
RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this document and in particular the risks and uncertainties described below before making an [REDACTED] in our H Shares. The information given is also subject to the cautionary statements in “Forward-Looking Statements.” The following is a description of what we consider to be our material risks.

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

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors. If we are unable to maintain the sales volume, pricing levels and profit margins of our products, our profitability could be adversely affected.

The development and commercialization of pharmaceutical products is highly competitive, we may not be able to compete effectively against current and future competitors on the basis of efficacy, safety, price or general market acceptance.

During the Track Record Period, our revenue was primarily derived from the sales of marketed generic drug products and APIs/intermediates, covering a wide range of therapeutic areas including infectious diseases, immunology and oncology. Before we generate revenue from the commercialization of our drug candidates, we expect that our revenue will continue to be concentrated in a limited number of marketed generic drug products and APIs/intermediates in the near future. The sales volumes, pricing levels and profitability of our products may be adversely affected by various factors, many of which are beyond our control, including: (i) exclusion from, or reduced coverage under, the national or other government-sponsored medical insurance programs; (ii) the impact of government pricing regulations, such as volume-based procurement; (iii) competition and lack of success in the centralized procurement process necessary for sales to public hospitals and other public medical institutions; (iv) sales of substitute products by competitors; (v) interruptions in the supply of raw materials, increases in the cost of raw materials; (vi) issues with product quality or side effects; (vii) intellectual property infringements; (viii) adverse changes in our sales and distribution network; and (ix) unfavorable policy, regulatory or enforcement changes. Failure to maintain the sales volume, pricing levels and profit margins of our marketed products could materially and adversely affect our business, financial condition and results of operations, which could hinder our ability to invest in and develop new products, thereby affecting our long-term growth prospects.

Our competitors primarily include large domestic and international pharmaceutical companies, as well as emerging biopharmaceutical companies, who may currently market and sell drugs or are pursuing the development of drugs for the treatment of the same indications as ours. Some of these competitors have greater financial, technology and other resources than us. Although we have established leading market positions in certain product categories, the presence of numerous competitors may exert continued downward pressure on pricing and erode our market share, which could materially and adversely affect our business, financial condition and results of operations. During the Track Record Period, micafungin sodium and oseltamivir phosphate were among our major marketed products and revenue contributors, both being generic drug products and therefore subject to significant market competition. As of the Latest Practicable Date, over 50 generic versions of oseltamivir phosphate and over 15 generic versions of micafungin sodium had been launched globally. According to CIC, in 2025, we held a 2.7% share of the global oseltamivir phosphate API and intermediate market and captured approximately 33.3% of the global market share for micafungin sodium APIs and intermediates. Furthermore, the competitive landscapes of our target

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markets are constantly evolving with the emergence of next-generation technologies and therapeutic approaches, which could drive the development of superior treatment options. We cannot guarantee that our marketed products and drug candidates, upon their commercialization, will compete effectively in this market environment, and their lack of competitiveness could result in the decrease of sales and loss of market share. The competitive dynamics of our product markets have contributed to, and may continue to contribute to, fluctuations in our revenue, gross profit margin and profitability.

Our commercial opportunities could be significantly reduced or even eliminated if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than our marketed products or drug candidates. Our competitors also may obtain approval from the NMPA or other comparable regulatory authorities for their drugs more rapidly than we can, potentially establishing a strong competitive position before our market entry. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our product candidates. Furthermore, there may also be consolidation in the pharmaceutical industry among our competitors, or alliances among competitors that may rapidly acquire significant market share. Through collaborative arrangements with large and established companies, smaller or early-stage biopharmaceutical companies may also prove to be significant competitors. If we fail to effectively compete with our competitors or adjust to structural changes in the pharmaceutical industry, our revenue and profitability may be materially and adversely affected.

Substantially all of our revenue during the Track Record Period was derived from generic drug products, and there is no assurance that our strategic transition to innovative drug development will be successfully implemented.

