

RISK FACTORS

An [REDACTED] in the H Shares involves various risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in the H Shares. The following is a description of what we consider to be our material risks. Any of the following risks, as well as additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial, could materially and adversely affect our business, financial condition, and results of operations. The [REDACTED] of the H Shares could significantly decrease due to any of these risks, and you may lose all or part of your [REDACTED]. 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 is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-Looking Statements.”

KEY RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Our business and prospects depend substantially on the successful clinical development, regulatory approval, and commercialization of our drug candidates.

We have systematically built a drug pipeline in oncology, autoimmune diseases, and hemostasis/hematology, consisting of four commercialized products, Zepsun[®], Zepuping, Zepuning and Zesuning, and a suite of innovative drug candidates undergoing clinical or preclinical development as of the Latest Practicable Date. Our business depends on our ability to successfully develop, obtain regulatory approval for, manufacture and commercialize our drug candidates. We have invested significant operational efforts and financial resources in researching, developing and commercializing our existing drug candidates; in 2023, 2024, 2025 and the six months ended June 30, 2025 and 2026, we recorded R&D expenses of RMB496.3 million, RMB388.0 million, RMB429.9 million, RMB196.5 million and RMB199.5 million, respectively, and we expect to continue incurring substantial and increasing expenditures for the development and commercialization of our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to: (i) successful enrollment and completion of clinical trials and preclinical studies; (ii) favorable safety and efficacy data; (iii) receipt of regulatory approvals; (iv) successful commercialization and market launch; (v) sufficient commercial manufacturing capabilities for swift market entry; (vi) protection and enforcement of intellectual property and regulatory exclusivity; (vii) obtaining and maintaining favorable governmental and private reimbursements for approved drugs; (viii) competition; and (ix) continued acceptable safety profiles.

Our clinical trials may also compete with trials for other drug candidates in the same therapeutic areas, potentially reducing the number and types of subjects available to us. Even if we enroll a sufficient number of subjects, delays in enrollment may increase costs or affect the timing or outcome of our clinical trials, which could prevent their completion and materially and adversely affect our ability to advance our drug candidates.

As of the Latest Practicable Date, our innovative drug pipeline includes 10 drug candidates across 29 key clinical programs. However, we cannot guarantee that we will obtain regulatory approvals for our drug candidates in a timely manner, or at all, and none of our drug candidates in our innovative drug pipeline has been approved for marketing in any jurisdiction. Our pipeline products may require additional preclinical and/or clinical development, regulatory approvals, substantial investment and significant marketing efforts before we can generate any revenue from product sales.

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If we fail to obtain timely regulatory approvals in the target markets for our drug candidates, or if the approval process is delayed, our business may suffer material and substantial damage.

Bringing drug candidates to market requires significant time, effort and expenses, and the regulatory approval process is inherently uncertain. Based on our experience and the nature of pharmaceutical development, the process from initiation of clinical trials to potential marketing approval may take several years, and in many cases approximately five to ten years or longer, depending on factors such as clinical trial design, patient enrollment, trial outcomes, regulatory requirements and review timelines. We cannot assure you that any of our drug candidates will be approved for sale. Before obtaining regulatory approval, we must conduct extensive clinical trials demonstrating the safety and efficacy of our drug candidates in humans. If clinical trial results are not positive, or only modestly positive, for proposed indications, or raise safety concerns, we may (i) be subject to substantial liabilities; (ii) be delayed in or prevented from obtaining regulatory approval; (iii) obtain approval for narrower indications than intended; (iv) be subject to additional post-marketing testing requirements; (v) be subject to restrictions on distribution or use; or (vi) be unable to obtain reimbursement for use of the product. Any of these events could materially and adversely affect our ability to commercialize the subject drug candidates and generate revenue.

The time required to obtain approvals from the NMPA, the FDA and other comparable regulatory authorities is often unpredictable and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates could fail to receive timely regulatory approval for many reasons, including but not limited to: (i) failure to begin or complete clinical trials; (ii) failure to demonstrate that a drug candidate is safe and effective for its proposed indication; (iii) failure of clinical trial results to meet the required level of statistical significance; (iv) participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and (v) failure of the CMC component of a regulatory submission to meet the requirements of the relevant regulatory authorities.

In addition, the NMPA, the FDA or a comparable regulatory authority may require more information to support approval, which may prolong, delay or prevent approval of our commercialization plans, or we may decide to abandon the development programs. Regulatory requirements and guidance may also change, requiring us to amend clinical trial protocols submitted to competent authorities. Resubmission may impact the cost, timing or successful completion of a clinical trial. Regulatory policies may also change, and additional government regulations may be enacted that could prevent, limit or delay approval of our drug candidates. If we are slow or unable to adapt to new or changed requirements or policies, or unable to maintain regulatory compliance, we may not obtain, or may lose, regulatory approvals, and we may not achieve or sustain profitability.

Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and approval in one country does not guarantee approval in any other. Approval procedures vary among countries and can involve additional product testing, validation and administrative review periods. We cannot assure you that we will meet the regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale there. Additional time, effort and expense may be required to bring approved drug candidates to international markets in compliance with different regulatory processes.

Delays, suspension or termination of clinical trials could materially harm development timelines, approval prospects and future revenues. Such delays will increase our costs, prolong our development and approval process, and jeopardize our ability to commence product sales and generate revenue for that candidate, which could significantly harm our business, financial condition and prospects. Many of the same factors that delay commencement or completion of clinical trials may also ultimately lead to denial of regulatory approval.

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We rely on the sales of certain major products in China, and our products may fail to achieve or maintain market acceptance or the expected market size, which could materially and adversely affect our business.

We rely on the sales of certain major products in China, which account for a substantial portion of our total revenue. During the Track Record Period, our revenue was derived from the sale of our commercialized products Zepsun[®], Zepuning, Zepuping and Zesuning, as well as from licensing activities. In 2023, 2024, 2025 and the six months ended June 30, 2025 and 2026, our total revenue amounted to RMB383.6 million, RMB531.5 million, RMB810.2 million, RMB375.5 million and RMB1,204.4 million, respectively, of which revenue from the sale of Zepsun[®] accounted for 100.0%, 99.7%, 74.3%, 78.6% and 23.0% of our total revenue for the respective period, and revenue from the sale of Zepuning accounted for nil, 0.3%, 20.0%, 18.2% and 9.9% of our total revenue for the respective period. The percentage of our revenue from the sale of Zepsun[®] experienced a major decrease due to the impact of the licensing revenue we received from AbbVie, which may not be sustainable, and therefore we expect revenue from the sale of these products to continue contributing a significant portion of our revenue in the near future. As a result, our results of operations and profitability are highly dependent on the continued commercial success of these products.

During the Track Record Period, our revenue has been, and we expect it will continue to be, concentrated in certain major products. We are therefore particularly susceptible to factors adversely affecting their sales volume, pricing or profit margins, including (i) market acceptance by physicians, hospitals and patients; (ii) reimbursement coverage, including NRDL inclusion and subsequent renewal cycles; (iii) pricing pressures and procurement dynamics; (iv) sales and promotion effectiveness; (v) availability, cost and quality of raw materials and manufacturing capacity; (vi) potential safety concerns, adverse events or unfavorable clinical perceptions; and (vii) intellectual property risks. Many of these factors are outside our control, and any factor adversely affecting sales volumes, pricing or profit margins could adversely affect our operations, revenue and profitability.

The commercial success of our products and future approved drug candidates also depends on continued market acceptance in the medical community, which may be affected by: (i) perceived advantages over, and availability and success of, competing products; (ii) safety and efficacy profiles and any side effects; (iii) pricing and cost effectiveness; (iv) sales and promotion effectiveness; (v) publicity concerning our products or competing products; (vi) our ability to respond to changing needs and preferences of healthcare practitioners and patients; and (vii) inclusion of our products in the NRDL. Failure to achieve or maintain market acceptance, or increased competition, could materially and adversely affect demand for our products, as well as our business and profitability.

The actual market size of our products and drug candidates may also be smaller than anticipated due to factors such as pricing, reimbursement and patient access. Any such developments could materially and adversely affect our business, financial condition and results of operations.

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

Undesirable adverse events caused by our drug candidates, alone or in combination with other drugs, such as serious or unexpected adverse reactions, dose-limiting toxicities, clinically significant laboratory abnormalities, immunogenic or hypersensitivity reactions, or drug-drug interactions, could result in clinical holds, delays or additional regulatory requirements, and could cause significant negative consequences, including but not limited to: (i) enhanced labelling, warnings or regulatory restrictions on approved drugs; (ii) suspension, delay or modification of development or commercialization; (iii) imposition or expansion of a risk evaluation mitigation

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strategy; (iv) changes to dosing, administration or approved use; (v) slower or insufficient patient enrollment, or higher trial attrition than expected; and (vi) product recalls, litigation or regulatory investigations. Any of these events could prevent us from achieving or maintaining market acceptance of an approved drug candidate and could significantly harm our business, results of operations and prospects.

During the Track Record Period, we made a one-off compensation payment to certain trial participants for adverse reactions in clinical trials to cover associated medical expenses and provide additional compensation. Under current GCP provisions, such payment was an industry compliance requirement and a statutory duty of the Company to safeguard trial participants’ rights.

However, adverse events in clinical trials may expose us to additional compensation obligations, claims, product liability litigation, and regulatory inquiries or investigations. There can be no assurance that similar adverse events will not occur in the future, or that we will not be required to make additional or more substantial compensation payments, which could be significant. Any such claims, litigation or compensation payments could result in substantial costs, divert management resources, and adversely affect our financial condition and results of operations. To manage these risks, we have purchased clinical trial liability insurance covering potential compensation, indemnification and related costs, and established reporting pathways and causality assessment mechanisms to ensure adverse events are handled in compliance with regulatory and ethical standards. Through this insurance coverage and process-control measures, we have kept these risks within a manageable range. However, such measures may not prevent all adverse events or eliminate the risk of litigation, compensation liability or reputational damage. During the Track Record Period and up to the Latest Practicable Date, we experienced no material adverse impact on our business as a result of such occurrence or relevant compensation payments. However, there can be no assurance that future adverse events, compensation claims, litigation or reputational harm will not have a material adverse effect on our business, financial condition, results of operations and prospects.

We recorded net cash outflows used in our operating activities during the Track Record Period, and we may need to obtain additional financing to fund our operations and execute our growth strategy. Any inability to obtain sufficient funding, or any failure to effectively manage or realize the returns on our R&D investments, could materially and adversely affect our business, financial condition, results of operations and prospects.

We had net cash used in operating activities of RMB289.9 million, RMB32.6 million, RMB10.3 million in 2023, 2025 and the six months ended June 30, 2025, respectively, primarily due to our high R&D expenditure and relatively slow revenue growth from our recently commercialized products. We had net cash generated from operating activities of RMB42.3 million in 2024, mainly attributable to the upfront payment we received from Grand Life Sciences in relation to our strategic promotional partnership; and we had net cash generated from operating activities of RMB814.6 million in the six months ended June 30, 2026, primarily attributable to the profit before tax arising from the upfront fee paid by AbbVie under the AbbVie Agreement and an increase in deferred income mainly representing the upfront payment received from Merck.

Specifically, we have incurred, and expect to continue to incur, significant R&D expenses as part of our growth strategy to advance our clinical-stage assets and enhance our R&D capabilities. In 2023, 2024, 2025 and the six months ended June 30, 2025 and 2026, our R&D expenses were RMB496.3 million, RMB388.0 million, RMB429.9 million, RMB196.5 million and RMB199.5 million, respectively. This investment aligns with our growth strategy to advance the clinical development of our differentiated pipeline assets. For more details, see “Business — Research and Development.” However, these expenses may not result in commercially viable products or generate revenue on a timely basis, or at all, and may negatively affect our net profit and cash flows. Our drug candidates require substantial investment for the completion of clinical development, regulatory review, manufacturing, commercialization and marketing before they can generate product sales revenue. Pursuing our growth strategy has resulted in, and will continue to result in,

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substantial demands on capital and other resources, and we expect our cash operating costs to continue accounting for a substantial portion of our revenue given our expanding clinical trial programs. Our future funding requirements will depend on many factors, including but not limited to: (i) scope, timing and cost of clinical and preclinical programs; (ii) development outcomes and regulatory timelines; (iii) discovery and early-stage development of our pipeline expansion; (iv) commercialization readiness and launch activities of our drug candidates; (v) manufacturing capacity and facility expansion for approved drugs; (vi) management of our collaboration partners and associated costs; (vii) sales, promotion and distribution expenses on approved drugs; and (viii) operating costs as a public company and related internal infrastructure upgrades.

