delay or suspend manufacturing. This might make securing alternative manufacturers difficult and lead to delays in clinical trials, manufacturing, and product availability. Rectifying these issues is costly and time-consuming. Non-compliance could also result in severe regulatory sanctions, including fines, injunctions, marketing approval failures, approval withdrawals, product recalls, operating restrictions, or criminal prosecutions, severely harming our business.

Failure to maintain effective quality control over our future approved drugs, particularly undetected errors or defects in our manufacturing, may harm our reputation or expose us to product liability claims.

The effectiveness of our quality control procedures depends on various factors, such as the procedures governing our manufacturing processes, the quality and reliability of our manufacturing facility and equipment, the qualification and experience of our manufacturing and quality control staff and our ability to ensure that the relevant personnel adhere to our quality control procedures. However, we cannot assure you that our internal policies and procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure of our quality control procedures could render our drugs unsuitable for use, adversely affect our ability to comply with applicable GMP requirements, jeopardize our manufacturing permits and/or harm our market reputation and relationship with business partners.

RISK FACTORS

We may rely on third parties to manufacture our drug candidates for clinical development and commercial sales. These third parties may fail to deliver our product orders in a timely manner or fail to do so at acceptable quality or price levels.

During the Track Record Period, we outsourced certain manufacturing activities to a reputable CMO partner in China. Going forward, we may continue to engage third-party CMOs to manufacture our drug candidates for our research and development activities and commercial sales. Reliance on third-party CMOs presents several risks, including that: (i) the number of qualified CMOs is limited and subject to regulatory approval, potentially impacting our production timeline due to their capacity constraints or limited manufacturing slots; (ii) we lack full control over CMO compliance with GMP and other regulations, and their failure to adhere could lead to manufacturing delays or inability to produce required quantities and quality; (iii) CMOs might not execute manufacturing procedures as agreed, or fail to protect our intellectual property, potentially leading to litigation or loss of IP; (iv) they could also infringe on third-party IP; (v) CMOs may terminate agreements due to disputes; (vi) the raw materials they procure might not be readily available elsewhere; and (vii) their manufacturing processes are vulnerable to interruptions from natural disasters, labor disputes, or political instability. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs, or adversely impact commercialization of our future approved drug candidates.

Risks Relating to Intellectual Property Rights

If we are unable to obtain and maintain patent protection for our drug candidates, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and the commercial prospects of our drug candidates would be materially and adversely affected.

We prioritize IP protection for our drugs, primarily through patent filings in China and potentially other countries, or by relying on trade secrets or regulatory protection. Failure to obtain or maintain this protection could materially harm our business.

The patent process is expensive, time-consuming, and complex, and we may not secure all desired patents cost-effectively or timely. For example, in China, the China National Intellectual Property Administration (CNIPA) may require us to amend our patent applications after substantive examinations, including reducing the patentable coverage, and if we fail to respond within a specified period, our applications will be deemed to be withdrawn. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories. Furthermore, the patent landscape in biotech and pharmaceutical industries is highly uncertain and litigious, making the issuance, scope, validity, enforceability, and commercial value of our patent rights unpredictable.

Patents and applications can be invalidated or rejected due to examiner discretion, prior art, or application defects. We cannot guarantee being the first to invent or file for our drug candidates, potentially leading to application rejections. We might also fail to timely identify patentable aspects of our R&D. Furthermore, if confidential or patentable R&D output is disclosed by employees or third parties before filing, our ability to obtain patent protection will be jeopardized.

Due to the lag in scientific literature publication and the delayed publication of patent applications, we cannot be certain we were the first to invent or file for our claimed inventions. Under the “first-to-file” systems in China and the U.S., others could secure patents for technologies we developed if they file first. Additionally, PRC Patent Law mandates reporting inventions made in China to CNIPA for confidential examination before foreign filing; failure to do so will result in the denial of a Chinese patent.

RISK FACTORS

The scope of patent protection is uncertain and our current or any future patents may be challenged and invalidated even after issuance, which would materially and adversely affect our ability to successfully commercialize any drug candidates.

The scope of patent protection is uncertain and evolving. Changes in patent laws or their interpretation could increase costs, diminish our ability to protect innovations, and narrow our patent rights. We cannot guarantee that our current or future patent applications will be granted, or, if granted, will provide meaningful protection, prevent competition, or offer a competitive advantage. Issued patents may be challenged, narrowed, circumvented, or invalidated by third parties. An adverse determination from such challenges in any jurisdiction could reduce our patent scope, allow competitors to commercialize our technology without payment, or prevent us from commercializing our own drug candidates without infringing on third-party rights. Such challenges are costly and divert management’s attention, even if ultimately successful.

Furthermore, there is no guarantee that we will be granted patent extensions. According to the Patent Law of the PRC, the patent administration department under the State Council may, upon request, extend terms for invention patents relating to new drugs that have obtained regulatory approvals for no more than five years, and the total term of the patent right may not exceed 14 years after the regulatory approval for the marketing of a new drug. Similarly in the United States, we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting NDA approval from the FDA. However, total patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the regulatory approval for the marketing of a new drug, only one patent may be extended, and only those claims covering the approved drug, a method for use, or a method for manufacturing may be extended. Following the expiration of our patents, it is possible that our competitors may develop and market generic version of such drugs, thereby materially and adversely affecting our ability to compete.

We may be subject to intellectual property infringement challenges, particularly those relating to our biosimilar drug candidates, misappropriation claims or other legal challenges, which could cause us to incur significant expenses, pay substantial damages and delay or prevent us from selling our products or using technologies incorporated in our drug candidates or future drugs.

Our success depends on avoiding infringement of others’ intellectual property and resolving claims efficiently. Pharmaceutical companies, including those behind reference drugs for our biosimilars, possess extensive global patent portfolios covering various product aspects. Not all these patents have expired, and patent term extensions sought by reference drug sponsors could delay our biosimilar launches. Innovative biologics face higher uncertainty regarding patent infringement as they don’t rely on reference drug patent expiration, and we might miss relevant third-party patents.

While our Freedom-to-Operate (“FTO”) analysis for Core Products in China suggests no known issued patents impede our R&D or commercialization within the contemplated timeframe, FTO has limitations. Patent applications are often not published for 18 months or more, meaning unidentified pending applications could later become issued patents that our drug candidates might infringe. The sheer volume of patents in our field, coupled with industry expansion, increases our risk of infringement claims.

IP infringement or misappropriation claims, regardless of merit, are complex, costly, and time-consuming, diverting management and harming our reputation and market position. Even weak claims require significant resources to defend. Such disputes could force us to cease product development, manufacturing, or sales; stop using certain names; obtain expensive licenses; redesign products; change business processes; or pay substantial damages, including for willful infringement. Any IP-related dispute, regardless of outcome, could materially and adversely affect our business, financial condition, and results of operations.

RISK FACTORS

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

Periodic maintenance fees, renewal fees, annual fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA and other patent regulatory authorities in other jurisdictions in several stages over the lifetime of a patent. The CNIPA and other patent regulatory authorities also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. Non-compliance with such provisions can lead to abandonment, loss of priority 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 or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may face challenges associated with protecting our intellectual property rights in other jurisdictions.

As of the Latest Practicable Date, we held 49 patents in China and one patent in Japan. As of the same date, we have applied for five PCT patent applications, we also had 18 patent applications pending in China and we had two patent applications pending overseas.

If we are able to commercialize our drugs on an international scale, we may face challenges associated with protecting our intellectual property rights in other jurisdictions. Filing, prosecuting, maintaining and defending patents in all other countries throughout the world require significant financial resources and management attention. Moreover, our intellectual property rights in other jurisdictions may be of different scope and strength as compared to those in our target markets. Consequently, we may not be able to entirely prevent third parties from using our intellectual property to produce, sell or import drugs in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs, and may also export otherwise infringing drugs to jurisdictions where we do not have patent protection or strong patent enforcement rights. Such occurrences may diminish our competitive advantages, prospects and market share.