We pursue a business model in which innovative drug research and development is our strategic priority, supported by a portfolio of marketed generic drug products. Our generics portfolio provides the revenue base that funds our R&D initiatives, and we intend to progressively increase our focus on innovative drug development over time. However, there can be no assurance that this strategy will be successfully implemented or that it will yield the results we expect. Our innovative drug candidates are at various stages of development and may not obtain regulatory approval on the timelines we anticipate, or at all, and even if approved, may not achieve the level of market acceptance or commercial success necessary to justify our R&D investment. At the same time, our generics portfolio, which provided the substantial majority of our revenue during the Track Record Period, may come under pressure from increasing competition, pricing reforms, or volume-based procurement policies in China, any of which could reduce the revenue available to sustain our operations and fund our R&D initiatives, requiring us to slow, scale back, or reprioritize our innovative drug development activities.

The successful transition from a generics-focused to an innovative pharmaceutical company requires capabilities that extend beyond drug development, including the regulatory expertise, medical affairs infrastructure, commercial capabilities, and market access strategies for novel therapies. We are continuously establishing certain of these capabilities, and there is no assurance that we will be able to do so in a timely or cost-effective manner, or that we will be able to attract and retain the specialized talent required. Furthermore, our business model is premised on synergies between our generics and innovative drug portfolios, including shared technology platforms and R&D infrastructure. If these synergies do not materialize to the extent we expect, or if the demands of our innovative drug programs divert resources and management attention from our generics business, both segments of our business could be adversely affected. If we are unable to successfully execute our strategic transition, our business, financial condition, results of operations, and prospects could be materially and adversely affected.

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Pricing regulations or other policies such as volume-based procurement that are intended to reduce healthcare costs could subject us to pricing and volume pressures and adversely affect our operations, revenue and profitability.

During the Track Record Period, a substantial majority of our revenue generated from the sales of finished dose generic products was derived from China. The PRC government may reform the schemes of pricing oversight and statutory tender processes for pharmaceutical products or revise other policies affecting prices of pharmaceutical products over time. In November 2018, the national pilot program for volume-based procurement (the “VBP”) scheme with minimum procurement quantities was launched in 11 cities in China, which has been extended nationwide since 2019. The initiative aims to secure larger quantities of pharmaceutical products at lower prices and thus may potentially impact how drugs are priced and procured in China. See “Regulatory Overview — Overview of Laws and Regulations in the PRC — National Centralized Procurement Program and Tendering Procedures” for details.

For the years ended December 31, 2023, 2024 and 2025, three, one and one of our marketed finished drug products, respectively, participated in national VBP tenders. We secured bids for two products in 2023 and the one product tendered in each of 2024 and 2025, achieving selection rates of 66.7%, 100.0% and 100.0%, respectively. As of December 31, 2025, five of our marketed finished drug products had been included in national VBP schemes. Revenue from these products sold pursuant to the implementation of national VBP schemes amounted to RMB62.3 million, RMB77.5 million and RMB83.9 million for the years ended December 31, 2023, 2024 and 2025, representing 5.4%, 6.2% and 7.0% of our total revenue, respectively. See “Business — Pricing — VBP Schemes” for details. The VBP schemes, while enabling larger sales volumes, exert downward pressure on our product pricing to win bids and influence the prices at which we sell our products to our customers, thus potentially affecting our revenue and profitability. In addition, for our sales of APIs and intermediates, the inclusion of our customers’ products under the VBP schemes may also have a material impact on our business performance. The VBP schemes, while enabling larger sales volumes, exert downward pressure on our product pricing to win bids and influence the prices at which we sell our products to customers, thus potentially affecting our revenue and profitability.

In addition, VBP schemes are implemented through periodic procurement cycles. We cannot accurately predict if more or fewer of our marketed products will be included in such schemes in the future. If our competitors win the bid under such schemes while we fail to do so, demand for our products may decrease, which could adversely affect our procurement volumes through public hospitals and our market penetration. Moreover, even if our products win the bid, there may be discrepancies between the estimated procurement volumes set out in the tender documents and the actual procurement volumes. Consequently, there are uncertainties regarding the impact of the implementation of the VBP schemes on the sales volume and revenue of the winning products.

National or other government-sponsored medical insurance programs may have a material impact on our sales, profitability and business prospects.