If the financial resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. However, there can be no assurance that such financing will be available in sufficient amounts, on acceptable terms, or at all. We may be required to delay, scale back or discontinue certain R&D programs, clinical trials, manufacturing scale-up, commercialization efforts or other operations, and may be unable to complete the development and commercialization of our drug candidates.

Our growth strategy also depends on our ability to continuously innovate and keep pace with new technologies and methodologies in the rapidly evolving pharmaceutical and biopharmaceutical industries. We intend to continue investing in human resources and technical capabilities in drug discovery, development and manufacturing, which are capital- and time-intensive. We cannot assure you that we will successfully identify new technological opportunities, develop or commercialize innovative drugs, obtain sufficient intellectual property protection, secure regulatory approvals in a timely and cost-effective manner, or achieve market acceptance. Any failure to do so may render our technologies or drug candidates less competitive or obsolete, and could materially and adversely affect our business, financial condition, results of operations and prospects.

We face substantial competition and our competitors may discover, develop or commercialize competing products faster or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition from pharmaceutical and biopharmaceutical companies worldwide, including large companies that currently market and sell drugs, or are pursuing development of drugs, for the same indications for which we are developing our drug candidates. In particular, we may face intense competition in oncology, autoimmune diseases, and hemostasis/hematology drug development. Some of these competitors have greater resources and expertise than we do. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. The competitive landscape of our target market is constantly evolving with the introduction of next-generation treatments and advanced technologies that could provide more effective or convenient treatment options. In light of the intense competition, we may not be able to compete effectively and obtain substantial market share even if we successfully develop and commercialize our drug candidates. We anticipate facing increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be significantly reduced or eliminated if competitors develop and commercialize drugs that are safer, more effective, more convenient or less expensive than ours. Competitors may also obtain approval from the NMPA, the FDA or other comparable regulatory authorities more rapidly than we do, allowing them to establish a strong market position before we enter the market and potentially rendering our drug candidates obsolete or non-competitive before we can recover our development and commercialization expenses.

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If the products we sell are excluded, removed, or limited from government-sponsored or commercial medical insurance programs, or are included in any national negative catalogs in China or assigned with black box warnings issued by the NMPA, the FDA, our sales, profitability and business prospects could be adversely affected.

If a pharmaceutical product is covered by medical insurance, whether provided by the government or a private entity, patients may be entitled to reimbursement for all or part of the cost. Consequently, the inclusion or exclusion of a product in insurance programs such as the NRDL, provincial medical insurance or other PRC health insurance schemes, and any limitations on coverage, will significantly affect patient demand. Inclusion within the scope of insurance coverage depends on factors such as efficacy, safety and price, which may be outside our control. Insurance providers may also periodically review, revise or change the scope of reimbursement for previously covered products. There can be no assurance that our currently covered products will maintain such coverage, or that changes in reimbursement scope will not negatively affect our product sales. If any of our products or their indications are removed from coverage, or reimbursement scope is reduced, demand for our products may decrease and our operations, revenue and profitability could be adversely affected.

In addition, inclusion in any national negative catalogs in China represents considerable risk. These catalogs require medical institutions to strictly monitor and control the clinical use of listed pharmaceuticals, significantly decreasing physicians’ capability and willingness to prescribe them. As of the Latest Practicable Date, none of our products was included in any national negative catalogs in China. There can be no assurance that similar catalogs will be issued at national level, nor can we predict their future pharmaceutical coverage. If any of our products are included in such catalogs, demand for our products may decrease and our revenue and profitability could be adversely affected.

Further, as we may in the future commercialize our drug candidates in the United States, an FDA black box warning for our drug candidates may impose significant risk. Such warnings, often based on late-stage clinical data or animal toxicity findings, indicate a significant risk of serious or life-threatening adverse effects. A black box warning can decrease physician prescribing, heighten liability concerns and substantially reduce sales, while also negatively affecting perceptions of our commitment to safety and harming our reputation and long-term business prospects.

If we are unable to conduct effective promotion or maintain a qualified sales force, the sales volume of our products and our operations, revenue, profitability and business prospects could be adversely affected.

Successful sales and academic promotion are crucial to increasing market penetration of our existing products, expanding our coverage of hospitals and other medical institutions, and promoting new products in the future. If we are unable to increase or maintain the effectiveness and efficiency of our sales and academic promotion activities, or to apply our experience from our marketed product portfolio to our innovative drug portfolio, our sales volumes and business prospects could be adversely affected.

In particular, our sales and academic promotion efforts consist of raising awareness and knowledge of our products and drug candidates among medical professionals, hospitals and other medical institutions. Our sales and academic promotion force must therefore possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, expertise in the relevant therapeutic areas and products, and sufficient promotion and communication skills. If we are unable to effectively train our in-house medical representatives and evaluate their academic promotion performance, our sales and academic promotion may be less successful than desired. See “Business — Sales, Promotion and Distribution — Sales and Promotion.”

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Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales and academic promotion professionals is especially important, as we primarily rely on our in-house sales and academic promotion force and third-party promoters to market and sell our products. Competition for experienced sales and academic promotion personnel is intense. If we are unable to attract, motivate and retain sufficient sales and academic promotion professionals, sales volume may be adversely affected and we may be unable to expand our hospital coverage or increase market penetration as planned. For details of our third-party promoters, see “Business — Sales, Promotion and Distribution — Sales and Promotion — CSOs.”

We may be subject to the risks associated with third-party payments.

During Track Record Period, we entered into an accounts receivables and debt collection agreement with a third-party payer in September 2025 and settled certain payment with an overseas distributor through such third-party payer in November 2025. As of the Latest Practicable Date, we had terminated the collaboration with such overseas distributor and were negotiating the terms of the termination agreement. For details, see “Business — Third-party Payment Arrangement” and “Business — Our Overseas Distribution Arrangement.” We may be subject to the risks relating to third-party payments, including (i) potential claims from the third-party payer seeking reimbursement of funds, and possible claims from liquidators representing the third-party payer; and (ii) potential money laundering risks, given our limited knowledge of the source and purpose of funds used by third-party payers. If legal proceedings are initiated against us regarding third-party payments, we may need to allocate additional financial and management resources to address them, which could adversely affect our business and financial performance.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Failure to adequately protect our intellectual property globally, or limitations in the scope of such protection, other pharmaceutical companies could compete against us directly or indirectly, which may have a material adverse impact on our business and results of operations.

Our success depends largely on protecting our proprietary technologies and drug candidates by obtaining, maintaining, defending and enforcing intellectual property rights, including patents. We do so through patent filings in China, the United States and other jurisdictions, and by relying on trade secrets and pharmaceutical regulatory protection, alone or in combination. As of June 30, 2026, we held 39 registered patents in the PRC and 113 registered patents in other jurisdictions, as well as 378 pending patent applications. As of the same date, we also held nine registered domain names and 30 registered trademarks in the PRC. See “Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Material Intellectual Property Rights.” In addition, the patent position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of extensive litigation in recent years. Accordingly, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Patent applications may not be granted, and issued patents may be invalidated or challenged; we may also fail to timely identify patentable aspects of our R&D output, which could delay or interfere with our commercialization in China and other markets. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in China, the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. China and the United States have adopted the “first-to-file” system, under which whoever first files a patent application is awarded the patent if all other patentability requirements are met. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or the first to file for patent protection of such inventions.

Furthermore, patent protection is time-limited. Given lengthy development and regulatory timelines, patents may expire before or shortly after commercialization, and our intellectual property may not provide sufficient exclusivity to prevent competition, which could materially adversely affect our competitive position, business, financial condition, results of operations and prospects. Even if we obtain protection for approved drug candidates, competition from generic or

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biosimilar products may arise upon patent expiration, and challenges to scope, validity or enforceability may limit exclusivity and materially adversely affect sales of that product. Our issued patents for our drug candidates are expected to expire on various dates as described in “Business — Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors, and our business and results of operations may be adversely affected.

We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may challenge the validity and enforceability of our patents, or infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, protect our trade secrets, or determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation and other proceedings can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expense and distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits we initiate, and any damages or other remedies awarded may not be commercially meaningful. Claims we assert against perceived infringers could also provoke counterclaims alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have far greater resources than we do to enforce and defend their intellectual property rights.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property rights. An adverse result in any such litigation could put our patents, and any patents that may issue from our pending applications, at risk of invalidation, unenforceability or narrow interpretation. Because intellectual property litigation typically requires substantial discovery, there is also a risk that our confidential information could be compromised through disclosure during such litigation. Thus, even if we ultimately prevail, or settle at an early stage, such litigation could burden us with substantial unanticipated costs. Moreover, we may not be able to detect infringement of our patents. Even if we detect infringement by a third party, we may choose not to pursue litigation or settlement. If we later sue that party for infringement, it may have legal defenses available that otherwise would not apply, due to the delay between when infringement was first detected and when suit was brought. Such defenses may make it impossible for us to enforce our patents against that third party.

In addition, although we are not currently experiencing any material claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an interest, as inventor or co-inventor, in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. Litigation may be necessary to defend against these and other inventorship claims. If we fail to defend any such claim, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property important to our drug candidates. Even if we successfully defend against such claims, litigation could lead to substantial costs and distract management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our patent protection may be challenged, invalidated, rendered unenforceable or lost due to legal proceedings or non-compliance with procedural requirements, which could materially harm our business.

Issued patents covering one or more of our drug candidates could be challenged, invalidated or held unenforceable in court. Despite measures we take to obtain and maintain patent and other intellectual property rights, our rights could be challenged or invalidated. For example, if we

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initiated legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could include an alleged failure to meet statutory requirements such as novelty, non-obviousness or enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (“USPTO”), China National Intellectual Property Administration (“CNIPA”), or the applicable foreign counterpart, or made a misleading statement during prosecution. Although we believe we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome of any legal assertions of invalidity and unenforceability during patent litigation is unpredictable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail, our patent claims may be construed in a manner limiting our ability to enforce them against the defendant and others. Even if we establish infringement, the court may decline to grant an injunction and instead award only monetary damages, which may not be an adequate remedy. If the breadth or strength of protection provided by our patents is threatened, it could also dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

Obtaining and maintaining patent protection also requires ongoing compliance with numerous procedural, documentary, fee payment and other requirements imposed by the CNIPA, the USPTO and other patent authorities in various jurisdictions. We work with our counsel and professionals to help us comply with these requirements. Although an inadvertent lapse can often be cured by payment of a late fee or other means under applicable rules, in certain circumstances non-compliance can result in abandonment, loss of priority or lapse of the patent or application, causing partial or complete loss of patent rights in that jurisdiction. Such non-compliance events include failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, competitors or other third parties might be able to enter the market, materially and adversely affecting our competitive position, business, financial condition, results of operations and prospects.

Changes in patent and other intellectual property laws of China, the United States or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future products.

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

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

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

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seek to protect such information partly by entering into non-disclosure and confidentiality agreements with our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, consultants, advisors and other third parties with access to such information.

However, we may not be able to prevent unauthorized disclosure or use of our trade secrets and confidential information by parties to these agreements. As a result, we could lose our trade secrets, and third parties could use them to compete with our drugs, drug candidates and technology. Litigation over such violations can be difficult, expensive and time-consuming, with unpredictable outcomes. Monitoring unauthorized uses and disclosures is difficult, and our protective measures may not be effective. We also cannot guarantee that we have entered into such agreements with all parties that may have or had access to our trade secrets or proprietary technology and processes. If any of our trade secrets were lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us, and our competitive position would be harmed.