Failure to adequately protect our know-how, trade secrets and other confidential proprietary information may adversely affect our competitiveness.

We rely on unpatented know-how and trade secrets to maintain our competitive position, which we seek to protect through confidentiality and intellectual property assignment agreements with our employees, partners, and consultants. However, these measures may not be effective. Our proprietary information could be disclosed by third parties, either intentionally or inadvertently, and our IT systems are vulnerable to security breaches. Any unauthorized use may be difficult to remedy, potentially allowing competitors to erode our competitive position, and any legal action to enforce our rights would be costly, time-consuming, and have an uncertain outcome.

Furthermore, we may not succeed in securing enforceable IP assignment agreements from all relevant parties, which could lead to ownership disputes. If we fail in defending such claims, we could lose valuable intellectual property rights and face monetary damages. Even successful litigation would result in substantial costs and be a distraction to management, any of which could materially harm our business and prospects.

RISK FACTORS

Even though we have relied on patents, trademarks, trade secrets and other forms of intellectual property protections, these protections may not be adequate and such rights may not necessarily protect us from all potential threats in competition.

We rely on patent, trademark, trade secret, and other intellectual property laws in China to protect our IP, but these protections may not prove commercially valuable. Issued patents are not conclusive regarding ownership, scope, validity, or enforceability and can be challenged globally. Such challenges, if unsuccessful, could narrow, invalidate, or render our patents unenforceable, limiting our ability to prevent competitors from using similar technologies or eroding our patent protection duration. Infringement claims against us could also prevent licensing on acceptable terms.

Even if patents are issued, they might not offer meaningful protection against competitors who can circumvent them with similar non-infringing methods. Given long development times, patents for new drug candidates may expire before or soon after commercialization, failing to sufficiently exclude others.

We also rely on unregistered rights like know-how and trade secrets, but confidentiality agreements may not prevent leakage or unauthorized disclosure. IP enforcement might be unavailable in some countries, and third parties could independently develop or access our proprietary information. Any disclosure or use of our IP by others could reduce our competitive advantage and harm our business. These IP-related issues could materially and adversely affect our business, financial condition, and results of operations.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors, including our senior management, were previously employed at other pharmaceutical or biotech companies, including our competitors or potential competitors. This exposes us to claims that we, or they, have used or disclosed former employers’ intellectual property, or that third parties have an inventor interest in our patents. While we are not currently aware of such claims, they could arise, potentially leading to monetary damages, loss of valuable IP or personnel if we fail to defend successfully. Even a successful defense would incur substantial costs and divert management.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property and impair the intellectual property protection of our drug candidates.

Changes in intellectual property laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the scope and value of our intellectual property rights.

Changes in patent laws, such as the U.S. Leahy-Smith America Invents Act’s shift to a “first-to-file” system, create uncertainty for our patent applications. Given the delay in publication of scientific discoveries and patent applications, we cannot be certain of being the first to invent or file, increasing prosecution costs and challenges in enforcing/defending our U.S. patents. Similarly, amendments to the PRC Patent Law and other changes in Chinese or foreign intellectual property laws could impact the value of our patent rights, hindering our ability to protect, defend, and enforce them, and materially affecting our competitive position, business, financial condition, results of operations, and prospects.

RISK FACTORS

Failure to adequately protect our trade names, trademarks and other intellectual property may affect our ability to build brand recognition.

We conduct our business under the brand name of “Jingze (景澤).” As of the Latest Practicable Date, we had registered 113 trademarks in the PRC. As of the same date, we were the registered owner of 27 domain names in the PRC. However, our intellectual property protection measures offer limited defense, and policing unauthorized use is difficult and costly. IP laws in China are evolving, making enforceability, scope, and validity subject to changes. We cannot guarantee timely and effective detection or enforcement of our IP rights. Litigation to protect IP could incur substantial costs and divert resources and management attention.

Our registered and unregistered trade names and trademarks may be challenged, infringed, or deemed generic, and we may struggle to protect these rights vital for brand recognition. As we expand, our reliance on trademarks increases, and failure to prevent third-party infringement or unfair competition could materially harm our business. There’s no guarantee we can always register our trademarks, which could lead to accusations of infringement against us or allow competitors to adopt similar marks, hindering our brand building. Ultimately, a failure to establish strong brand recognition may prevent effective competition and diminish our future prospects.

Risks Relating to Government Regulations

Pharmaceutical products are heavily regulated, and such regulations are subject to change.

We intend to develop and commercialize drug candidates in heavily regulated global jurisdictions, including China, the U.S., and the EU. While regulatory strategies for development, manufacturing, and marketing are broadly similar, differences across regimes create a complex and costly compliance burden. Obtaining and maintaining regulatory approvals demands substantial time and capital. Failure to comply at any stage can lead to severe sanctions, such as refusal or withdrawal of approval, license revocation, clinical holds, product recalls, production suspension, injunctions, fines, and civil or criminal penalties, all of which could materially harm our reputation, business, and financial stability.

Key markets like China and the U.S. impose high standards for drug efficacy and strict rules for development, requiring applications like INDs, NDAs, or BLAs. Non-compliance can result in fines, research termination, data disqualification, or sales bans, significantly impacting our reputation, business, and financial performance. Even defending against alleged violations can incur substantial legal expenses, divert management, and damage our reputation and financial results.

We may face extra obstacles in the commercialization of our biosimilar drug candidate, due to the uncertainty in approval pathway for biosimilars in the jurisdiction we operate and heightened risks relating to potential patent litigation.

The approval pathway for biosimilars in the jurisdiction we operate continues to develop, which may adversely affect the regulatory approval of our biosimilar drug candidate. See “Regulatory Overview — Regulations Relating to New Drug — Regulations of Biosimilars”. Various uncertainties surrounding the application and interpretation of such regulations could adversely affect the regulatory approval of our existing biosimilar drug candidates. For example, the regulatory policies and guidelines may change in the future, and it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines to replace or supplement related guidelines or requirements, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

RISK FACTORS

Recent and potential changes in healthcare policies, drug approval processes and related regulations (including tariffs and export controls) may materially and adversely affect our business.

Evolving regulatory frameworks and agency practices, exemplified by recent substantial changes at the FDA (such as workforce reductions, policy shifts, delayed timelines, and longer regulatory interactions), could materially and adversely affect our business. Similar developments in other markets are possible. Such changes may lead to slower or less predictable timelines, evolving data requirements, inconsistent feedback, or requests for additional information, potentially delaying or increasing the cost of our clinical development plans, regulatory submissions, and approvals. We cannot predict the timing, scope, or impact of these regulatory shifts.

In addition, elements of our supply chain may involve imported equipment, raw materials and consumables, whether procured directly by us or through third parties. Changes in tariffs, customs procedures, sanctions or export-control and import-licensing policies in any relevant jurisdiction could increase costs and lead times, disrupt logistics or restrict cross-border transfers, which could adversely affect our research activities, manufacturing scale-up and regulatory processes.