Insurance coverage is a critical factor in a patient’s ability to afford treatments, and without it, the demand for our products could diminish. 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 a portion of the cost. Consequently, the inclusion or exclusion of a pharmaceutical product in or from insurance program such as the NRDL or other government-sponsored medical insurance programs in China will significantly affect patient demand. As of December 31, 2025, nine of our marketed finished drug products sold in China were included in the NRDL. Revenue recognized from sales of the relevant products following their NRDL inclusion amounted to RMB118.9 million, RMB144.3 million and RMB160.8 million in 2023, 2024 and 2025, respectively, representing 10.2%, 11.5% and 13.4% of our total revenue for the corresponding years. The selection of pharmaceutical products for listing in medical insurance catalogs is based on a variety of factors, including clinical needs, frequency of use, effectiveness,

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safety and price. There can be no assurance that any of our products will remain in or be added to the NRDL. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from the sales of approved products would be highly dependent on patient self-payment, which can make our products less attractive. Patients may choose other products with similar efficacy but lower price which have been included in the NRDL.

Moreover, the PRC government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that were previously covered. Therefore, there can be no assurance that any of our products currently listed in these medical insurance catalogs will remain listed, or that changes in the scope of reimbursement will not negatively affect our products. If any of our products or their indications are removed from any medical insurance catalog, or if the scope of reimbursement is reduced, demand for our products may decrease and our revenue and profitability could be adversely affected. Even if the government authorities were to accept our application for the inclusion of products in the catalog, our potential revenue from the sales of these products could still decline as we may be required to significantly lower their prices to secure such inclusion.

Our future approved drugs may be subject to downward pricing pressure arising from VBP schemes and national reimbursement drug listing requirements.

We expect to commercialize additional generic and innovative drug candidates in China in the foreseeable future. Certain products currently available in the market for the same or similar indications as such drug candidates may already have been included in national or regional VBP schemes or the NRDL. As a result, our future products may face direct or indirect downward pricing pressure at launch or after commercialization, even before they are themselves included in any such schemes, as existing VBP or reimbursement outcomes may establish pricing benchmarks and influence hospital procurement decisions, physician prescribing preferences and patient affordability expectations. For our finished drug products that are not yet included under the VBP schemes, such as eribulin mesylate and budesonide suspension for inhalation, if they become subject to VBP schemes, we may be required to offer significantly reduced prices to participate in or win VBP tenders, and there can be no assurance that any increased sales volume would offset reduced prices. For our innovative drug candidates, if we seek NRDL inclusion, we may need to accept substantial price reductions or other reimbursement terms, and if competing products are already included in the NRDL, our products may be at a competitive disadvantage in hospital access and physician adoption if they are not similarly included or are included on less favorable terms.

We derived the majority of our revenue during the Track Record Period from the sales of APIs and intermediates, which may experience fluctuations that could affect our results of operations.

We derived the majority of our revenue from sales of our APIs and intermediates during the Track Record Period. If we are unable to maintain the sales volumes, pricing levels or profit margins of these products, our revenue and profitability could be adversely affected. Sales of our APIs and intermediates accounted for 81.4%, 83.5% and 80.9% of our total revenue for the years ended December 31, 2023, 2024 and 2025, respectively. We expect that sales of APIs and intermediates will continue to comprise a substantial portion of our total revenue in the near future. Any reduction in sales or profit margins of APIs and intermediates could therefore have a direct adverse impact on our business, financial condition and results of operations. Sales of APIs and intermediates may fluctuate due to various factors, including changes in government pricing and procurement policies affecting our downstream customers, variations in customer demand, intensified market competition, fluctuations in the prices of raw materials, disruptions to manufacturing or logistics, and product quality or compliance issues, all of which could lead to revenue and profitability volatility and materially affect our overall operating performance.

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Our marketed products and drug candidates approved in the future may fail to achieve or maintain the degree of market acceptance by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community necessary for commercial success, and the actual market size of our product candidates could be smaller than expected.

The commercial success of our products is highly dependent on their continued market acceptance among patients, healthcare practitioners, and others in the medical community. We believe that the market acceptance of our products and drug candidates depends on many factors, including: (i) the perceived advantages of our products over competing products and the availability and success of competing products; (ii) the safety and efficacy of our products; (iii) the pricing, cost effectiveness and patient switching costs of our products; (iv) the effectiveness of our sales and marketing efforts; (v) publicity concerning our products or competing products; and (vi) our ability to respond to changes in needs and preferences of healthcare practitioners and patients.