Furthermore, our employees, consultants and advisors, including our senior management, may currently be, or may have previously been, employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that these personnel do not use others' proprietary information or know-how in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail to defend any such claim, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we successfully defend against such claims, litigation could result in substantial costs and distract our employees and management.

We typically require personnel involved in developing intellectual property to assign such rights to us, but we may be unsuccessful in executing such agreements with every party who develops intellectual property we regard as our own. Even where we obtain such assignment agreements, they may be ineffective or breached, resulting in claims by or against us regarding ownership of what we regard as our intellectual property. Such disputes may also arise from competing obligations to third parties, including academic institutions. Failure to prosecute or defend such claims could result in monetary damages and loss of valuable intellectual property rights.

In addition, we may be subject to claims by former employees, consultants or other third parties asserting an ownership interest in our owned or licensed patents or patent applications. An adverse determination in any such proceeding may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, and could limit our ability to stop others from using or commercializing similar drug candidates or technology without payment to us. Such challenges may also dissuade companies from collaborating with us to license, develop or commercialize current or future drugs and drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build brand awareness in our target markets and our business may be adversely affected.

We currently own issued trademark registrations, which may be subject to governmental or third-party objection that could prevent their registration or maintenance. We cannot assure you that any future trademark applications will be approved; we may receive rejections during registration proceedings that we are unable to overcome. In addition, the CNIPA, USPTO or comparable agencies in many foreign jurisdictions permit third parties to oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are

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unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature and our reliance on trademarks to differentiate us from competitors increases, our business could be materially adversely affected if we are unable to prevent third parties from adopting, registering or using infringing, diluting or otherwise violating trademarks, or from engaging in unfair competition, defamation or other violations of our rights.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic, or found to infringe other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build market name recognition. Competitors or other third parties may adopt similar trade names or trademarks, impeding our ability to build brand identity and possibly causing market confusion. There could also be claims from owners of other registered trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

Claims that our products and drug candidates or the sale or use of our products and drug candidates infringes, misappropriates or otherwise violates the patent, trademark, or other intellectual rights of third parties could result in costly litigation, the outcome of which would be uncertain, or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends on our ability to develop, manufacture, market and sell our drugs and drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. The pharmaceutical and biopharmaceutical industries are characterized by extensive patent and other intellectual property litigation. We cannot guarantee that our drugs and drug candidates, or their uses, do not and will not in the future infringe third-party patents, trademarks, or other intellectual property rights. It is also possible that we have failed, or may in the future fail, to identify relevant patents or patent applications held by third parties that cover our drugs and drug candidates. Additionally, published pending patent applications can, subject to certain limitations, later be amended in a manner that could cover our products or their use.

Third parties might allege that we are infringing their patent rights, misappropriating their trade secrets, or otherwise violating their intellectual property rights, whether regarding how we have conducted our research, or the use or manufacture of compounds we have developed or are developing. Such parties might resort to litigation against us or other parties we have agreed to indemnify. Parties making infringement, misappropriation or other intellectual property claims against us may obtain injunctive or other equitable relief that could block our ability to further develop and commercialize one or more of our drugs and drug candidates. Defending these claims, regardless of merit, would involve substantial litigation expense and divert management and employee resources from our business. Even if we believe third-party intellectual property claims are without merit, there is no assurance a court would find in our favor on questions of validity, enforceability, priority or non-infringement.

To avoid or settle potential claims regarding third-party intellectual property rights, we may choose or be required to seek a license and pay substantial license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. Even if we obtain a license, the rights may be non-exclusive, potentially giving competitors access to the same intellectual property and requiring substantial licensing and royalty payments. Ultimately, if we are unable to enter into licenses on acceptable terms as a result of actual or threatened patent or other intellectual property claims, we could be prevented from commercializing future approved drugs, or forced, by court order or otherwise, to cease some or all aspects of our operations. We could also be found liable for significant monetary damages for intellectual property infringement, including treble damages and attorneys' fees if we are found to willfully infringe a third party's patent.

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Defending against claims of patent infringement, misappropriation of trade secrets or other intellectual property violations could be costly and time-consuming, regardless of outcome. Thus, even if we ultimately prevail, or settle at an early stage, such litigation could burden us with substantial unanticipated adverse impacts on our business.

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

As intellectual property rights have limitations, they do not necessarily protect us from all potential threats in our competition with other pharmaceutical and biopharmaceutical companies. For example: (i) others may be able to manufacture drugs similar to our drug candidates, or apply similar technology, that is not covered by patents we own or license, now or in the future; (ii) competitors may independently develop similar drugs using methods or means that do not technically infringe, misappropriate or otherwise violate our intellectual property rights, particularly where protection is limited by applicable laws, regulations or judicial or administrative decisions; (iii) we might not have been first to file patent applications covering certain of our inventions; (iv) our pending or future patent applications may not result in issued patents; (v) we may not develop additional patentable proprietary technologies; (vi) we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently patent such intellectual property; (vii) our patents may be rendered invalid or unenforceable through legal challenges by competitors; and (viii) competitors may conduct R&D activities in jurisdictions where we lack patent protection and use the resulting information to develop and commercialize competing products in our key markets. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We engage with third parties for certain aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.

We rely on third parties, such as collaboration partners, medical institutions, clinical investigators and contract laboratories, in developing our drug candidates and conducting our clinical trials. We are also dependent on third parties for the commercialization or distribution of our products or drug candidates. Our business will be harmed if business or economic conditions, or future developments in laws and regulations in the PRC, U.S. or other jurisdictions, deteriorate our service providers’ operations and reduce their provision of services to us. If these parties, whom we do not control, fail to carry out their contractual duties or regulatory obligations, fail to meet expected deadlines, lack the ability or resources to complete their objectives, or choose not to continue their relationship with us, our development efforts could be delayed, suspended or terminated, or our commercialization efforts delayed, impaired or terminated. If the quality or accuracy of data obtained through third parties is compromised due to failure to adhere to our clinical protocols or regulatory requirements, our preclinical or clinical activities could be delayed and we may not be able to obtain regulatory approval for our drug candidates.

Actions taken by our distributors in violation of the relevant agreements or taken by the distributors with whom we have not entered into distribution agreements could materially and adversely affect our business, prospects and reputation.

Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize distribution channels that ensure timely delivery of our products across China and, in the future, other jurisdictions where market demand is generated through our promotion and marketing activities or otherwise. Consistent with industry practice, we sell all of our products through

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third-party distributors in China. As of June 30, 2026, we had a distribution network of 166 distributors spanning 30 provinces in China, on which we rely to distribute a substantial portion of our products. However, all of our distributors are Independent Third Parties over whom we have limited control.

While we rely on our distribution agreements and the policies and measures we have in place to manage our distributors, we cannot guarantee that we will effectively manage our distributors or that they will abide by our agreements and policies. If our distributors take any of the following actions, our business, results of operations, prospects and reputation may be adversely affected: (i) failing to distribute our products as agreed, impairing the effectiveness of our distribution network; (ii) breaching the distribution agreements or our policies and measures; (iii) failing to maintain requisite licenses, permits or approvals, or failing to comply with applicable regulatory requirements; and (iv) violating applicable anti-corruption, anti-bribery, competition or other laws and regulations. Any such actual or alleged violation or noncompliance by our distributors with the distribution agreements, our policies, or applicable laws and regulations could erode our goodwill, expose us to liabilities, disrupt our distribution network, and create an unfavorable public perception of our products’ quality.

Delivery delays and poor handling by third-party logistics service providers may adversely affect our business, financial condition and results of operations.

We have entered into logistics service agreements with third-party logistics providers for the transportation of our products. Although these providers are required to deliver in a safe and timely manner, delays may occur for reasons beyond our control, including poor handling, labor disputes or strikes, acts of war or terrorism, health epidemics, earthquakes and other natural disasters, and could result in delayed or lost deliveries. Any major interruption to or failure in these third parties’ services could prevent timely or successful delivery of our products, affecting our business. We have purchased cargo insurance for our products, but cannot guarantee this coverage is sufficient to compensate for actual losses. If products are not delivered on time, or are delivered damaged, customers may refuse to accept them and claim refunds, and may lose confidence in our services. Poor handling could also cause product contamination or damage, potentially leading to product recalls, returns or exchanges, product liability, increased costs and reputational damage, adversely affecting our business, financial condition and results of operations.

Our relationships with certain principal investigators, key opinion leaders and leading hospitals may affect the clinical development and future marketing of our products.

Our relationships with principal investigators, KOLs and leading hospitals play an important role in our R&D and marketing activities. We implement a clinical demand-oriented, highly responsive R&D strategy by establishing extensive interaction channels with principal investigators, KOLs and leading hospitals to gain first-hand knowledge of clinical needs and practice trends, which is critical to developing new market-responsive drugs and improving our existing drug candidates. We are committed to enhancing our collaborations with KOLs, top hospitals and academic institutions to ensure timely access to cutting-edge research and support our existing and future pipeline.

However, we cannot assure you that we will maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs and leading hospitals, or that such efforts will yield successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, or choose to cooperate with our competitors instead of us. Even if they continue to cooperate with us, their market insights and perceptions, which we factor into our R&D process, may be inaccurate and lead us to develop drugs lacking significant market potential. Even if their insights are correct, we may fail to develop commercially viable drugs. If we are unable to develop new drugs or generate returns from these relationships as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

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Our collaborations and strategic partnerships may not achieve expected benefits and may result in increased costs, operational disruption, or loss of control over development and commercialization.

As we continue to develop and expand our drug products portfolio, we may form or seek additional strategic partnerships, licensing arrangements or other collaborative relationships with third parties that we believe will complement or augment our R&D and commercialization efforts. Any of these relationships may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute existing shareholders, or disrupt our management and business. Our strategic collaborations involve various risks, including that we may not achieve the expected revenue and cost synergies. These synergies are inherently uncertain and subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and beyond our control. The synergies from our collaborations may also be offset by other costs, increases in expenses, operating losses or unrelated business problems. As a result, there can be no assurance that expected synergies will be achieved in due course, or at all.

We may face challenges finding appropriate strategic partners, as negotiation is time-consuming and complex. We may also be unsuccessful in establishing strategic partnerships or other arrangements for our drug candidates, which third parties may view as too early-stage for collaboration, or as lacking the requisite potential for safety, efficacy or commercial viability. If and when we collaborate with a third party on developing and commercializing a drug candidate, we can expect to relinquish some or all control over that candidate’s future success. For drug candidates we seek to in-license, we may face significant competition from pharmaceutical or biopharmaceutical companies with greater resources or capabilities, and any agreement we enter into may not deliver the anticipated benefits.

Collaborations involving our drug candidates are subject to specific risks, including, but not limited to: (i) collaborators’ discretion in allocating resources and prioritizing activities; (ii) collaborators’ decisions to delay, deprioritize or discontinue development or commercialization due to strategic shifts, acquisitions of competing products, funding constraints or other external factors, including business combinations that divert resources or create competing priorities; (iii) collaborators may delay clinical trials, provide insufficient funding, discontinue a trial, repeat or conduct new trials, or require a new formulation for clinical testing; (iv) collaborators could independently develop, or develop with third parties, drugs that compete with our drug candidates or future drugs; and (v) disputes may arise between us and a collaborator, delaying or terminating research, development or commercialization, or resulting in costly litigation or arbitration that diverts management attention and resources.

As a result, we cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies it. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail development of a product candidate, reduce or delay its (or another) development program, delay potential commercialization or reduce the scope of sales or marketing activities, or increase our expenditures and undertake development or commercialization at our own expense. If we elect to fund and undertake such activities on our own, we may need additional expertise and capital, which may not be available on acceptable terms or at all. Either outcome would harm our business, financial condition, results of operations and prospects.

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RISKS RELATING TO MANUFACTURING OF OUR PRODUCTS

If we suffer substantial disruption to any of our production facilities or encounter problems in manufacturing our products, our business and results of operations could be adversely affected.