- **Regarding tariffs**, in February 2025, the United States imposed a 20% tariff on certain categories of Chinese goods (the “**Fentanyl Tariff**”). Subsequently, on April 2, 2025, the United States imposed a 10% baseline tariff on all imports from its trading partners, along with additional country-specific tariffs for various countries (the so-called “Reciprocal Tariff”, as adjusted from time to time). These actions have led to a series of retaliatory measures by other countries, including China, and further countermeasures by the United States. On November 4, 2025, the President of the United States issued executive orders that, among other things, reduce the Fentanyl Tariff from 20% to 10%, effective November 10, 2025, and continue the suspension of heightened China-specific Reciprocal Tariff rates through November 10, 2026, thereby maintaining the 10% Reciprocal Tariff baseline on imports from China during that period. The United States and China are engaged in trade discussions, but there is no assurance that the higher tariffs will be suspended further or that a long-term agreement will be reached, and there is no assurance that the tariff policy will remain in its current form. At the same time, on May 28, 2025, the U.S. Court of International Trade ruled that many of the tariffs the current administration put in place exceeded the president’s legal authority, which was affirmed by the U.S. Court of Appeals for the Federal Circuit on August 29, 2025. On February 20, 2026, the U.S. Supreme Court issued its opinion affirming the lower court’s ruling, striking down the tariffs pursuant to the International Emergency Economic Powers Act (IEEPA). Following this decision, the administration rescinded the IEEPA-based tariffs but concurrently imposed new 10% tariffs for a 150-day period under separate statutory authority. The international tariff policies are rapidly evolving, and the final outcome, including whether the tariff level can be implemented as proposed, is highly uncertain.
- **Regarding sanctions and export control**, the most significant controls are those administered by the U.S. Department of the Treasury’s Office of Foreign Assets Control (“**OFAC**”), which prohibit the provision of products to certain countries or regions, governments, entities and persons targeted by U.S. sanctions. Regarding U.S. export controls, in October 2022, the Bureau of Industry and Security of the United States Department of Commerce (“**BIS**”) issued an interim final rule (the “**BIS October 2022 IFR**”) to limit China’s access to advanced computing integrated circuits, supercomputers, and advanced semiconductor manufacturing. In October 2023, the BIS released another interim final rule (the “**BIS October 2023 IFR**”) that updated and expanded the restrictions from the BIS October 2022 IFR (together with the BIS’s April 2024 interim final rule, the “**BIS 2022/23 IFRs**”). Among other measures, the BIS 2022/23 IFRs added certain advanced and high-performance computing integrated

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circuits and related computer commodities to the Commerce Control List, imposing new or expanded license requirements for items subject to the U.S. Export Administration Regulations (“**EAR**”) intended for use in developing or producing supercomputers, advanced node integrated circuits, and advanced semiconductor manufacturing equipment in certain jurisdictions, including China. Most recently, in January 2025, the BIS issued an interim final rule (the “**BIS January 2025 IFR**”) to further limit China’s access to advanced computing integrated circuits and advanced semiconductor manufacturing equipment. In addition, from September 29, 2025, the Entity List restrictions apply not only to parties included on the Entity List, but also to any person that is 50% or more owned, directly or indirectly, by parties on the Entity List or certain other restricted party lists (the “**BIS Entity List Affiliate Rule**”). However, on November 12, 2025 the BIS issued a one-year suspension of the BIS Entity List Affiliate Rule, set to end on November 9, 2026, absent a future extension.

If such policy or regulatory changes are prolonged or significant, we cannot assure you that our development timelines, costs, market access and business prospects will not be materially or adversely affected. Such adverse effects include uncertainties to global supply chains, limited access to raw materials, equipment and components, and increased production and compliance costs and uncertainties for companies operating in affected industries. As of the Latest Practicable Date, we believe that we are not subject to any trade restrictions, tariff developments or sanctions risks that would materially affect our operational and financial condition, and we have no plan to pursue the clinical development or commercialization of any of our drug candidates for any indications in jurisdictions with high sanction risks. In addition, as of the same date, we had not generated any revenue, do not plan to directly export any of our commercialized products to overseas markets, and had implemented sanction compliance measures to ensure our ongoing compliance. If these trade restrictions or geopolitical tensions escalate, we may face additional risks such as supply chain restraints, reduced access to key markets, strained customer relationships and loss of market opportunities. Increased compliance costs and operational challenges arising from adhering to complex export control regulations and sanctions could strain our resources. Tariffs, quotas and local content rules may further raise production costs, impacting the profitability and competitiveness of our products. As the Entity List and other sanctions and export control laws and regulations, including the EAR’s de minimis rules and foreign direct product rules, continue to evolve, future sanctions and export controls may significantly impact our business and increase our compliance burdens.

Additionally, biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay or prevent the commercial launch of a drug candidate. Many pharmaceutical companies, including the ones that developed the reference drugs for which we are developing biosimilars, have developed worldwide patent portfolios of varying sizes and breadth. Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructions, vectors, growth media, production processes and purification processes. Not all such patents have expired globally, including potentially in the jurisdictions where we intend to commercialize our biosimilar drug candidate. Relevant parties may submit applications for patent term extensions in jurisdictions where extensions are available, seeking to extend patent protection. If approved, such extension may interfere with or delay the launch of our biosimilar product. As such, we cannot assure you that any current biosimilars in our pipeline or future biosimilars we may develop will be approved under the Biosimilars Guideline, in a timely manner or at all, and we may not ultimately be able to develop and market it successfully if we are subject to related intellectual property infringement or misappropriation claims.

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Policies on pricing, reimbursement and centralized procurement may constrain our pricing of biosimilars and adversely affect our margins.

As of the Latest Practicable Date, prices in China are generally market-regulated. However, NHSA-led NRDL negotiations set uniform national payment standards and, together with national or provincial volume-based procurement programs where applicable, can significantly influence transaction prices at public medical institutions. If our biosimilar candidates are approved and become subject to such mechanisms, we may need to offer significant price concessions to secure reimbursement and hospital access. Budget controls, the zero mark-up policy at public hospitals and the “two-invoice system” in distribution may further compress terminal prices and channel margins, limiting pricing flexibility and adversely affecting our revenues and profitability.

The regulatory approval processes of the NMPA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm.

Obtaining regulatory approvals from authorities like the NMPA is unpredictable, often taking many years due to numerous factors, including regulatory discretion. We cannot assure meeting diverse jurisdictional requirements or securing approval for our drug candidates. Additional time, effort, and expense may be needed to comply with varying international regulatory processes for market entry. Reasons for potential regulatory disapproval include disagreements on clinical trial design or implementation, failure to demonstrate safety and effectiveness, insufficient or suboptimal clinical data, or not meeting statistical significance. Non-compliance with GCP inspections, unexpected regulatory changes making data insufficient, clinical site audit failures leading to data invalidation, or manufacturing deficiencies are also significant risks.

Regulatory authorities may delay or deny approval by: (i) requesting additional data; (ii) approving fewer or undesired indications; or (iii) making approval contingent on post-marketing trials. Failure to secure timely or comprehensive approval, or to demonstrate sufficient safety and efficacy, will negatively impact commercial prospects, cause reputational damage, and prevent revenue generation, materially affecting our business, financial condition, results of operations, and prospects.

Even after we obtain regulatory approval for the commercialization of our drug candidates, our future approved drugs will continue to remain subject to regulatory scrutiny, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our drug candidates, our commercialization efforts may be adversely and materially affected.

After regulatory approval, our drug candidates face continuous oversight from the NMPA and other authorities concerning production, labeling, storage, distribution, advertising, and post-marketing studies. Our manufacturing facilities must also adhere to current GMP standards. New drug safety legislation could increase compliance costs. Ongoing monitoring may necessitate submitting new applications or conducting costly supplemental clinical trials to maintain approvals or expand patient populations. This requires significant time and resources for regulatory compliance and inspections. We cannot assure cost-effective compliance with these post-commercialization regulations, and any failure could materially and adversely affect our business, financial condition, and results of operations.

Changes in laws and regulations relating to the biopharmaceutical industry, including the ongoing healthcare reform in China and the U.S. BIOSECURE Act, may result in additional compliance risks and costs.