In addition, market acceptance of a product is also affected by whether it is included in the NRDL or other government-sponsored medical insurance programs. See also “— National or other government-sponsored medical insurance programs may have a material impact on our sales, profitability and business prospects.” If our products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are more cost-effective or are received more favorably by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community, the demand for our products may decline and our business and profitability may be materially and adversely affected.

Furthermore, the actual market size of our product candidates may not be as large as we anticipate, influenced by various factors such as market acceptance, pricing, and patient availability. The number of patients in the addressable markets may turn out to be lower than expected, or new patient identification and access may become more challenging. Any of these unfavorable developments could adversely affect our business, financial condition and results of operations.

We may not be able to accurately predict the safety profile of our marketed products and drug candidates. If our marketed products and drug candidates cause, or are perceived to cause, severe side effects, our operations, results of operations and business prospects could be adversely affected.

We may experience unexpected safety issues in new patient populations or new indications. For instance, the same drug could have different effects on patients with different physical conditions or on other medications, and the corresponding reactions could be unpredictable. In addition, we may not be able to accurately predict how the products we sell or drug candidates we develop or market will interact with other drugs, including causing possible adverse side effects not directly attributable to each drug used as a monotherapy that could compromise the safety profile of these drugs when used in combination therapies. Safety issues associated with our products could lead to product liability claims, increased regulatory scrutiny and additional requirements such as revised labeling, product withdrawals, or fines and penalties. The dissemination of adverse safety events involving our products or products similar to ours, and public perception about such events, could undermine confidence in our products and harm our reputation. Any of the foregoing may result in liabilities, loss of revenue, material write-offs of inventory, and other adverse impacts on our business, financial condition and results of operations.

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

Pharmaceutical products may be subject to off-label use, which involves the use of a product for an indication, dose or dosage form that differs from the approved labeling. Certain drug classes, such as GLP-1 receptor agonists, may be particularly vulnerable to off-label use due to their potential application across multiple therapeutic areas and populations. While the NMPA, the FDA and other regulatory authorities actively enforce regulations prohibiting the promotion of off-label use, our products may still be prescribed for unapproved patient populations, doses or dosage forms. Such off-label use could make our products less effective or cause adverse events. This could

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generate negative publicity and materially affect our reputation, product brand and operations. Off-label use may also expose us to legal liability, reduce sales of our marketed products, or delay our clinical trials or prevent regulatory approval of drug candidates.

We rely on our distribution network to sell and distribute our drugs, and if we fail to maintain, manage and expand our distribution network, our business could be adversely affected.

Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize distribution channels. Consistent with industry practice, during the Track Record Period, we sold our products either by ourselves or through distributors in China. For the years ended December 31, 2023, 2024 and 2025, we generated 33.6%, 45.0% and 46.2% of our total revenue through sales to distributors, respectively. To the best knowledge of our Directors, all our distributors during the Track Record Period and up to the Latest Practicable Date were Independent Third Parties. See “Business — Sales and Marketing” for details. In addition, during the Track Record Period, to the extent permissible under the two-invoice system, we do not prohibit our regional distributors to engage sub-distributors for products sold to pharmacies and private medical institutions. Non-compliance by any of our distributors or sub-distributors may adversely affect the sales and distribution of our products. Nor can we guarantee their continuous compliance with our sales policies or prevent potential competition among them for market share of our products.

Failure by these distributors and sub-distributors to sell our products efficiently, manage inventory appropriately, or adhere to our pricing and marketing strategies could disrupt our commercial operations and sales performance. Specifically, any actual or alleged violation or noncompliance by our distributors of the distribution agreements, our internal policies or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our products. In line with industry practice in China, we typically enter into distribution agreements with our distributors for a prescribed term. See “Business — Sales and Marketing — Sales Channels — Distributors” for details. Our distributors may elect not to renew their distribution agreements with us or otherwise terminate their business relationships with us or reduce their purchases of our products for various reasons, including if the pricing regulations or other factors substantially affect their profitability. In addition, we may not be able to establish business relationships with new distributors to support the continued growth of our business. Any of the foregoing may materially and adversely affect our business, financial condition and results of operations.

If we are unable to maintain a qualified sales force or effectively promote our drug products, our business and results of operations could be adversely affected.