We currently operate three production facilities comprising several production workshops with corresponding production lines, all located in Kunshan, Jiangsu Province. The continued operation of production facilities and production safety can be substantially and materially interrupted by factors outside our control, including fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars or other natural disasters, as well as expiry of land use rights, loss of licenses, certifications and permits, changes in governmental planning for the underlying land or its vicinity, and regulatory changes. If any facility’s operation is substantially disrupted, we may not be able to replace equipment or inventories, or secure a replacement facility or contractor to continue production, in a legal, timely and cost-effective manner, or at all. Although we maintain property insurance for our facilities and equipment, we do not maintain business interruption insurance, and our insurance coverage may not be sufficient to cover losses from a significant disruption. Manufacturing problems may also arise from equipment malfunction, failure to follow protocols and procedures, problems with raw materials, delays in constructing or expanding facilities, regulatory capacity constraints, changes in production requirements, man-made or natural disasters, and environmental factors. Any such disruption or manufacturing problem may prevent us from fulfilling contract obligations or meeting market demand, adversely affecting our business, revenue and profitability.

The expansion of our production facilities may not be as successful as we have planned. If we fail to increase our production capacity in response to the increasing demand of our customers, our business prospects could be adversely affected.

We are undergoing expansion of our existing production facilities and lines to meet increasing demand and prepare for expected commercialization of our drug candidates, if approved. Financing and completing this expansion involves regulatory approvals and reviews by various authorities in relevant jurisdictions, including urban planning, construction and environmental protection authorities. We cannot assure you that we will obtain all required approvals, permits and licenses, or that expansion will be completed on the anticipated timetable or within budget. We may also be unable to fully utilize the expanded production capacity. Any of these factors could materially and adversely affect our results of operations and prospects and result in lost business opportunities.

If we fail to perform proper quality control or assurance, or our products are not produced to the necessary quality standards, our business and reputation could be harmed, and our revenue and profitability could be adversely affected.

Our products and manufacturing processes are required to meet certain quality standards. We have established a quality control and assurance management system and standard operating procedures to help prevent quality issues. See “Business — Quality Management” for further details of our quality control system and procedures. Despite this system, we cannot eliminate the risk of errors, defects or failures. We may fail to detect or cure quality defects due to a number of factors outside our control, including but not limited to: (i) manufacturing errors; (ii) technical or mechanical malfunctions in the manufacturing process; (iii) human error or malfeasance by our quality control personnel; (iv) tampering by third parties; and (v) quality issues with the raw materials we purchase or produce.

In addition, when we expand our production capacity, we may not be able to ensure consistent quality between products manufactured in existing and new facilities without incurring substantial costs. If we acquire other pharmaceutical companies, we may also not be able to immediately ensure their production facilities and processes meet our quality standards. Failure to detect quality

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defects, or to prevent defective products from reaching end-users, could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenue and profitability.

Our operations are dependent on the supply of certain raw materials. If the supply of raw materials decreases or the cost increases, or there are disruptions in the supply chain, our ability to conduct our business could be materially impaired and our operations, revenue and profitability could be adversely affected.

Purchases of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period, representing 71.8%, 71.8%, 40.2%, 36.8% and 34.3% in 2023, 2024, 2025 and the six months ended June 30, 2025 and 2026, respectively. To manufacture our products, we must obtain sufficient high-quality raw materials at commercially acceptable prices and in a timely manner. During the Track Record Period, we sourced chemical raw materials, specialized intermediates, ancillary materials and packaging materials for all our pharmaceuticals from screened and approved suppliers. For more details, see “Business — Quality Management — Procurement of Raw Materials and Quality Control.” Should any supplier fail to supply sufficient quantities of acceptable-quality raw materials, we may be unable to obtain substitutes elsewhere in a timely manner, or at all, or may be forced to obtain materials from different suppliers who may require commercially unreasonable prices. Although we have not experienced material interruptions in our supply chain or raw material supplies in the past, any interruption could delay production and delivery schedules, resulting in lost customers and revenue. Raw material market prices may also fluctuate significantly due to various factors; we cannot assure you that we could pass on any cost increase to our customers, and substantial fluctuations may materially increase our costs and impact profitability. Potential supply chain disruptions, such as natural disasters, geopolitical tensions, transportation issues or other unforeseen events, could further exacerbate these challenges, resulting in delays, increased costs or production interruptions.

Failure to manage our inventory effectively would materially and adversely affect our results of operations, financial condition and cash flows.

Our inventory consists of raw materials, work-in-progress and finished goods. To operate successfully and meet customer demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We regularly monitor inventory to ensure timely supply and reduce overstocking risk. We maintain inventory levels based on internal forecasts, which are inherently uncertain. We are exposed to inventory risk from rapid changes in product life cycles, changing clinical demands, uncertainty of product development and launches, and the volatile economic environment in the jurisdictions where we operate. There can be no assurance that we can accurately predict these trends and avoid over- or under-stocking our products. Demand could also change significantly between the time products are ordered and when they are ready for delivery, and forecasting demand for a new product is particularly difficult. As of December 31, 2023, 2024 and 2025 and June 30, 2026, we had inventories of RMB110.9 million, RMB182.9 million, RMB173.3 million and RMB192.9 million, respectively. In 2023, 2024, 2025 and the six months ended June 30, 2026, our inventory turnover days were 213 days, 521 days, 392 days, and 265 days, respectively. For more details, see “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Inventories.” We may face increased inventory risk from accumulated excess inventory of products or raw materials, some of which are subject to expiration. Excess inventory may increase holding costs, obsolescence risk or impairment losses. Conversely, if forecasted demand is lower than actual demand, we may be unable to maintain adequate inventory levels or manufacture products in a timely manner, and may lose sales and market share to competitors.

Furthermore, because cash invested in raw materials and work-in-progress is not recovered until finished products are sold and settled, our business is subject to significant working capital requirements given our high inventory level and turnover days. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

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Our therapeutic biological products, like any other biological product, may involve risks of contamination.

Manufacturing therapeutic biological products usually requires cultivation steps, including growth of the appropriate organism and use of substances of animal origin, which makes it easy to introduce a contaminant and amplify low levels of contamination. Cross-contamination could also result from manufacturing activities at shared equipment and facilities, which are common, and other activities such as diagnosis and research frequently linked to manufacturing may create further opportunities for cross-contamination. Improper handling during long-distance transportation, storage and delivery may also result in contamination.

In the event of contamination or resulting injury, we could be liable for damages to patients, and face product recalls, confiscation and/or destruction. We could also incur significant costs from civil or criminal fines and penalties for non-compliance with laws and regulations. Contamination could also cause customers or other business partners to lose confidence in our products’ quality and manufacturing reliability, adversely affecting our sales and profits, and could expose us to product liability claims, criminal charges and administrative sanctions if contaminated products are unknowingly distributed.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses during the Track Record Period and may incur losses for the foreseeable future, and we may not maintain profitability.

We recorded net losses of RMB295.1 million, RMB150.3 million and RMB165.1 million in 2023, 2024 and 2025, respectively, and a net loss of RMB68.1 million for the six months ended June 30, 2025, compared to a net profit of RMB640.0 million for the same period in 2026. Our net losses during the Track Record Period were primarily due to: (i) substantial investment in R&D activities, mainly pre-clinical and clinical research expenses and staff costs; and (ii) selling and distribution expenses used to promote and market our commercialized drug products. We recorded net profit during the six months ended June 30, 2026 primarily due to the upfront fee paid by AbbVie under the AbbVie Agreement, see “Business — Our Collaboration and License Arrangement.”

In addition to market dynamics, our ability to sustain profitability depends on our successful execution of our business strategy across various aspects, including (i) maintaining and expanding sales of our commercialized products; (ii) maintaining and expanding our profit margins; (iii) researching and developing our diversified product portfolio; (iv) maintaining a strong liquidity position; and (v) leveraging our stable core management team. For details, see “Financial Information—Business Sustainability.”

We have incurred indebtedness and may incur additional indebtedness in the future, which may materially and adversely affect our financial condition and results of operations.

During the Track Record Period, we incurred indebtedness, mainly bank borrowings and lease liabilities. As of December 31, 2023, 2024 and 2025 and June 30, 2026, our total current liabilities amounted to RMB1,135.2 million, RMB1,373.4 million, RMB1,427.9 million and RMB1,185.2 million, respectively. See “Financial Information — Indebtedness” for more details. Our indebtedness could, among other consequences: (i) increase our financial risk and adversely affect our ability to operate as a going concern; (ii) require a substantial portion of operating cash flows for interest and principal payments, reducing funds available for other purposes; (iii) limit our flexibility in planning for, or reacting to, changes in our business and industries; (iv) increase our vulnerability to adverse economic and industry conditions; (v) place us at a competitive disadvantage; (vi) increase our borrowing cost; (vii) limit our ability to borrow additional funds; and (viii) require asset sales to fund working capital, capital expenditures, acquisitions or other purposes, if needed.

Our ability to generate sufficient cash to satisfy our outstanding and future debt obligations will depend on our future operating performance, which will be affected by prevailing economic conditions, governmental regulation, market demand and other factors largely beyond our control.

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If we do not generate sufficient cash flow to pay our anticipated operating expenses and service our debt, we will be forced to adopt an alternative strategy that may include reducing or delaying capital expenditures, disposing of assets, restructuring or refinancing our indebtedness, or seeking equity capital. If we are unable to fulfill our repayment obligations or otherwise comply with the restrictions and covenants in our current or future loan and other agreements, we could be in default under those agreements. In the event of default, lenders may accelerate repayment of outstanding debt or, for secured borrowings, enforce the security interest. If any of these events occur, we cannot assure you that our assets and cash flow would be sufficient to repay all our indebtedness, or that we would obtain alternative financing on favorable or acceptable terms. As a result, our cash flow, financial condition and results of operations may be materially and adversely affected.

We are exposed to credit risk in relation to our trade and bills receivables.

Our trade and bills receivables consist of amounts due from customers, including distributors who on-sell our products to hospitals and, to a lesser extent, pharmaceutical retail chains. As of December 31, 2023, 2024 and 2025 and June 30, 2026, we had trade and bills receivables of RMB101.1 million, RMB143.6 million, RMB154.3 million and RMB204.3 million, respectively. In 2023, 2024, 2025 and June 30, 2026, trade and bills receivables turnover days were 89 days, 83 days, 66 days, and 64 days, respectively. See “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Trade and Bills Receivables.”

We are exposed to the risk that customers or other business partners may delay, or be unable to make, payment in accordance with our agreements, or may never pay. Although we closely monitor our outstanding trade and other receivables, we cannot assure you that we will fully recover outstanding amounts in a timely manner, or at all. As our business continues to scale, our trade and other receivables may continue to grow, increasing our credit risk. Any substantial delay in or default of customers’ payments could materially and adversely affect our cash flows, and we could be required to terminate distributor relationships in a manner that impairs effective distribution of our products. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

The discontinuation of any of the financial incentives, such as preferential tax treatment or government grants, currently available to us could adversely affect our operations, revenue and profitability.

During the Track Record Period, we benefited from government grants and subsidies. Our other income related to government grants amounted to RMB81.5 million, RMB35.8 million, RMB49.7 million, RMB27.1 million and RMB21.3 million in 2023, 2024, 2025 and the six months ended June 30, 2025 and 2026, respectively. We also enjoyed preferential tax treatment during the Track Record Period. See “Financial Information — Description of Certain Consolidated Statements of Profit or Loss and Other Comprehensive Income — Other Income and Gains” and “Financial Information — Income Tax Credit” for more details. These incentives are, to some extent, subject to the discretion of relevant government authorities, which could eliminate or reduce them at any time, generally with prospective effect. Because our receipt of financial incentives or preferential treatments is subject to periodic time lags and inconsistent government practice, our net income in a particular period may be higher or lower than in other periods depending on changes in these incentives, in addition to any business or operational factors. Therefore, discontinuation of financial incentives currently available to us could have a material adverse effect on our financial condition, results of operations, cash flows and prospects.

We may face exposure to fair value change for financial assets at FVTPL and valuation uncertainty due to the use of unobservable inputs.