In China and other jurisdictions we may operate in future, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the biopharmaceutical industry and the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

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In particular, PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products. In an opinion issued in January 2021, the General Office of the State Council further encouraged the collective procurement of public hospitals through the centralized purchase of drugs in large quantities. A centralized tender process will be initiated once the demand for certain drugs reaches a certain quantity or amount, with the emphasis on those high-priced drugs included on the NRDL in great demand. This policy is intended to reduce the retail prices of pharmaceutical products by cutting the intermediaries between hospitals and manufacturers. Consolidated procurement and direct settlement between hospitals and manufacturers may increase the bargaining power of hospitals and increase the pricing pressure on our future drug candidates. If PRC government authorities implement other reforms on the current tender process for pharmaceutical products or revise other policies affecting pharmaceutical prices, which result in downward adjustments to the retail prices of our future drug candidates, our wholesale prices, our revenue and profitability could be adversely affected.

In addition, evolving U.S. biosecurity measures, including the BIOSECURE Act, could restrict eligibility for U.S. federal contracts, loans and grants where covered biotechnology equipment or services are used. We have procured certain CRO/CDMO services from PRC-based affiliates of WuXi AppTec and WuXi Biologics (see “Business — Our Suppliers”). If such measures are enacted, we may need to modify, phase out or transition some engagements, which could require technology transfer and vendor re-qualification, increase costs and lead times, and delay our program. While we are qualifying alternative providers with comparable capabilities and broadly similar pricing, there is no assurance that suitable alternatives will be available on similar terms or within required timelines. The final scope and timing of any enacted legislation remain uncertain. See “Regulatory Overview — U.S. Regulations Potentially Impacting Our Operations — BIOSECURE Act.”

These legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug candidates in the future. The varying interpretations and changing guidance of these laws create ongoing compliance uncertainty and necessitate additional costs for revising disclosure and governance practices. Failure to comply with these laws and their subsequent changes could lead to penalties and harm our business.

The interpretation and enforcement of PRC laws, rules and regulations may continue to develop, which may affect our operations.

We primarily operate in China and are governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In the late 1970s, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. Because these laws, rules and regulations are evolving and may give the relevant regulator discretion in how to enforce them, and because of the limited number of published decisions and binding interpretations, the enforcement of these laws, rules and regulations may continue to develop, which may affect our operations.

Our failure to obtain or renew certain approvals, licenses, permits and certificates required for our business, in addition to those related to our manufacturing, may materially and adversely affect us.

Pursuant to relevant laws and regulations, we are required to obtain and maintain various licenses, permits and certificates from relevant authorities to operate our business. Some of these licenses, permits and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities suspending our operations, and corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations.

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Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect requiring us to obtain any additional approvals, licenses, permits and certificates that were previously not required to operate our existing businesses, facilities or any planned future business or facilities, we cannot assure you that we will successfully obtain such approvals, licenses, permits and certificates. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict our ability to conduct our business, which, in turn, could have a material adverse effect on our business, financial condition and results of operations. For further details, please see “Business — Licenses, Permits and Approvals.”

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity.

The regulatory framework for the data privacy and security in China is evolving and new laws, regulations, rules and policies are likely to be introduced in this regard for the foreseeable future. See “Regulations — Regulations Relating to Information Security and Data Protection”. Among them, even though we are not subject to the Outbound Data Transfer Security Assessment Measures as of the Latest Practicable Date, we may be subject to such outbound data security assessment as we decide to expand overseas. We will closely monitor and assess any relevant legislative and regulatory development and prepare for a security assessment when necessary.

Maintaining rigorous and continuous compliance with evolving data privacy, security, and transfer laws is a time-intensive process that may incur additional operational costs or necessitate changes to our data processing practices. Non-compliance by us or our third-party vendors, collaborators, or consultants in China or other jurisdictions could lead to enforcement proceedings, significant fines, penalties, judgments, and severe negative publicity or reputational damage, all of which could materially and adversely affect our business, financial condition, and results of operations.

We are subject to environmental protection, health and safety laws and regulations, and may be exposed to potential costs for compliance and liabilities, including consequences of accidental contamination, biological hazards or personal injuries.

We are subject to national and local environmental and health and safety laws, and those of future operating jurisdictions, governing aspects like pollutant discharge and the use of hazardous chemicals in biologics discovery and manufacturing. Biologics development inherently carries risks of accidental contamination or biological hazards, which could lead to liability for damages, clean-up costs, administrative actions, and significant manufacturing disruptions. Our facilities require environmental and health/safety approval or examination before operation. As these laws evolve and become more stringent, we may face difficulties or substantial costs in complying, potentially resulting in rectification orders, fines, damages, or suspension of operations. Any such negative developments could materially and adversely impact our business, financial condition, results of operations, and prospects.

Failure to comply with anti-corruption laws could subject us to investigations, sanctions or fines, which may harm our reputation and materially and adversely affect us.

We have implemented policies to ensure our staff and third parties comply with anti-bribery and anti-corruption laws, particularly those from the PRC government targeting the health sector. These regulations mandate internal controls and risk management, subject to periodic inspections. However, we cannot guarantee full compliance by our employees or collaborators, such as CROs, PIs, hospitals, medical professionals, nor can we assure detection of all improper practices. Any incidents of bribery or corruption involving us could lead to investigations, sanctions, fines, and significant reputational damage.

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We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (the “Scientific Data Measures”) (《科學數據管理辦法》), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term “state secret” is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Risks Relating to Our General Operations

Our future success depends in part on our ability to retain our senior management, scientific researchers and other qualified personnel.

We are highly dependent on the expertise and insights of our senior management team, and recruiting and retaining qualified scientific, technical, clinical, manufacturing, and sales/marketing personnel is critical for our success. The loss of these individuals could impede our research, development, and commercialization objectives, and despite non-compete clauses, increase competitive pressure. Replacing such specialized personnel is difficult and time-consuming due to a limited talent pool and intense industry competition. This may force us to offer higher compensation, adversely affecting our financial condition, and we risk not keeping pace with technological and regulatory standards. Any inability to attract, motivate, train, or retain qualified personnel could have a material adverse effect on our business, financial condition, and prospects.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Our future financial performance and our ability to commercialize our drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see “Business — Our Strategies.” As we continue to implement our development strategies, we intend to expand our operations and add a significant number of managerial, R&D, manufacturing, sales and marketing, and other personnel. Our recent and future growth will significantly increase management’s responsibilities, including identifying, recruiting, integrating, maintaining, and motivating employees. This also involves effectively managing internal development efforts, particularly clinical and regulatory processes, while fulfilling contractual obligations, and continuously improving operational, financial, and management controls, reporting systems, and procedures. If we cannot effectively manage our growth and further expand our organization, we may not be able to successfully develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our services. We intend to continue to enhance our

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technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. We cannot assure you that we will successfully develop, enhance, or adapt to new technologies, identify new opportunities, bring new products to market, secure intellectual property protection, or obtain timely and cost-effective regulatory approvals. Even if products are introduced, market acceptance is not guaranteed. Failure in these areas could render our technologies obsolete, significantly reducing demand for our services and harming our business and prospects.

Increased labor costs could slow our growth and affect our profitability.

Our operations depend in part on the skills and know-how of our employees. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further increase in labor cost, which may adversely affect our operations and financial condition. In addition, share options and other share-based incentives granted under our existing or future share-based incentive arrangements and scheme could adversely affect our costs and our results of operations. See also “— Risks Relating to Our Financial Position and Need for Additional Capital — We have incurred and may continue to incur share-based payments. The issuance of share-based payment awards may cause dilution to our existing Shareholders and may affect the market price of our H Shares.”

Our relationships with PIs, leading hospitals and medical practitioners may affect the clinical development and future marketing of our products.