During the Track Record Period, our financial assets at FVTPL comprised (i) financial products issued by reputable commercial banks in the PRC, redeemable at any time or at maturity, and (ii) listed debt instruments representing treasury bonds issued by the United States Federal Government. We recorded financial assets at FVTPL of RMB137.0 million, RMB40.5 million, nil

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and RMB375.6 million as of December 31, 2023, 2024 and 2025 and June 30, 2026. We may continue such investments as part of our cash management and treasury measures and therefore may face exposure to fair value changes on these assets. We cannot assure you that we can recognize comparable fair value gains in the future; we may instead recognize fair value losses, affecting our results of operations for future periods. The valuation of these fair value changes is also subject to estimation uncertainty, involving professional judgment and certain bases, assumptions and unobservable inputs that are, by nature, subjective and uncertain. As such, our FVTPL valuation has been, and will continue to be, subject to estimation uncertainties that may not reflect the actual fair value of these assets and could result in significant fluctuations in profit or loss from period to period.

We may be affected by exchange rate fluctuations.

The value of the Renminbi against the Hong Kong dollar, U.S. dollar and other currencies may fluctuate, affected by, among other things, changes in global political and economic conditions. Any significant appreciation or depreciation of the Renminbi against the Hong Kong dollar and U.S. dollar may affect our revenues, earnings and financial position, and the value of, and any dividends payable on, our Shares. Under current PRC foreign exchange regulations, foreign exchange transactions under the current account conducted by us, including dividend payments, do not require advance SAFE approval, but we must present relevant documentary evidence of such transactions and conduct them at designated foreign exchange banks in China licensed to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses. To the extent we need to convert Hong Kong dollars received from this [REDACTED] into Renminbi for our operations, appreciation of the Renminbi against the Hong Kong dollar would adversely affect the Renminbi amount we receive. Conversely, if we convert our Renminbi into Hong Kong dollars for dividend payments on our ordinary shares or other business purposes, appreciation of the Hong Kong dollar against the Renminbi would negatively affect the Hong Kong dollar amount. Further changes to the exchange rate system may occur as the foreign exchange market develops. Any significant fluctuation in relevant currencies could adversely affect our business, results of operations and financial condition, and the value of any dividends payable in Hong Kong dollars. As of the Latest Practicable Date, we have not entered into any hedging transactions to reduce our foreign currency exchange risk exposure. While we may decide to do so in the future, the availability and effectiveness of such hedges may be limited, and we may not be able to adequately hedge our exposure, or at all.

RISKS RELATING TO GOVERNMENT REGULATIONS

The pharmaceutical and biopharmaceutical industries are subject to change of regulations, which may affect our operations, revenue and profitability or impose additional compliance burden on us.

We operate in the pharmaceutical and biopharmaceutical industries in China, the U.S. and other jurisdictions, which are subject to comprehensive government regulation and supervision, including governance around the approval, registration, manufacturing, packaging, licensing, marketing, sales and distribution of drugs. Remaining compliant with the various rules and regulations can be time- and cost-consuming, particularly for a company like us operating in multiple jurisdictions with different policies. For example, obtaining regulatory approvals and maintaining compliance requires substantial time and financial resources. Recently enacted and future legislation may increase the difficulty and cost of obtaining regulatory approval for, and commercializing, our drug candidates, and affect the prices we may obtain. We also face legal uncertainties across markets that follow civil or common law systems: under civil law, prior judgments carry limited precedential value, while newly enacted laws may be incomplete, with unclear interpretation, enforcement and application to our business.

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Changes in government regulations or practices relating to the pharmaceutical and biopharmaceutical industries, such as relaxed regulatory requirements or simplified approval procedures lowering entry barriers for potential competitors, or increased regulatory requirements raising the difficulty of compliance, may materially adversely affect our business, financial condition, results of operations and prospects.

We are also subject to scheduled and unscheduled periodic inspections of our facilities to monitor regulatory compliance. During the Track Record Period, we passed all the inspections and obtained clearance for the manufacturing of our drug candidates and drugs from regulatory authorities in all relevant jurisdictions in all material respects. However, we cannot assure you that we will continue to do so.

Failure to comply with applicable regulatory requirements in any jurisdiction where we operate, at any time during drug development, the approval process, or after approval, may subject us to administrative or judicial sanctions, including a regulator’s refusal to approve pending applications, withdrawal of approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

If we or our business partners fail to maintain the necessary licenses for the development, production, promotion, sales and distribution of our products, our ability to conduct our business could be materially impaired and our revenue and profitability could be adversely affected.

We are required to obtain, maintain and renew various permits, licenses, approvals and certificates to develop, produce, promote and sell our products, and the third parties we rely on to develop, produce, promote, sell and distribute our products may be subject to similar requirements. For more details, see “Business — Licenses, Permits and Certificates.” We and the parties we rely on, such as distributors and suppliers, may be subject to regular inspections, examinations, inquiries and audits by regulatory authorities, and an adverse outcome may result in the loss or non-renewal of relevant permits, licenses, approvals and certificates. The criteria for reviewing applications for, or renewals of such permits may also change from time to time, and there is no assurance we or the parties we rely on will meet any new criteria imposed. Many of these permits, licenses, approvals and certificates are material to our business, and failure to maintain or renew them could materially impair our ability to conduct business. While we have been able to maintain and renew our material permits, licenses, approvals and certificates, there is no assurance we will continue to do so in the future.

Any changes in the standards governmental authorities use to renew or reassess our licenses, permits, approvals and certificates, or any new regulations restricting our business conduct, may also decrease our revenue and increase our costs, materially and adversely affecting our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws changes, or new regulations require us or parties we rely on to obtain additional permits, licenses, approvals or certificates previously not required, there is no assurance that we or such parties will successfully obtain them.

Our approved drug products remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses or penalties for non-compliance or unanticipated issues with future approved drug candidates.

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

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Any approvals we receive may be subject to limitations on approved indicated uses or other conditions, which could adversely affect a drug’s commercial potential or require potentially costly post-marketing testing and surveillance to monitor its safety and efficacy. The NMPA, the FDA or a comparable regulatory authority may also require a risk evaluation mitigation strategy as a condition of, or following, approval.

Once a drug is approved for marketing, previously unknown problems may subsequently be discovered, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things: (i) restrictions on marketing or manufacturing, withdrawal from the market, or voluntary or mandatory drug recalls; (ii) fines, warning letters or holds on clinical trials; (iii) refusal by the NMPA, the FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals; (iv) drug seizure or detention, or refusal to permit the import or export of drugs; and (v) injunctions or the imposition of civil, administrative or criminal penalties.

In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. Accordingly, we and the third parties we work with must continue to expend time, money and effort on regulatory compliance, including manufacturing, production and quality control. We cannot predict the likelihood, nature or extent of governmental policies or regulations arising from future legislation or administrative actions in China, the United States or other jurisdictions, where the regulatory environment is constantly evolving. If we are unable to maintain regulatory compliance, or are slow or unable to adapt to new requirements or policies, we may lose regulatory approvals we have obtained, and we may not achieve or sustain profitability.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, the United States and other jurisdictions, which may increase our compliance costs and expose us to investigations or allegations arising from our interactions with third parties.

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements through which we conduct our operations, including how we market, sell and distribute our products and drug candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), the PRC Criminal Law (《中華人民共和國刑法》), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, the Health Insurance Portability and Accountability Act of 1996, and the U.S. Physician Payments Sunshine Act. Ensuring our business arrangements with third parties comply with these laws will involve substantial cost, and we may be required to respond to audits, inquiries, investigations or allegations relating to our commercial or clinical activities, including conduct by third parties with whom we do business, which could divert management resources, disrupt operations and adversely affect our reputation and results of operations.

Our management of clinical trial data and other personal or sensitive information, and our reliance on third-party service providers, subject us to information security, operational disruption and regulatory change risks.

We receive, collect, generate, store, process, transmit and maintain de-identified codes of subjects enrolled in our clinical trials and the corresponding clinical trial data, relying on third-party institutions and service providers (such as clinical sites, CROs and other vendors) in doing so. Our internal computer systems, and those of our current and future third-party vendors, collaborators, consultants and other service providers, as well as our clinical sites and regulatory authorities, are critical to our operations and vulnerable to damage, interruption or unauthorized access from

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computer viruses and other malicious code, phishing and other cyber-attacks, natural disasters, terrorism, and telecommunication and electrical failures. We are therefore subject to applicable data protection and privacy laws, regulations and standards governing the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the jurisdictions where we operate and conduct clinical trials, as well as contractual obligations. As of the Latest Practicable Date, we are primarily subject to PRC laws and U.S. federal and state data protection and privacy laws. Recent regulatory developments in the PRC and the United States have further increased compliance complexity, such as the Health Information Technology for Economic and Clinical Health Act in the U.S. For relevant PRC laws, see “Regulatory Overview — Overview of Laws and Regulations in the PRC.”

Complying with all applicable data privacy, security and transfer laws, regulations, standards and obligations may cause us to incur substantial operational costs or require us to modify our data processing practices. Regulatory scrutiny, enforcement actions or claims could arise from privacy issues related to our data collection and use practices and other data privacy laws, including claims for misuse or inappropriate disclosure of data, or unfair or deceptive practices. Any of the foregoing could result in significant fines, penalties, judgments, negative publicity, operational disruption and reputational harm, or could materially adversely affect our competitive position, business, financial conditions, results of operations and prospects.

Although we have not experienced any such material system failure, accident or security breach to date, any such event could disrupt our drug candidate development and business operations, including through loss of trade secrets or other proprietary information. Any theft, destruction or compromise of data or intellectual property resulting from such an event could harm our competitive position and delay development or commercialization of our drug candidates.

In addition, our clinical trials involve professionals from third-party institutions working on-site with our staff and enrolled subjects. Our ability to manage these risks depends partly on controls implemented by third-party institutions and service providers, which may not be fully within our control. We also work with third parties, including principal investigators, hospitals, CROs and other contractors and consultants, for our clinical trials and operations. Information maintained in our systems and those of our vendors and clinical sites could be subject to misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss, including personal information of our employees and clinical study participants, as well as company and vendor confidential data. Any leakage or abuse of patient data by third-party partners may be perceived as our fault or negligence, and third parties may attempt to penetrate our systems or those of our vendors, or fraudulently induce our personnel to disclose sensitive information. If a material breach of our information technology systems or those of our vendors occurs, our reputation and credibility could be damaged, and we could be required to expend significant resources to remediate affected systems. Changes in relevant laws and regulations could also affect our ability to use medical data and subject us to liability for using it for previously permitted purposes. Although we develop and maintain systems and controls to prevent and mitigate such incidents, these measures are costly and require ongoing monitoring and updating as technologies change and security threats become more sophisticated. Any failure or perceived failure to prevent information security breaches or comply with privacy laws, or any compromise resulting in unauthorized release of personal or patient data, could erode trust and expose us to legal claims. As we outsource more information systems to vendors, engage in more electronic transactions, and rely more on cloud-based systems, related security risks may increase, requiring additional resources to protect our technology and information systems. Our systems and those of third parties may not always be sufficient to protect against breakdowns, service disruption, or data loss from system malfunctions, cyber-attacks, security breaches, industrial espionage or insider threats, which could result in financial, legal, business or reputational harm.

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If we are unable to expand or upgrade our production and R&D capabilities to meet evolving regulatory requirements, our development timelines and commercialization plans may be delayed and our business could be adversely affected.

Expanding production lines and R&D centers to meet global regulatory standards requires substantial financial and operational investment, including construction or renovation of facilities, acquisition of advanced equipment, implementation of quality control systems, and hiring skilled personnel. Maintaining compliance with the diverse regulatory requirements of different countries and regions, such as the FDA in the United States, the EMA in the European Union, and the NMPA in China, is complex and costly. Each authority has its own standards and guidelines, and failure to meet them may result in delays, additional costs, or inability to obtain necessary approvals.

The regulatory landscape is also subject to change. New regulations, amendments, or shifts in regulatory priorities can occur at any time, potentially rendering previous investments in facilities and R&D centers obsolete or insufficient and requiring further financial outlays to align with updated regulatory expectations, which may result in delays or additional costs.

Expanding production lines and R&D centers also involves inherent risks such as construction delays, cost overruns, technical challenges, and difficulties obtaining required permits and approvals. Any of these issues could disrupt our operations, delay product development and commercialization timelines, and ultimately impact our ability to generate revenue. If we are unable to secure sufficient funding or manage these expansion projects effectively within the required timeframe and budget, our ability to maintain global regulatory compliance and successfully commercialize our products internationally may be adversely affected.