Our relationships with principal investigators, leading hospitals and medical practitioners play an important role in our R&D and marketing activities. We implement a clinical demand-oriented and highly responsive R&D strategy by establishing extensive interaction channels with principal investigators, leading hospitals and medical practitioners to gain first-hand knowledge of clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs and improve our existing drug candidates. We are planning to develop our own commercialization team and network, with an initial focus on key hospitals and leading physicians across China’s extensive local markets. We are also committed to enhancing our collaborations with top hospitals and academic institutions in China to ensure our timely access to cutting-edge research and support our existing and future pipeline. See also “Business — Strategies” and “Business — Commercialization, Sales, Marketing and Distribution.”

We cannot assure the maintenance or strengthening of our clinical collaborations with principal investigators, KOLs, and leading hospitals, nor that these efforts will lead to successful new product development. Industry participants may cease cooperation or work with competitors. Their market insights, despite influencing our R&D, could be inaccurate, leading to drugs with low market potential, or even if correct, we may still fail to develop commercially viable drugs. Failure to develop new drugs or generate anticipated returns from these relationships could materially and adversely affect our business, financial condition, and results of operations.

Our reputation is important to our success. Negative publicity with respect to us, our substantial shareholder, management, employees, business partners, affiliates, CMOs, CROs, PIs and hospitals or our industry may materially and adversely affect our reputation, business, results of operations and prospects.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CMOs, PIs and hospitals, to advance our clinical development programs, expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

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Disputes, legal proceedings, regulatory inquiries, investigations, or perceived unethical conduct involving us, our shareholders, management, employees, partners, or affiliates could significantly harm our reputation and business. Regardless of the merits or outcome, such events can impede our ability to attract talent and partners, and hinder business growth.

Changes in relations between China and other countries may cause disruptions to our clinical development, drug manufacturing processes and other aspects of our business and operations.

Uncertain U.S. government actions regarding trade policies with China could lead to new tariffs, laws, or renegotiated trade agreements, potentially impacting our industry. Although we have not commenced commercial sales, unfavorable policies like capital controls or tariffs could disrupt raw material import/export, drug development, and manufacturing. Such changes might also negatively affect hiring R&D personnel, drug demand and competitiveness, and even prevent sales in certain countries. Any such shifts could materially and adversely affect our business, financial condition, results of operations, and prospects.

We may be involved in litigation, legal disputes, claims or administrative proceedings in the ordinary course of business, including product liabilities, which could be costly and time-consuming to resolve.

We may face legal proceedings and claims in the ordinary course of business or from governmental enforcement. These could incur substantial costs and divert management’s attention and resources. Initially minor disputes can escalate due to changing facts, increased stakes, or involved parties. Our insurance might not cover all claims, provide sufficient funds, or remain available on acceptable terms.

We face an inherent risk of product liability from clinical testing and future commercialization of our drug candidates, including: (i) claims of manufacturing or design defects, failure to warn, negligence, strict liability, or breach of warranties; (ii) an unsuccessful defense against such claims, or inability to obtain indemnification from partners, could lead to substantial liabilities or commercialization limits; (iii) even a successful defense would consume significant financial and management resources; (iv) product liability claims can result in reduced demand for our drugs, reputational damage, withdrawal of clinical trial participants, inability to commercialize, revenue loss, substantial monetary damages, and product recalls or marketing restrictions; and (v) failure to defend ourselves could expose us to civil liability for adverse events, criminal liability, and administrative actions like license revocation if our products are deemed defective.

Beyond product liability, we face risks from employee labor disputes or occupational injuries, and limited control over employee/partner behavior that could harm customer interests. We may also become subject to legal proceedings and claims arising from collaborations, with shareholders, or other third parties. Such disputes, even if successfully defended, could incur substantial costs, divert management attention and resources, and damage our reputation, materially affecting our business, financial position, and brand value.

PRC laws mandate product liability insurance for clinical trials, which may be prohibitively expensive or insufficient to cover potential liabilities, thus hindering drug candidate commercialization. Claims against us could exceed insurance limits or fall under exclusions, requiring us to pay uncovered amounts. We may lack, or be unable to obtain, sufficient capital to cover such liabilities.

We depend on information technology and other infrastructure that are exposed to certain risks, including cyber security risks.

We rely on a variety of information technology and automated operating systems to manage or support our operations, including protecting our intellectual property. The proper functioning of these systems is critical to the efficient operation and management of our business. In addition, these systems may require modifications or upgrades as a result of technological changes or growth

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in our business. These changes may be costly and disruptive to our operations and could impose substantial demands on management time. Our systems, the systems of our CROs, CMO partner, hospitals, PIs, consultants and the systems of third-party providers for the foregoing may be vulnerable to damage or disruption caused by circumstances beyond our control, such as catastrophic events, power outages, natural disasters, computer system or network failures, viruses or malware, physical or electronic break-ins, unauthorized access, cyber-attacks and thefts. We cannot assure you that the measures and steps we, other third-parties such as CROs and third-party service providers take to secure our and their systems and electronic information are adequate. Any significant disruption to our systems, other third-parties and the third-party providers could result in unauthorized disclosure of confidential information and adversely affect our business and operating results.

Our business and operations could be adversely affected by the effects of health pandemics or epidemics, including the outbreak of COVID-19, in regions where we, or third parties on which we rely, have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Health pandemics, such as COVID-19, can significantly disrupt our business, creating volatility and uncertainty. Such outbreaks could lead to employee quarantines, impact raw material availability and cost, and negatively affect our manufacturing capabilities, business operations, and clinical program timelines. Clinical trials may experience delays in site initiation and patient enrollment due to hospital resource prioritization, patient movement restrictions, or difficulties in recruiting investigators and staff. The economic fallout from pandemics can also disrupt global financial markets, making capital access more difficult and negatively impacting our liquidity, business, and share value.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see “Business — Insurance.” This coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Our insurance coverage may be insufficient for claims such as product liability, fixed asset damage, or employee injuries. Any liabilities or damages exceeding our coverage could lead to substantial costs and divert resources.

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

The property valuation report prepared by Colliers, an independent property valuer, set out in the Property Valuation Report set out as Appendix III to this document with respect to the appraised values of our properties is based on various assumptions, which are subjective and uncertain in nature. The assumptions that Colliers used in the property valuation report include that the seller sells the property interest in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interest. Certain of the assumptions used by Colliers in reaching the appraised value of our properties may be inaccurate or unreasonable. 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 appraised value 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. You should not place undue reliance on such values attributable to these properties as appraised by Colliers.

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We are subject to governmental approvals and compliance requirements in relation to the lands and buildings that we own and our construction in progress.

We are required to obtain various permits, certificates and other approvals from, or filings with, relevant government authorities at different stages of construction of property development, including but not limited to the real estate ownership certificate, planning permits, construction permits, certificates for passing environmental assessments, certificates for passing fire control assessments, certificates for passing construction completion inspections and filings for construction completion inspections.

During the Track Record Period, we commenced certain stages of some of our construction in progress before we obtained the Construction Permit and the approval for the environmental impact report. We may be subject to order to stop construction, order to rectify within a time limit and fines not less than 1% but not more than 2% of the project contract price for commencing construction before obtaining Construction Permit. For commencing construction before obtaining approval for the environmental impact report, depending on the severity of the violation and the consequences of the harm, a fine of not less than 1% but not more than 5% of the total investment of the construction project may be imposed, and such construction entity may be ordered to restore the original state. We have rectified such incidents by obtaining relevant certificates and approvals thereafter. However, we cannot guarantee you that we will not be subject to any administrative fines or other penalties due to the lack of the requisite certificates and approvals during the Track Record Period. We may also in the future encounter difficulties in obtaining the relevant permits, certificates, approvals and filings for the construction and development of our new facilities, which may negatively affect our growth strategies. For Directors’ views, see “Business — Properties — Owned Properties.”

In addition, one of our land parcels in Chengdu, may be classified as idle land, subject to a land idle fee at 20% of the land transfer or allocation price or clawback of land rights without compensation. As of the Latest Practicable Date, we have not received any formal notification from government authorities indicating such land is idle land. Our PRC Legal Adviser and the PRC legal adviser to the Joint Sponsors have conducted interviews with an officer in charge of the consulted matters of Chengdu Wenjiang High-Tech Industrial Park Management Committee (成都溫江高新技術產業園區管委會) in May 2025 and obtained relevant confirmation therefrom in June 2025, and have further conducted interviews with an officer in charge of the consulted matters of Chengdu Wenjiang District Planning and Natural Resources Bureau (成都市溫江區規劃和自然資源局) in June 2025.

We are subject to risks in relation to leased properties.

We may be subject to a number of risks in relation to the leased properties in the ordinary course of the businesses, including but not limited to the following:

- For one of our leased properties that we use for offices, the lessor with whom we enter into lease agreements did not provide the valid property ownership certificates, hence we cannot ensure that it has the rights to lease such property to us. If the lessor’s right to such property has any defect or is challenged by any third party, or is subject to any third party’s right, our lease could be invalidated or terminated. However, we will proactively seek remedies from the lessor according to our lease agreement in case of any challenges of defects are raised, and in the event that our leases are deemed invalidated or terminated, as such leased property is only used for office, we do not foresee any material obstacles for relocation of such office to a new premise.
- In addition, all of our lease agreements had not been registered and filed with the relevant land and real estate administration bureaus in the PRC. As advised by our PRC Legal Adviser, the relevant government authorities may impose a fine ranging from RMB1,000 to RMB10,000 on each lease agreement and RMB8,000 to RMB80,000 in the aggregate if we fail to rectify within the prescribed period after receiving notices from the relevant PRC government authorities.

For Directors’ views, see “Business — Properties — Leased Properties.”

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Our potential engagement in acquisitions or strategic partnerships in the future 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.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others.

Any completed, in-process, or potential acquisition or strategic partnership carries numerous risks, including that: (i) there is substantial time and expense during negotiations without guaranteed success, and adverse impacts on financial results such as goodwill impairment, increased operating expenses, and higher cash requirements; (ii) we might assume additional debt or contingencies, or our shareholders could face dilution from equity issuance; (iii) integration challenges are significant, encompassing operations, intellectual property, products, and personnel, potentially failing to achieve intended synergies; (iv) such endeavors can also divert management’s attention from existing programs, risk the loss of key employees, and jeopardize crucial business relationships; and (v) we face uncertainties related to the other party’s prospects and existing products, the potential inability to generate sufficient revenue from acquired assets, and the discovery of deficiencies in internal controls, data integrity, product quality, or regulatory compliance within the acquired business, which could lead to penalties or lawsuits.

Further, any difficulties in the integration of acquired businesses, products or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our reputation, business, financial condition and results of operations. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Changes in economic, political and social conditions could have a material and adverse impact on our future prospects, business, results of operations and financial condition.

A substantial portion of our future revenue is expected to be derived from our businesses in the PRC. Accordingly, our prospects, business, results of operations, and financial condition are, to a material extent, subject to economic, political and legal developments in the PRC. If the macroeconomic condition in China experiences significant adverse changes, demand for our products and our ability to maintain our operations may suffer, which could consequently lead to a material and adverse impact on our business, results of operations and financial condition.

China’s economy has experienced significant growth over the past decades since the implementation of reform and opening-up policy. In recent years, the PRC government has implemented measures emphasizing the utilization of market forces in economic reform and the establishment of sound corporate governance practices in business enterprises. These economic reform measures may be adaptively adjusted from industry to industry or across different regions of the country. Changes in China’s business environment and changes in the business environment in jurisdictions we may operate in the future could have a material and adverse impact on our business, results of operations and financial condition.

We are subject to the currency exchange regulatory system.

Our revenue is denominated in Renminbi, and we convert a portion to other currencies for foreign obligations, such as H Share dividends. While current PRC laws allow this with procedural compliance, the government may, in the future, restrict access to foreign currencies. This could prevent us from paying foreign currency dividends or meeting other foreign exchange requirements, such as funding capital expenditures. Any such insufficiency would materially and adversely impact our future prospects, business, results of operations, and financial condition.

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Fluctuations in exchange rates may adversely affect our results of operations.

The value of RMB against the Hong Kong dollar, the U.S. dollar and other currencies fluctuates, is subject to changes resulting from the PRC government’s policies and depends to a large extent on domestic and international economic and political developments as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between the RMB and the Hong Kong dollar, the U.S. dollar or other currencies in the future.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the Hong Kong dollar, the U.S. dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any 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.

Our operations are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. The PRC tax laws and regulations might be subject to interpretations and adjustments by relevant authorities from time to time. As a result, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could have a material and adverse impact on our future prospects, business, results of operations and financial condition.

We may be required to pay late payment fines or other penalties in connection with our failure to contribute to social insurance and housing provident funds.

In accordance with applicable PRC laws and regulations, we are obliged to contribute to social insurance and housing provident funds for our employees. During the Track Record Period, except for employees of Shanghai Jingze, one of our subsidiaries, we did not fully contribute to social insurance and housing provident funds for all of our employees.

According to the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), if we fail to pay the full amount of housing provident fund contributions as required, the housing provident fund management center may require payment of the outstanding amount within a prescribed period. If the payment is not made within the prescribed deadlines, an application may be made to the relevant PRC courts for compulsory enforcement. The cumulative under-provided amount for housing provident fund is RMB1.7 million as of April 30, 2026, which is our maximum financial exposure for non-compliance with housing provident fund requirements. According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), for outstanding social insurance fund contributions that we did not fully pay within the prescribed deadlines, the relevant PRC authorities may demand that we pay the outstanding social insurance contributions within a stipulated deadline and we may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount for each day of delay. If we fail to repay the outstanding social insurance contributions within the stipulated period, we may be liable to a fine of one to three times the outstanding contribution amount. The cumulative under-provided amount for social insurance is RMB5.8 million as of April 30, 2026, and our maximum financial exposure for non-compliance with social insurance requirements is therefore three times this amount plus late fee.

During the Track Record Period, we had not made social insurance and housing provident funds for some of our employees in full in accordance with the relevant PRC laws and regulations mainly in Chengdu. In 2024, 2025 and four months ended April 30, 2026, our shortfall for social insurance and housing provident fund amounted to RMB0.6 million, RMB0.3 million and RMB0.5 million. During the Track Record Period and up to the Latest Practicable Date, we had not been imposed any administrative penalties as a result of our non-compliance with social insurance and housing provident fund related PRC laws and regulations, or received any significant employee reports, complaints, or material claim related to social insurance or housing provident fund matters, nor had we experienced any strike or labor dispute with our employees which had or may have a material impact on our business.

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Our PRC Legal Adviser and the PRC legal adviser to the Joint Sponsors have conducted interviews with an officer in charge of the consulted matters of Chengdu Wenjiang District Human Resources and Social Security Bureau (成都市溫江區人力資源和社會保障局) in May 2025. The interviewee confirmed that (i) Chengdu Wenjiang District Human Resources and Social Security Bureau is the competent authority of management, recovery, and punishment of social insurance (excluding medical and maternity insurance) premiums before January 2024, (ii) the bureau typically conducts inspections of employers’ contribution compliance when receiving employee complaints or reports, and if deficiencies in payment are verified during such inspections, employers are generally required to rectify the shortfall within a specified period and make up the unpaid contributions, and provided the employer fulfills these corrective measures on time, no further penalties will be imposed; and (iii) at present, no investigations, recovery actions, warnings, notifications, or administrative penalties have been initiated against Chengdu Jingze, and no employee complaints or reports regarding Chengdu Jingze’s social security contribution compliance have been received to date.