Our use of hazardous materials and operation of laboratories and manufacturing facilities expose us to environmental, health and safety incident risks and evolving regulatory standards, which may result in increased costs, operational disruption and liabilities.

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

We could also incur significant costs from civil or criminal fines and penalties for failure to comply with such laws and regulations, and may incur substantial costs to comply with current or future environmental, health and safety laws, which may impair our product candidate R&D efforts. There is also increasing stakeholder pressure on companies to diligence environmental, social and governance matters in the supply chain. Negative publicity regarding production and packaging methods, alleged practices, or workplace or related conditions of our suppliers, CROs or other third-party service providers could adversely affect our reputation and force us to locate alternatives, increasing costs and delaying supply of components or manufacturing, or otherwise disrupting our operations.

Our manufacturing facilities can be put into operation only after relevant environmental protection and health and safety authorities examine and approve them. We cannot assure you that we will obtain all regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining these approvals may affect our ability to develop, manufacture and commercialize our drug candidates as planned.

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Our operations are subject to and may be affected by changes in tax rates, the adoption of new tax legislation in the jurisdictions in which we operate, or exposure to additional tax liabilities.

The nature of our operations subjects us to local, state, regional and national tax laws in jurisdictions including China and the United States. As a “New High-tech Enterprise,” we are subject to an enterprise income tax rate of 15% under the tax-related PRC regulations applicable during the Track Record Period. During the Track Record Period, three subsidiaries of our Company, Suzhou Zelgen, Shanghai Zelgen and Zhejiang Zelgen, qualified as “Small and Low-profit Enterprises” and were eligible for the preferential EIT rate of 20% in 2023 and 2024; our subsidiary Zhejiang Zelgen remains eligible for the preferential EIT rate of 20% in 2025 and the six months ended June 30, 2026. Further adjustments or changes to applicable tax laws and regulations, and any resulting uncertainty, could adversely affect our business, financial condition and results of operations. We cannot assure you that future examinations by relevant tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition, results of operations and reputation.

Dividends received by foreign holders of our H Shares and gains derived from the disposition of our H Shares by such holders may be subject to PRC taxation.

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

According to the Individual Income Tax Law of the PRC and its Implementation Regulations, both effective January 1, 2019, the tax rate applicable to non-PRC resident individuals is a proportionate 20% on dividends obtained from within China or gains on transfer of shares, withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “**Arrangements**”) executed on August 21, 2006, the PRC Government may levy tax on dividends paid by PRC companies to Hong Kong residents in accordance with PRC law, but where the beneficial owner does not directly hold at least 25% of the equity interest in the paying company, the levied tax shall not exceed 10% of the total dividends.

Under the Enterprise Income Tax Law of the PRC, revised and implemented on December 29, 2018, and its Implementation Regulations, revised and implemented on January 20, 2025, a non-resident enterprise with no presence or establishment in China, or whose income has no actual connection with such presence or establishment, pays enterprise income tax on China-derived income at a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or under PRC law. However, if the beneficial owner is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of total dividends if the Hong Kong resident is a company directly owning at least 25% of the capital of the PRC resident enterprise paying dividends; or (ii) otherwise, 10% of total dividends.

Considering the above, non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

To the extent our drug candidate R&D is subject to relevant scientific data measures and any subsequent laws required by government authorities, our R&D may be hindered if we are unable to obtain necessary approvals in a timely manner, or at all, which may materially and adversely affect our business, operations, financial condition and prospects. If relevant government authorities consider our transmission of scientific data to violate the scientific data measures, we may be

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subject to fines and other administrative penalties. Cross-border data transfer from other jurisdictions may also be limited if we fail to comply with relevant requirements, such as obtaining subject authorization for the use, transfer and retrieval of personal information or data, and adopting measures to ensure data safety during transfer. Cross-border transfer of personal data is also subject to general data privacy regulations in various jurisdictions, so any failure to comply with data privacy protection requirements may restrict our ability to transfer data across jurisdictions.

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

Products distributed or sold in the pharmaceutical market may be subject to off-label use, i.e., prescribing a product for an indication, dosage or dosage form not in accordance with approved usage and labelling. Although the NMPA, the FDA and other comparable regulatory authorities actively enforce laws prohibiting the promotion of off-label use, our products remain at risk of off-label use in a patient population, dosage or dosage form not approved by competent authorities, rendering them less effective or entirely ineffective and potentially causing adverse drug reactions. Any such occurrence can generate negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including our share price, and may expose us to liability, delay our clinical trials, and ultimately result in failure to obtain regulatory approval for our drug candidates.

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

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to social insurance and housing provident funds for our employees. During the Track Record Period, we did not make full contributions for certain employees in accordance with the relevant PRC laws and regulations. Under those laws, (i) we may be requested by relevant PRC authorities to pay outstanding social insurance contributions within a prescribed period, plus an overdue charge of 0.05% of the outstanding amount per day of delay; if we fail to pay within that period, we may be liable to a fine of one to three times the overdue amount; and (ii) if we fail to pay the full amount of housing provident funds required, the relevant PRC authorities may order payment within a prescribed time limit, failing which the relevant PRC authorities may apply to the PRC courts for compulsory enforcement. Our PRC Legal Adviser has further advised that if we fail to pay social insurance and housing provident funds under the relevant PRC law, the relevant employee has the right to terminate the labor contract and claim economic compensation.

As of the Latest Practicable Date, (i) to our knowledge and based on the Special Credit Reports for Market Entities issued by the competent government authorities of our Company, we had not been subject to any administrative penalties in relation to the shortfall in such contributions; (ii) according to the Emergency Circular of the General Office of the Ministry of Human Resources and Social Security on Applying the Spirit of the Executive Meetings of the State Council to Practically and Effectively Stabilize the Collection of Social Insurance Contributions (《人力資源社會保障部辦公廳關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) issued on September 21, 2018, relevant authorities are prohibited from organizing a centralized collection of enterprises' historical social insurance arrears; (iii) we were not aware of any material pending employee complaints or labor disputes with employees regarding social insurance and housing provident funds; (iv) we had not received notification from relevant PRC authorities requiring us to collectively pay shortfalls or overdue charges for social insurance and housing provident funds; and (v) we undertake to make timely payment of outstanding amounts and late charges as soon as requested by the competent government authorities. Based on the foregoing, and provided there are no significant changes in current policies, regulations, local government

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supervision and law enforcement requirements related to social insurance and housing provident funds, our PRC Legal Adviser is of the view that, the likelihood of our being subject to material administrative penalties by relevant authorities is remote. Our Directors accordingly believe that our failure to fully contribute to social insurance and housing provident funds during the Track Record Period would not have a material adverse effect on our business operations or results of operations, and as a result we made no provisions for these non-compliances during the Track Record Period.

As laws and policies related to social insurance and housing provident funds may continue to evolve, we cannot assure you that our employment policies and practices will always be regarded as fully compliant with relevant PRC laws and regulations, and we may face labor disputes or government investigations. The PRC government may strengthen its measures and requirements on social insurance and housing provident fund collection, leading to stricter enforcement. Compliance with stricter requirements may increase our operating expenses, particularly staff costs. We cannot guarantee that our required social insurance contributions will not increase, or that we will not be required to pay any shortfall or be subject to penalties or fines, any of which may materially and adversely affect our business and results of operations.

Changes in international trade policies, tariffs, sanction regimes and political tensions may adversely impact our business and results of operations.

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

Recent changes in international trade policies, including the imposition or increase of tariffs, have created uncertainty in global markets. For example, the U.S. has implemented several new tariffs and increased existing tariffs, prompting retaliatory measures from other countries. These tariffs, or the threat of further tariffs, could increase the cost of importing and exporting clinical and raw materials to and from the U.S., part of our current operations, and could affect our potential future commercialized products in the U.S. market. We may also face tariffs if our exports increase or change based on future operations. Changes in trade policy may also negatively impact companies reliant on international trade, including our potential collaborators and suppliers, indirectly affecting our business. Uncertainty surrounding future trade policies, tariffs and regulations may complicate our ability to plan for and manage costs, adversely affecting our business operations and financial performance. Retaliatory tariffs or other trade restrictions may also impact our ability to compete effectively in certain markets, particularly the U.S., hindering our growth and long-term prospects.

In addition, as we expand our business, in particular to international markets, our business may be adversely affected by the imposition, expansion or enforcement of laws and regulations relating to sanctions and export control in the relevant jurisdictions. See “Business — Sales, Promotion and Distribution — Our Overseas Distribution Arrangement.” Sanctions laws are administered and enforced by multiple authorities, including the U.S. Department of the Treasury’s Office of Foreign Assets Control (“OFAC”), the European Union, the United Kingdom and other regulators, which may restrict or prohibit transactions with, or investment into, certain countries, entities, or individuals. Such restrictions could limit our ability to supply products to, and derive

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revenue and receive payments from, affected entities and jurisdictions, and violations may subject us to penalties affecting our business expansion, growth prospects and financial condition. Although we do not believe we have engaged in any activity that would result in material sanctions risk, we cannot guarantee that competent authorities would not interpret these laws differently or unfavorably. Even where transactions are not expressly prohibited, heightened compliance requirements and reputational risk may discourage counterparties from engaging with us. International sanctions regimes are also complex and subject to frequent changes in scope, interpretation and enforcement. Any expansion of sanctions could result in termination of existing agreements, or penalties for violations. Such developments may materially and adversely impact our business, financial condition, results of operations, cash flow and prospects.

Adverse macroeconomic and geopolitical conditions may reduce demand for our products, disrupt our operations or supply chain, and adversely affect our financial condition and results of operations.

The global macroeconomic environment faces numerous challenges. There is significant uncertainty about the future relationship between the U.S. and its major trading partners, including China, regarding trade policies, treaties, government regulations and tariffs. The growth rate of the Chinese economy has generally been slowing since 2012, and this trend may continue. There is also considerable uncertainty over the long-term effects of expansionary monetary and fiscal policies adopted by central banks and financial authorities of leading economies, including the U.S. and China, as well as concerns over relations between China and other countries, including the U.S. and surrounding Asian countries, which may have economic effects. For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo titled the “America First Investment Policy” (the “**America First Memo**”), outlining the ongoing review of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, directed energy, and other areas implicated by the PRC’s national military-civil fusion strategy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments and other limited partner investors. Such political tensions and policy changes would adversely affect global economic conditions, the stability of global financial markets, and international trade policies. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policy and perceived overall economic growth in China. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations and financial condition.

We may be unable to identify, discover, in-license, acquire or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, in order to expand or maintain our current product pipeline.

Although a substantial amount of our effort will focus on continued clinical testing, potential regulatory approval, and commercialization of our existing drug candidates, our business—’s success also depends in part on our ability to continue discovering, developing, licensing, or commercializing additional drug candidates. We may not succeed in discovering and developing new drug candidates. Although we have developed proprietary technology platforms that we believe will help us continue developing new drug candidates to enrich our pipeline, we cannot guarantee success in this regard. We may also pursue collaboration with third parties in discovering and developing potential drug candidates, but cannot assure you such collaboration will deliver the intended results.

Research programs to discover and develop new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation: (i) the research

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methodology used may not successfully identify potential indications and/or new drug candidates; (ii) potential drug candidates may, after further study, show adverse effects or other characteristics indicating they are unlikely to achieve desired efficacy; or (iii) it may require greater resources to identify additional therapeutic opportunities for our drug candidates or develop suitable new candidates, limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will be able to discover and develop new drug candidates, identify additional therapeutic opportunities for our existing drug candidates, or develop suitable new potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects.

If safety, efficacy, manufacturing or supply issues arise with any product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidates or may experience significant regulatory delays or supply shortages.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination. For example, we plan to conduct clinical trials for combination therapies of ZG006 with ADC therapies for SCLC treatment, and evaluation of the combination of ZG005 with bevacizumab for liver cancer treatment. If the NMPA, the FDA or another comparable regulatory agency revokes or denies approval of a component therapeutic, at any stage from clinical design through commercialization, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays, or stop our commercialization efforts.