Our PRC Legal Adviser and the PRC legal adviser to the Joint Sponsors have conducted interviews with an officer in charge of the consulted matters of Chengdu Wenjiang District Medical Security Bureau (成都市溫江區醫療保障局) in May 2025. The interviewee confirmed that (i) Chengdu Wenjiang District Medical Security Bureau is the competent authority of the management and recovery data of medical and maternity insurance premiums before January 2024, (ii) the bureau typically conducts inspections of employers’ contribution compliance when receiving employee complaints or reports and by big data comparison within the system, and if deficiencies in payment are verified during such inspections, employers are generally required to rectify the shortfall within a specified period and make up the unpaid contributions, and provided the employer fulfills these corrective measures on time, no further penalties will be imposed; and (iii) at present, no investigations, recovery actions, warnings, notifications, or administrative penalties have been initiated against Chengdu Jingze, no employee complaints or reports regarding Chengdu Jingze’s medical and maternity insurance contribution compliance have been received to date, and the big data comparison within the system does not indicate any inconsistency of Chengdu Jingze.

Our PRC Legal Adviser and the PRC legal adviser to the Joint Sponsors have conducted interviews with an officer in charge of the consulted matters of Chengdu Housing Provident Fund Management Center (成都住房公積金管理中心溫江服務部) in May 2025. The interviewee confirmed that (i) Wenjiang Service Department of Chengdu Housing Provident Fund Management Center is the competent department for housing provident fund collection and punishment, (ii) typically, the center will not actively request the employer to make up the payment, deposit within a time limit or impose punishment if no complaints or reports are filed, and no further measures will be imposed if the rectification is completed within the specified time limit; and (iii) currently, there are no complaints or reports against Chengdu Jingze.

For relevant Director and PRC Legal Adviser views, please see “Business — Employees.”

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

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

We are primarily a clinical-stage biopharmaceutical company with a relatively short operating history. See “History and Development.” Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our drug candidates, forging collaboration and strategic partnerships for commercialization, and organizing and staffing our operations. We have limited experience in commercial-scale manufacturing, sales, and marketing. This makes predicting our future performance difficult, and we may face unforeseen expenses, challenges, and delays, which could adversely affect our business if not addressed successfully.

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We incurred net losses during the Track Record Period, and we anticipate we will continue to incur losses in the near future and may not achieve or maintain profitability in the future.

Investment in the development of biopharmaceutical drug candidates is highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we financed our operations primarily through borrowings from banks and proceeds from our various series of financing. We had not generated any revenue from the sales of commercialized products as of the Latest Practicable Date, and we continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. In 2024, 2025 and the four months ended April 30, 2025 and 2026, our net losses were RMB242.7 million, RMB270.4 million, RMB82.2 million and RMB89.3 million, respectively.

Substantially all of our net losses during the Track Record Period resulted from costs and expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials. In 2024, 2025 and the four months ended April 30, 2025 and 2026, research and development expenses amounted to 72.3%, 60.5%, 66.3% and 55.1% of our total operating expenses, respectively. See “Financial Information — Principal Components of Results of Operations” for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We anticipate continued and increasing net losses in the foreseeable future as we: (i) advance clinical and preclinical studies; (ii) discover, develop, and in-license new drug candidates; (iii) seek regulatory approvals; (iv) manufacture for trials and commercial sale; (v) manage license and collaboration arrangements; (vi) commercialize approved drugs; (vii) expand our intellectual property; (viii) attract skilled personnel; and (ix) incur expenses associated with operating as a public company.

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our net losses have had, and will continue to have, an adverse effect on our working capital and shareholders’ equity. Our failure to become and remain profitable may affect investors’ perception of the potential value of our Company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the market price of our H Shares. A decline in the market price of our H Shares could cause potential investors to lose all or part of their investment in our business.

We had net liabilities, net current liabilities and net operating cash outflows as of the end of and during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

As of December 31, 2024 and 2025 and April 30, 2026, we had net liabilities of RMB1,258.4 million, RMB1,486.5 million and RMB1,568.1 million, respectively. In addition, we recorded net current liabilities of RMB1,324.7 million, RMB1,563.8 million and RMB1,651.5 million as of December 31, 2024, 2025 and April 30, 2026, respectively, mainly attributable to bank loans and redemption liabilities on equity shares, respectively, as of the same dates, which we borrowed primarily from various banks in China and raised additional funds through equity financing to fund our investments in our business. A net liabilities position can expose us to the risk of shortfalls in liquidity, in which case our ability to raise funds or obtain bank loans will be materially and adversely affected.

We had net cash used in operating activities of RMB121.8 million, RMB118.1 million, RMB29.2 million and RMB37.0 million in 2024, 2025 and the four months ended April 30, 2025 and 2026, respectively, primarily for our research and development activities. We may experience net cash outflows from our operating activities from time to time. See “Financial Information — Liquidity and Capital Resources.” Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

RISK FACTORS

If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need to obtain substantial additional financing to fund our operations and may be forced to accept unfavorable terms or limitations on our operation during the process. If financing is not available on terms acceptable to us, or at all, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we financed our operations, including our R&D activities in relation to our preclinical studies and clinical trials, primarily through interest-bearing loans from banks and proceeds from our various rounds of financing.

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license-out arrangements and collaboration agreements, and net [REDACTED] from the [REDACTED]. Upon the successful commercialization of more drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. We may require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. Our future funding requirements will depend on numerous factors, including: (i) the progress, timing, scope, and costs associated with our clinical trials, patient enrollment, and regulatory approvals for our drug candidates; (ii) the expenses for discovering and early developing additional drug candidates, preparing for their commercialization and product launches, and meeting manufacturing needs for both clinical and approved products; (iii) milestone and royalty payments; (iv) the costs of intellectual property protection; (v) cash needs for future acquisitions or in-licensed drugs; and (vi) the expenses related to headcount growth.

As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

Our ability to raise funds will also depend on the prevailing financial, economic and market conditions and factors from other aspects, such as our relationship with commercial banks, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities, or the commercialization of one or more of our drug candidates, which may adversely affect our business prospects.

We had substantial indebtedness and net current liabilities during the Track Record Period, and may continue to incur significant debt going forward, which may expose us to liquidity risk.

We had interest-bearing loans of RMB111.2 million as of April 30, 2026. We had loan from a shareholder amounting to RMB121.1 million as of April 30, 2026. A large balance of indebtedness, whether from banks or related parties, may require that we devote our financial resources to servicing such debt rather than funding our operating activities and investments in research and development, which constrains our capital flexibility and may in turn adversely affect our drug development timetable. It may also be a challenge for us to service our interest and principal repayments in a timely manner or at all, which could trigger cross-defaults with other debt, as applicable, as well as limit our ability to obtain further debt financing. Given our historical reliance on external financing, such developments could have a material adverse effect on our business, financial condition and results of operations.

RISK FACTORS

We benefit from certain preferential tax treatments and government grants, the expiration of or changes to which could adversely affect our business, financial condition and results of operations.

We currently benefit from certain preferential tax treatments. According to the EIT Law and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. Shanghai Jingze, Chengdu Jingze and the Company qualified as High and New Technology Enterprises and enjoyed preferential income tax rate of 15% from 2024 to 2025.

We cannot assure you that these preferential tax treatments will continue to be available to us in the future, or that these preferential tax treatments will not be changed, as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected. See “Note 11 to the Accountant’s Report in Appendix I” to this document for details.

Moreover, we recorded government grants of RMB10.5 million, RMB1.8 million, RMB0.4 million and RMB0.3 million in 2024, 2025 and the four months ended April 30, 2025 and 2026, respectively. These government grants primarily represent government subsidies for the purpose of compensating us for the expenses in relation to our R&D activities and construction of our manufacturing facilities. These government grants are provided to us at the discretion of the relevant government authorities, who could determine at any time to eliminate or reduce these financial incentives, and may therefore vary from period to period going forward. For more details, please see “Financial Information — Principal Components of Results of Operations — Other income.”