We may enter into collaboration agreements for the supply of certain drugs used in our combination trials in the future. Even with such arrangements in place, we may still be subject to unstable supply. If we cannot purchase sufficient quantities of component drugs from their manufacturers or distributors, or experience any supply shortage, the clinical development of our drug candidates may be disrupted. The supply shortage may also delay the regulatory approval of our drug candidates or our ability to timely meet market demand for our products upon receipt of marketing approval, which will adversely affect our business and prospects.

We have used companion diagnostic tests in developing our drug candidates, such as DLL3-positive detection kits for ZG006 in treating NEC and MUC17-positive detection for ZGGS34. Depending on the therapeutic context and clinical requirements, it is common industry practice to use companion diagnostic tests to detect a predictive biomarker and evaluate a patient's likely response to a given treatment. In the United States, the FDA has generally required *in vitro* companion diagnostics intended to select patients likely to respond to cancer treatment to obtain pre-market approval, which can take several years, simultaneously with approval of the biologic product. Regulations in China governing companion diagnostic tests used for patient identification are still developing, and it remains uncertain whether future regulatory changes will impose additional restrictions or requirements. If we develop companion diagnostic tests for patient screening, or our drug development entails their use, China's developing regulations would present uncertainties for our drug development and commercialization and may adversely affect our business and results of operations.

Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, top-line or interim data from our preclinical studies and clinical trials, based on a preliminary analysis of then-available data, the results, findings and conclusions of which are subject to change following a more comprehensive review. We also make assumptions, estimations, calculations and conclusions as our analyses progress, without necessarily having the opportunity to fully evaluate all data. Others, including regulatory agencies, may interpret or weigh such assumptions, estimations and calculations

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differently. Accordingly, the results we report may differ from future results of the same studies, or may be qualified by different conclusions, once additional data has been received and fully evaluated. Top-line data also remains subject to audit and verification procedures that may produce final data materially different from the preliminary data previously published. Top-line data should therefore be viewed with caution until final data is available.

The data and information that we gather in our R&D process could be inaccurate or incomplete, which could affect the clinical development of our drug candidates and harm our business, reputation, financial condition and results of operations.

We receive, collect, aggregate, process and analyze data and information from our preclinical studies and clinical trials, and engage in substantial information gathering following identification of a promising drug candidate. Because healthcare industry data is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed is often subject to challenge, the degree of data knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing our data quality. If we make mistakes in capturing, inputting, or analyzing this data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We manage and submit data to governmental entities to obtain necessary regulatory approvals. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies, interim, top-line or preliminary clinical trial data that we announce or publish from time to time may change as more patient data becomes available, and remains subject to audit and verification procedures that could result in material changes to the final data, in which case we may be exposed to liability to a patient, court or government agency that concludes our storage, handling, submission, delivery or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials, this coverage may prove inadequate or could cease to be available on acceptable terms, or at all. Even unsuccessful claims could result in substantial costs and divert management time, attention and resources. A claim against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing preclinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third parties fail to meet our standards for data accuracy or completeness, data from those trials may be compromised, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “— Risks Relating to Our Reliance on Third Parties — We engage with third parties for certain aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.”

We may seek to rely on accelerated approval pathways to use registrational trial data for our drug candidates. If we are not able to use such pathways, we may be required to conduct additional clinical trials increasing costs and delaying, or preventing, marketing approvals.

The NMPA, the FDA and comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and grant accelerated approval to a drug candidate that provides meaningful therapeutic benefit over available therapies for a serious or life-threatening condition. This determination is based on a finding that the drug candidate has an effect on a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit. For example, the FDA considers clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality.

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For accelerated approval purposes, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure thought to predict clinical benefit but not itself a measure of it. An intermediate clinical endpoint is reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity or mortality. The accelerated approval pathway may be used where the advantage of a new drug over available therapy is not a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. Before seeking accelerated approval, we will continue to seek feedback from the NMPA and the FDA and otherwise evaluate our ability to seek and receive it.

There can be no assurance that regulatory authorities will agree with our proposed surrogate or intermediate clinical endpoints, or that we will decide to pursue or submit any NDAs, BLAs or other comparable applications for accelerated approval or any other expedited pathway. Similarly, even if we initially decide to pursue accelerated approval, there is no assurance we will continue to do so after receiving regulatory feedback, or that any submission or application will be accepted for filing, or that expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated or other expedited approval for our drug candidates would result in a longer commercialization timeline, could increase development costs, and could harm our competitive position. Even if we obtain accelerated approval based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate and, if the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.

OTHER RISKS RELATING TO OUR OPERATIONS

If we, our employees, agencies, distributors or other business partners engage, or are perceived to engage, in misconduct, breaches, or if they are involved in negative publicity or allegations, our operations and reputation could be adversely affected, and we could be exposed to regulatory investigations, costs and liabilities.

We are subject to risks from actions taken by us, our employees, agencies, distributors or other business partners that may constitute violations of applicable anti-corruption and other related laws, including China’s anti-bribery and corruption laws, which generally prohibit companies and their intermediaries from making payments to government officials to obtain or retain business or secure any other improper advantage. For details, see “Regulatory Overview — Laws and Regulations in Relation to Anti-money Laundering, Anti-corruption and Anti-bribery.” We are also subject to the U.S. Foreign Corrupt Practices Act (the “FCPA”), which generally prohibits improper payments to non-U.S. officials to obtain or retain business. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption laws to our operations has increased. There have also been instances of corrupt practices in the pharmaceutical industry in recent years, including provision of kickbacks, bribes or other illegal gains or benefits to pharmacies, hospitals and medical practitioners from manufacturers, distributors and pharmacies in connection with prescribing of pharmaceutical products. Any allegations of such conduct against us, our employees, agencies, distributors, other business partners or the pharmaceutical industry generally could generate negative publicity and materially and adversely affect our reputation and business prospects.

We do not, and cannot, fully control the conduct of our employees, agencies, distributors or other business partners. In their interactions with hospitals, medical institutions and medical professionals, they may attempt to increase our products’ sales volume through means that violate applicable anti-corruption and other related laws. If they engage in corrupt or other improper conduct violating anti-corruption laws in the PRC, the United States or other jurisdictions, our reputation could be harmed. While we have implemented specific anti-corruption and anti-bribery measures, there is no assurance that we can entirely prevent such activities, whether past or future. We may be held liable for actions taken by our employees, agencies, distributors or other business partners, exposing us to regulatory investigations and penalties. Regulatory or judicial interpretations that differ from ours, or new anti-bribery or anti-corruption laws, could also require us to change our operations. Our reputation, corporate image and business operations may be

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materially and adversely affected if we, our employees, agencies, distributors or other business partners fail to comply with these measures or become subject to negative publicity from such actions, which may in turn materially adversely affect our results of operations and prospects.

In addition, we are required to comply with anti-corruption and confidentiality requirements in our agreements with business partners. Any breach of these requirements by us may result in negative consequences, including penalties and termination of agreements, which could have a material adverse effect on our business, financial condition, results of operations and profitability. Our business may also be materially and adversely affected if our business partners breach confidentiality requirements, or if our employees breach the non-disclosure, non-compete and non-solicitation clauses in their employment agreements.

Our business depends on our key senior management members, development personnel and marketing and sales personnel. If we are unable to retain our key employees or to attract and retain skilled and experienced personnel, our ability to conduct our business could be materially impaired and our business prospects could be adversely affected.

We depend on the continued contributions of our senior management, especially the executive officers listed in "Directors and Senior Management" in this document, and other key employees, many of whom are difficult to replace. Our future success depends on our ability to attract qualified employees and retain existing key employees, especially product development, technology, marketing and sales professionals. Competition for such personnel is intense where we operate, and our efforts to recruit, retain and motivate employees may require increased compensation-related costs, including share-based compensation, and competitive compensation packages and a high-quality work environment. In addition, our senior management team has limited experience running H share listed public companies, requiring us to expend additional resources on hiring support staff. To the extent we hire personnel from competitors, we may also face allegations that they were improperly solicited or divulged proprietary or confidential information.

From time to time, we, our management or our directors may also become involved in litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of business. Such matters may divert management and director attention, consume significant time and resources, and disrupt our operations. Matters initially immaterial may escalate depending on the facts, parties involved, and amounts at stake. Negative publicity from such proceedings could damage our reputation and brand image. If an adverse judgment or award is rendered against us, we may be required to pay significant damages, assume additional liabilities, or suspend or terminate related business activities.

If we are unable to retain our existing employees, attract qualified personnel, or effectively manage litigation and related distractions, we may be unable to manage our business effectively, including development, marketing and sales, which could adversely affect our business, operating results and financial condition, and the price of our [REDACTED] could suffer.

If we or our brand names fail to maintain a positive reputation, many aspects of our business and our business prospects could be adversely affected.

We depend on our reputation and product brand names in many aspects of our business, including but not limited to: (i) gaining access to, and favorable perception by, medical institutions and healthcare professionals who drive patient demand; (ii) effectively working with authorities that regulate our business; (iii) gaining the trust of patients and consumers; (iv) competitively positioning ourselves in the centralized tender process required to sell to public hospitals and medical institutions; (v) successfully attracting employees, distributors and other business partners; and (vi) increasing market share through brand recognition.

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However, there can be no assurance that we will maintain a positive reputation or brand name for all our products. Our reputation and brand names may be adversely affected by factors largely outside our control, including but not limited to: (i) adverse associations with our products, including their efficacy or side effects; (ii) the effects of counterfeit products purporting to be our products; (iii) lawsuits and regulatory investigations against us or otherwise relating to our products or industry; (iv) improper or illegal conduct by our employees, distributors, suppliers and third-party promoters, whether or not authorized by us; and (v) adverse publicity associated with us, our products or our industry, whether founded or unfounded.

If we or our product brand names fail to maintain a positive reputation as a result of these or other factors, our products may be perceived unfavourably by hospitals, medical professionals, regulators and patients, and our operations and business prospects could be adversely affected.

Similarly, if counterfeits of our products become available in the market, this could negatively affect our sales, damage our reputation and product brand names, and expose us to liability claims. Some products distributed or sold in pharmaceutical markets may be manufactured without proper licenses or approvals, or fraudulently mislabeled regarding their content or manufacturer; these are generally referred to as counterfeit products. Because counterfeit products are usually sold at lower prices, and in some cases closely resemble authentic products, they can quickly erode our sales volume for the affected product. Counterfeits may also have a different chemical composition than our products, making them less effective, entirely ineffective, or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may result in litigation against us. As a result, the continued proliferation of counterfeit products could affect our sales, damage our reputation and brand names, and expose us to liability claims.

In addition, despite our internal guidelines and supervision efforts, our employees or distributors may fail to follow such guidelines, which may adversely affect our sales and reputation. For details, see “— Actions taken by our distributors in violation of the relevant agreements or taken by the distributors with whom we have not entered into distribution agreements could materially and adversely affect our business, prospects and reputation.”

Our business could be adversely affected by natural disasters, public health crises, political relationships and crises, economic downturns or other unexpected events.

Natural disasters, health epidemics, acts of war or terrorism, or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of people in the regions where we conduct business. Our operations may be threatened by natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, and other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks.

A disaster or prolonged outbreak of epidemic illness, or other adverse public health developments in the world, could materially disrupt our business and operations. These uncertain and unpredictable factors include adverse economic effects of a pandemic, potential delays to our ongoing and future clinical trials, and disruptions to our business partners’ and CROs’ operations. A disaster or epidemic illness may also heighten other risks described in this document, including those relating to our ability to initiate or continue clinical trials for our drug candidates.

With our international footprint, our business is subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in the countries and regions where we operate, and we may face various risks relating to legal compliance in different jurisdictions, exposure to potential disputes and litigation, geopolitical actions, trade restrictions or prohibitions, foreign exchange rates, local market conditions, cultural and language difficulties, geopolitical risks, competition, and taxes. As a result, international political relationships among

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jurisdictions where we operate and conduct business may affect our cost structure, product demand and collaboration with business partners. Any such relationship tensions and political concerns may adversely affect our business, results of operations and prospects. Any economic downturn, decrease in economic growth rates, or other uncertain economic outlook in our markets could also affect our business, financial condition and results of operations.

Acts of war or terrorism may also injure our employees, cause loss of life, disrupt our business network and destroy our markets. Any of these events, and other events beyond our control, could adversely affect overall business sentiment and environment, cause uncertainty in the regions where we conduct business, and cause our business to suffer in unpredictable ways, materially and adversely impacting our business, financial condition and results of operations.

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

We face an inherent risk of product and professional liability from the clinical testing and any future commercialization of our drug candidates in China, the United States and other relevant jurisdictions. For example, we may be sued if our drug candidates cause, or are perceived to cause, injury, or are found otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Such product liability claims may allege defects in manufacturing or design, failure to warn of inherent dangers, negligence, strict liability or breach of warranties, and claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend against such claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even a successful defense would require significant financial and management resources. Regardless of merits or outcome, liability claims may result in: (i) decreased demand for our drug candidates; (ii) injury to our reputation; (iii) withdrawal of clinical trial participants and inability to continue trials; (iv) initiation of regulatory investigations; (v) litigation defense costs; (vi) diversion of management time and resources; (vii) substantial monetary awards to trial participants or patients; (viii) product recalls, withdrawals, or labelling, marketing or promotional restrictions; (ix) loss of revenue; (x) exhaustion of available insurance and capital resources; (xi) inability to commercialize any approved product candidate; and (xii) a decline in the [REDACTED] of our H Shares.

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

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute the value of your [REDACTED] in our H Shares, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including, but not limited to: (i) dilution to existing Shareholders from issuing additional equity securities; (ii) loss of key personnel and uncertainty in maintaining key business relationships; (iii) risks and uncertainties in assimilating the operations, corporate culture, intellectual property, products and personnel of the acquired company or business; and (iv) changes in accounting principles for recognizing and measuring our investments that may significantly impact our financial results.

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Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets resulting in significant future amortization expenses. We may also be unable to locate suitable acquisition opportunities, which could impair our ability to grow or obtain access to technology or products important to our business’s development.

Further, under the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》) issued by the State Council, a concentration of business undertakings by merger, acquisition or contractual arrangement allowing one market player to control or exert decisive impact on another must be notified in advance to the MOFCOM once the relevant threshold is crossed, and cannot be implemented without prior notification clearance.

We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (“CFIUS”) and other agencies, including the Foreign Investment Risk Review Modernization Act.

In the future, we may grow our business by acquiring complementary businesses. Complying with the above regulations and other relevant rules to complete such transactions could be time-consuming, and required approval or filing processes, including with CFIUS, the SAMR, the MOFCOM, the CSRC, the SAFE or other agencies, may delay or inhibit our ability to complete such transactions. These agencies may also make determinations that increase scrutiny of our future acquisitions in the United States or the PRC, or prohibit such acquisitions. Our ability to expand our business or maintain or expand market share through future acquisitions would be materially and adversely affected as a result.

Increased labor costs could result in exceeding expenses, slow our growth and affect our profitability. In the event of labor shortages, labor disputes or striking, our business operation and financial performance may be materially adversely affected.

Our success depends in part on our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, sales and academic promotion, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors seek the same pool of talent and our remuneration packages may not be as competitive as theirs. Increasing market competition may intensify demand and competition for qualified employees.

As our production process requires skilled technical workers in design, operation and quality control, we cannot guarantee that we can retain and attract sufficient qualified employees on reasonable terms. If we cannot retain existing skilled workers, recruit sufficient replacements, cope with our expansion plan on a timely basis at reasonable cost, or train new workers quickly enough amid high turnover, our production process could be severely affected or interrupted. Labor shortages, significant increases in labor costs, higher turnover, or changes to labor laws could significantly increase our operating costs, materially adversely affecting our results of operations. Labor disputes could also lead to fines by governmental authorities and settlement costs, and make it more difficult to recruit new employees due to reputational damage.

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

We maintain insurance policies required under relevant laws and regulations, which we believe are in line with market practice and adequate to safeguard against risks and unexpected events, including environmental liability insurance, property loss insurance, and social welfare insurance for our employees. However, our insurance coverage may be insufficient to cover claims we may have. Any liability or damage to, or caused by, our facilities or personnel beyond our insurance coverage may result in substantial costs, diversion of resources, and negative impacts on our drug development and overall operations.

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Our legal right to certain properties may be challenged.

Under applicable PRC laws and regulations, property lease contracts must be registered with the local branches of the Ministry of Housing and Urban Development. As of the Latest Practicable Date, ten lease agreements for our leased properties, leased from third parties and used for production or office purposes, had not been registered and filed with relevant land and real estate management departments in China. Under relevant PRC laws and regulations, the parties to a lease agreement must register and file it. As advised by our PRC Legal Adviser, the validity of the lease agreements is unaffected by the failure to register or file them with relevant government authorities. Under relevant PRC regulations, we may be ordered to register the relevant lease agreements within a prescribed period, failing which we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each unregistered lease. As of the Latest Practicable Date, we have not received any order from relevant government authorities requiring us to register these lease agreements. We undertake to cooperate fully to facilitate registration once notified of any requirement by the relevant government authorities.

You may have limited resources in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management named in the documents based on Hong Kong or other foreign laws.

A substantial part of our assets, and a majority of our Directors and senior management, are located in China. As a result, it may not be possible for [REDACTED] to effect service of process on us, or on our Directors or senior management who reside in China. China has not entered into treaties or arrangements for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, the Supreme People’s Court of the PRC and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the 2006 Arrangement. Under this Arrangement, where a designated PRC or Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a written choice of court agreement, any party concerned may apply to the relevant court for recognition and enforcement. A choice of court agreement in writing is one entered into after the Arrangement’s effective date, expressly selecting a Hong Kong or mainland court as having sole jurisdiction for the dispute.

On January 18, 2019, the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), or the New Arrangement, was signed between the Supreme People’s Court of the PRC and Hong Kong and effective on January 29, 2024, superseding the 2006 Arrangement. The New Arrangement establishes a bilateral legal mechanism with greater clarity and certainty for reciprocal recognition and enforcement of judgments between Hong Kong and the PRC in civil and commercial matters under both legal systems, setting out the scope, specific matters covered or excluded, jurisdictional grounds for recognition and enforcement, and grounds for refusal. The 2006 Arrangement remains applicable to a “choice of court agreement in writing” within its meaning made before the New Arrangement’s effective date. As the New Arrangement took effect relatively recently and its implementation and interpretation are still evolving, [REDACTED] may have limited resources when seeking recognition and enforcement of judgments obtained from non-PRC courts against us or our Directors or officers living in the PRC.

RISKS RELATING TO THE [REDACTED]

The [REDACTED] characteristics and [REDACTED] bases of the A Share and H Share markets differ; fluctuations in the price of our A Shares may adversely affect the [REDACTED] of our H Shares, and vice versa.

Our A Shares were listed on the SSE STAR Market in January 2020. Following the [REDACTED], our A Shares will continue trading on the SSE STAR Market and our H Shares will [REDACTED] on the Stock Exchange. Under current PRC laws and regulations, our H Shares and

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A Shares are neither interchangeable nor fungible, and there is no trading or settlement between the two markets. With different [REDACTED] characteristics, the H Share and A Share markets have divergent [REDACTED], liquidity and [REDACTED] bases, and differing levels of retail and institutional [REDACTED] participation. As a result, the [REDACTED] performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the [REDACTED] of our H Shares, and vice versa, and may also affect our [REDACTED] in Hong Kong. Due to these differing market characteristics, the historical prices of our A Shares may not indicate the [REDACTED] of our H Shares, and you should not place undue reliance on our A Share trading history when evaluating an [REDACTED] in our H Shares.

An active [REDACTED] for our H Shares may not develop or be sustained.

Prior to the [REDACTED], there has been no [REDACTED] for our H Shares. We cannot assure you that a [REDACTED] for our H Shares with adequate liquidity will develop and be sustained following completion of the [REDACTED]. The [REDACTED] of our H Shares may also not indicate their [REDACTED] following completion of the [REDACTED]. If an active [REDACTED] for our H Shares does not develop, their [REDACTED] and liquidity could be materially and adversely affected.

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

The [REDACTED] and [REDACTED] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including general market conditions for securities in Hong Kong and elsewhere. In particular, the business, performance and [REDACTED] of shares of other companies in similar businesses may affect the [REDACTED] and [REDACTED] of our Shares. Beyond market and industry factors, our share [REDACTED] and [REDACTED] may be highly volatile for specific business reasons, such as fluctuations in our revenue, earnings, cash flows, investments, expenditures, regulatory developments, drug and drug candidate developments, movements or activities of key personnel, or actions by competitors. Shares of other companies listed on the Hong Kong Stock Exchange with significant China operations and assets have experienced price volatility in the past, and our H Shares may similarly be subject to [REDACTED] changes not directly related to our performance.

You will experience immediate and substantial [REDACTED] and may experience further [REDACTED] if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Purchasers of the [REDACTED] will therefore experience immediate [REDACTED] in [REDACTED] net tangible asset value. To expand our business, we may consider [REDACTED] and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience further [REDACTED] in net tangible asset value per share if we issue additional Shares at a price lower than the then-net tangible asset value per Share. We may also issue Shares under share incentive schemes, further diluting Shareholders’ interests.

Future sales or perceived sales of significant amounts of our H Shares in the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares.

The [REDACTED] of our H Shares could decline due to substantial future [REDACTED] of our H Shares or related securities in the [REDACTED], or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our Shares could materially and adversely affect the [REDACTED] of our H Shares.

Facts, forecasts and statistics in this document obtained from official government sources or publicly available sources may not be fully reliable.

This document, particularly the “Industry Overview” section, contains information and statistics, relating to the PRC, the PRC economy and the healthcare industry in the PRC derived from various official government publications or publicly available sources. We believe these sources are appropriate and have taken reasonable care in extracting and reproducing this information. We have no reason to believe that such information and statistics are false or misleading in any material respect, or that any fact has been omitted that would render them false or misleading in any material respect. Neither we, the [REDACTED], nor our or their respective

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affiliates or advisors have verified the facts, forecasts and statistics, or ascertained the underlying economic assumptions relied upon, and no representation is given as to their accuracy. We cannot assure you that such information is stated or compiled on the same basis, or with the same degree of accuracy, as information in other jurisdictions.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations, the [REDACTED] and [REDACTED] may decline.

If research analysts do not establish and maintain adequate research coverage, or if one or more analysts covering us downgrade our Shares or publish inaccurate or unfavorable research about our business, the [REDACTED] of our Shares would likely decline. If one or more of these analysts cease coverage of our company, or fail to publish reports on us regularly, we could lose visibility in the financial markets, which could cause the [REDACTED] or [REDACTED] of our Shares to decline.

You should not place any reliance on any information released by us in connection with the listing of our A Shares on the SSE STAR Market.

Following the listing of our A Shares on the SSE STAR Market, we have been subject to periodic reporting and other information disclosure requirements in the PRC. As a result, we periodically publicly release information, including financial statements and data, on the SSE STAR Market or other media outlets designated by the SSE STAR Market, the CSRC or other regulatory bodies. However, information we announce in connection with our A Shares is based on PRC securities regulatory requirements and market practices that differ from those applicable to the [REDACTED], and such information does not and will not form part of this document. Prospective [REDACTED] in our H Shares are therefore reminded that, in deciding whether to [REDACTED] our H Shares, they should rely only on the financial, operating and other information in this document. By [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed not to rely on any information other than that contained in this document, the [REDACTED] and any formal announcements we make in Hong Kong regarding the [REDACTED].

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

Subsequent to the date of this document but prior to completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain financial information, projections, valuations and other forward-looking information about us. We have not authorized disclosure of any such information in the press or media and do not accept responsibility for its accuracy or completeness. We make no representation as to the appropriateness, accuracy, completeness or reliability of any projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent or conflict with information in this document, we disclaim responsibility for them. Prospective [REDACTED] are accordingly cautioned to base [REDACTED] decisions solely on the information contained in this document and should not rely on any other information.

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