Our receipt of government grants and eligibility for preferential income tax treatment are subject to discretionary approval, meaning our net income can fluctuate significantly based on changes to these benefits. There is no assurance we will continue to receive grants at current levels or remain eligible for preferential tax treatment. The discontinuation of these financial incentives could adversely affect our financial condition, results of operations, cash flows, and prospects.

We have incurred and may continue to incur share-based payments. The issuance of share-based payment awards may cause dilution to our existing Shareholders and may affect the market price of our H Shares.

In 2024, 2025 and the four months ended April 30, 2025 and 2026, we recognized share-based payment expense of a net reversal of RMB0.08 million, and expenses of RMB12.9 million, RMB0.1 million and RMB7.7 million, respectively. We only granted shares to our certain key employees during the Track Record Period. In the future, we may issue options and shares to our Directors, senior management and/or key employees to incentivize their performance and align their interests with ours. As a result, we may incur equity-settled share-based payments, which could have a material adverse effect on our net profits. Furthermore, the grant of equity-accounted share-based payments may result in an immediate and potentially substantial dilution to our existing Shareholders and could result in a decline in the value of our H Shares.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares.

Prior to the [REDACTED], there was no public market for our H Shares. The [REDACTED] for our H Shares to the public was the result of negotiations between us and the [REDACTED] (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price for our H Shares following the [REDACTED]. We have applied for [REDACTED] of, and permission to deal in, our H Shares on the Stock Exchange. Pursuant to the applicable PRC laws, all of the Shares in issue as of the date of this document will be subject to a lock-up period of one year from the [REDACTED]. Further, the [REDACTED] to be issued to the Cornerstone Investors are subject to a six-month lock-up period following the [REDACTED] pursuant to the terms of the Cornerstone Investment Agreements. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active trading market for our H Shares will develop, or if it does develop, will be sustained following the [REDACTED] or that the market price of our H Shares will not decline following the [REDACTED].

RISK FACTORS

The trading volume and market price of our H Shares may be volatile, which may result in substantial losses for investors subscribing for or purchasing our H Shares pursuant to the [REDACTED].

The price and trading volume of our H Shares may be highly volatile due to various factors, some of which are beyond our control, including: (i) actual or anticipated fluctuations in our results of operations (such as variations arising from foreign exchange rate fluctuations); (ii) news regarding the recruitment or loss of key personnel by us or our competitors; (iii) announcements of competitive developments, acquisitions, or strategic alliances in our industry; (iv) changes in earnings estimates or recommendations by financial analysts; (v) potential litigation or regulatory investigations; (vi) changes in general economic conditions or other developments affecting us or our industry; (vii) changes in any relevant government policies or regulations; (viii) price movements on international stock markets, the operating and stock price performance of other companies, other industries, and other events or factors beyond our control; and (ix) the release of lock-up or other transfer restrictions on our outstanding Shares, or sales or perceived sales of additional Shares by substantial shareholders or other shareholders.

Future sales or perceived sales or conversion of substantial amounts of our Shares in the public market, including any future offering of H Shares, could have a material adverse effect on the prevailing market price of our H Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholding.

The market price of our H Shares could decline as a result of future sales or issuances of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the perception that such sales or issuances may occur. Moreover, such future sales or perceived sales may also adversely affect the prevailing market price of our H Shares and our ability to raise capital in the future at a favorable time and price. The H Shares held by the substantial shareholder are subject to certain lock-up undertakings for a period of up to twelve months after the [REDACTED]. See “[REDACTED]” for further details. We cannot assure you that they will not dispose of their Shares they may own now or in the future.

Furthermore, if additional funds are raised through our issuance of new equity or equity-linked securities other than on a pro-rata basis to existing Shareholders, the percentage ownership for such Shareholders may be reduced. Such new securities may also confer rights and privileges that take priority over those conferred by the H Shares.

You will incur immediate and significant dilution and may face further dilution if we issue additional Shares in the future.

The [REDACTED] for our H Shares is higher than the net tangible assets book value per H Share initially issued to our Shareholders prior to the [REDACTED]. Consequently, purchasers of our H Shares in the [REDACTED] will face an immediate dilution, and our Shareholders prior to the [REDACTED] will experience an increase in the [REDACTED] consolidated net tangible assets book value per H Share of their H Shares. Moreover, we may in the future consider seeking a [REDACTED] of our Shares in jurisdictions other than Hong Kong, which would similarly dilute the holdings of our H Share investors.

We cannot assure you that the H Shares will remain [REDACTED] on the Stock Exchange of Hong Kong.

We cannot guarantee the continued [REDACTED] of the H Shares. Among other factors, our Company may not continue to satisfy the [REDACTED] requirements of the Stock Exchange. Holders of H Shares would not be able to sell their H Shares through [REDACTED] on the Stock Exchange if the H Shares were no longer [REDACTED] on the Stock Exchange.

RISK FACTORS

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

Prior to and immediately following the completion of the [REDACTED], our Single Largest Group of Shareholders have remained substantial control over our Company. Subject to the Articles of Association, our Single Largest Group of Shareholders will be able to exercise significant control and exert significant influence over our business or otherwise on matters of significance to us and other Shareholders by voting at the general meeting of the Shareholders and at Board meetings. The interest of our Single Largest Group of Shareholders may differ from the interests of other Shareholders and they are free to exercise their votes according to their interests. To the extent that the interests of our Single Largest Group of Shareholders conflict with the interests of other Shareholders, the interests of other Shareholders can be disadvantaged and harmed.

Payment of dividends is subject to restrictions under the PRC law and there is no assurance whether and when we will pay dividends.

No dividend has been paid or declared by our Company during the Track Record Period. Under the applicable PRC laws, the payment of dividends may be subject to certain limitations. The calculation of our profit under applicable accounting standards differs in certain respects from the calculation under IFRS. As a result, we may not be able to pay a dividend in a given year even if we were profitable as determined under IFRS. Our Board may declare dividends in the future after taking into account our results of operations, financial condition, cash requirements and availability and other factors as it may deem relevant at such time. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the PRC laws and regulations and requires approval at our shareholders’ meeting. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

The dividends payable to investors and gains on the sale of our H Shares by our investors are subject to PRC tax.

Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the sale or other disposition of our H Shares. See “Appendix IV — Taxation and Foreign Exchange — PRC Taxation”. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax.

Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including HKSCC Nominees). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H shares through the sale or transfer by other means of H shares.

The interpretation and application of the relevant PRC tax laws by the PRC tax authorities are subject to changes and evolving, and there remain uncertainties as to whether and how individual income tax or EIT on gains derived by holders of our H Shares from their disposition of our H Shares may be collected. If any such tax is collected, the value of our H Shares may be materially and adversely affected.

RISK FACTORS

Certain facts, forecasts and statistics in this document relating to the biopharmaceutical industry are derived from a third-party report or publicly available sources and may not be fully reliable.

This document, particularly the section headed “Industry Overview” contains information and statistics relating to the pharmaceutical industry. Certain statistics, information and data contained in this document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications or other third-party reports. In particular, we have extracted and disclosed in this document certain statistics, information and data from publications and other publicly available sources relating to the drugs and drug candidates of third parties and scientific research, theories and mechanisms. We have taken reasonable care in the reproduction or extraction of the official government publications and other third-party reports for the purpose of disclosure in this document. However, we cannot guarantee the quality or reliability of such source materials. Investors should give consideration as to how much weight or importance they should attach to or place on such facts.

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].

Prior to the publication of this document, there has been coverage in the media regarding us and the [REDACTED], which contained 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 any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this document. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.