Successful sales and marketing efforts are crucial for us. Our ability to attract, motivate and retain a sufficient number of qualified sales professionals is key to our success. Given the intense competition for experienced commercial talent in the pharmaceutical industry, any failure to maintain an effective sales force could limit our ability to achieve targeted sales volumes, expand hospital coverage, or grow market share as planned. Our sales and marketing efforts include raising awareness and knowledge of our marketed products and drug candidates among medical professionals, hospitals, other medical institutions and pharmacies. Therefore, our sales and marketing force must possess adequate technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we are unable to effectively train and develop our in-house sales force, our sales and marketing may be less successful than desired. See “Business — Sales and Marketing” for details.

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

The illegal importation of competing products from countries where government pricing oversights or other market dynamics result in lower prices may adversely affect the demand for our existing and future products and, in turn, may adversely affect our sales and profitability in

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jurisdictions where we sell our products. Cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our existing and future products and exert commercial pressure on pricing within one or more markets. Furthermore, certain pharmaceutical products distributed or sold may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers, commonly referred to as counterfeit pharmaceutical products, and enforcement system, particularly in developing markets, may be inadequate to discourage or eliminate the manufacturing and sale. Since counterfeit pharmaceutical products often resemble the authentic pharmaceutical products but are generally sold at lower prices, counterfeits could adversely affect the demand for our products. The distribution of counterfeit or unauthorized pharmaceutical products poses significant risks, including potential harm to patients, product liability exposure, regulatory investigations, and reputational damage, which in turn affects our business, financial position and results of operations.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, our business and prospects could be materially and adversely affected.

Our future revenue and profitability are dependent on our ability to complete the development of our drug candidates, obtain the requisite regulatory approvals, and successfully manufacture and commercialize our drug candidates.

As of the Latest Practicable Date, we had six major innovative drug candidates in our pipeline. See “Business — Our Product Portfolio” for details. Notably, BGM0504, our lead innovative drug candidate — a dual agonist of GLP-1 and GIP receptors targeting major metabolic diseases including T2DM and obesity/overweight — is currently in Phase 3 trials in China, with parallel overseas clinical development underway, including the completion of bridging study in the U.S. In recent years, the GLP-1 receptor agonist market has emerged as one of the most competitive and rapidly evolving sectors in pharmaceutical development, driven by unprecedented demand for effective diabetes and obesity/overweight treatments. See also “Industry Overview — Overview of the Global and China Metabolic Disease Market — Overview of GLP-1 Therapies.” As a result, we face intense competition from existing products and drug candidates under development for the treatment of T2DM, obesity/overweight and other related diseases.

If we fail to achieve the anticipated development, regulatory and commercial milestones for one or more of our drug candidates, our business and prospects could be adversely affected. Our drug candidates, given their novelty and differentiated features, may carry inherent development risks that could result in delays in clinical development, regulatory approvals or commercialization. Such setbacks may require additional technical, human, and financial resources to resolve, potentially resulting in cost overrun, or even leading to the suspension or discontinuation of the process. If competitors advance similar products ahead of us due to these delays, our ability to successfully commercialize our candidates could be significantly impaired. This may have a material and adverse effect on future profits generated from our drug candidates, which in turn affects our competitive position, business, financial condition and results of operations.

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

The clinical development process of pharmaceutical products is capital-intensive, time-consuming and inherently uncertain. We may encounter unexpected difficulties while executing our clinical development plans for our drug candidates, which could necessitate adjustments to our resource allocation strategy and clinical development plans. Failure may occur at any time or stage during the clinical development process, including: (i) regulators or ethics committees refusing authorization for trials or specific sites; (ii) the need to amend, suspend, or

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terminate trials due to safety risks or lack of efficacy; (iii) difficulties in negotiating agreements with CROs and trial sites; (iv) intellectual property disputes or failure to secure protection; (v) manufacturing issues, such as CDMO negotiations or supply shortages; and (vi) insufficient or slower patient enrollment or high dropout rates.

Furthermore, the results of preclinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and despite the level of scientific rigor in the design of such studies and trials and the adequacy of their execution. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, such as differences in the size and demographics of the enrolled patients, their adherence to the treatment regimen and pre-existing medical conditions, and differences in the number of clinical trial sites and regions involved.

Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results at an earlier stage. We cannot guarantee that the results from our future research and development efforts will be favorable based on currently available clinical and preclinical data, which could result in delays in clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. See also “— Risks Relating to Government Regulations — The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain timely regulatory approvals for our drug candidates in the target markets, our business may be subject to actual or perceived harm.”

We face intense competition and rapid technological change, and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The pharmaceutical industry in which we operate is highly competitive and rapidly evolving, driven by continuous technological innovation and evolving treatment paradigms. See also “— Risks Relating to Our Business and Industry — We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors. If we are unable to maintain the sales volume, pricing levels and profit margins of our products, our profitability could be adversely affected.”

Disruptive technologies and medical breakthroughs continue to emerge, accelerating innovation and intensifying competition. These advances could render our current drug candidates or underlying platforms obsolete or significantly less competitive. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or may develop and commercialize drug candidates with differentiated mechanisms of action, better efficacy, more favorable safety profiles, or greater market acceptance compared to our drug products. Failure to stay ahead of emerging technologies or to effectively differentiate our products from those of our competitors may result in the loss of market opportunities, erosion of our competitive position, and adverse impact on our business, financial condition and future prospects.

We cannot assure you that we will be able to effectively identify or discover new drug candidates, or to expand the therapeutic opportunities for our drug candidates.

A substantial amount of our effort will focus on the continued clinical testing, potential regulatory approval, and commercialization of our existing drug candidates. At the same time, the success of our business also depends in part upon our ability to identify or discover new drug candidates and explore additional therapeutic opportunities for our drug candidates.

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However, there can be no assurance that our efforts in discovering and developing new drug candidates will yield successful results. We have developed proprietary technology platforms that we believe will continue to facilitate the development of new drug candidates and enrich our pipeline, see “Business — Technology Platforms” for details. However, research programs aimed at discovering and developing new drug candidates require substantial technical, financial, and human resources. We may direct our efforts and resources on programs or drug candidates that ultimately prove to be unsuccessful for a number of reasons, including (i) the research methodologies employed may not effectively identify viable indications or drug candidates, (ii) potential drug candidates may, upon further study, exhibit adverse effects or other characteristics that limit or preclude the expected therapeutic benefits, and (iii) the substantial resources required to identify additional therapeutic opportunities or develop suitable drug candidates may not be justified by the potential returns, thereby limiting our ability to diversify and expand our product portfolio.

We may not achieve successful outcomes from our substantial investments in research and development, and may fail to capitalize on more promising opportunities due to resource allocation decisions.

The global biopharmaceutical market is constantly evolving, requiring us to continuously invest significant human and financial resources to advance our product pipeline and enhance our technology platforms. For example, we incurred research and development expenses of RMB248.6 million, RMB297.5 million and RMB304.9 million for the years ended December 31, 2023, 2024 and 2025, respectively. Such continuous investments in research and development have affected, and are expected to continue to affect, our financial performance. Despite these substantial investments, we may not be able to successfully develop or commercialize new technologies or drug candidates in a timely or cost-effective manner, or secure adequate intellectual property protection. Failure to achieve expected outcomes could render our prior efforts obsolete and negatively affect our competitiveness.

Given these resource constraints and development uncertainties, we prioritize research programs and drug candidates targeting selected indications within our product pipeline as part of our strategic focus and resource planning and may forgo or delay pursuing opportunities related to other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Such resource allocation decisions may prevent us from capitalizing on viable commercial products or profitable market opportunities, result in impairment losses on related intangible assets, or otherwise negatively affect our financial condition and results of operations. If our current pipeline priorities do not yield the anticipated outcomes, we may need to adjust our resource allocation strategy and clinical development plans. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we could potentially relinquish valuable rights to that drug candidate through suboptimal collaboration or licensing arrangements, or inefficiently allocate internal resources where collaboration would have been more cost-effective, either of which could adversely affect our future growth and prospects.

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects in a timely manner. Inadequate enrollment or delays in enrollment could result in significant delays in our clinical trials, prolonging timelines for data readouts or regulatory submissions, and increasing overall development costs. In addition, some of our competitors may have ongoing clinical trials for drug candidates targeting the same indications as ours. As a result, subjects who would otherwise meet the applicable criteria set out in our protocol may instead enroll in our competitors’ trials, which may further delay our clinical trial enrollments.

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Subject enrollment for our clinical trials may be affected by a variety of factors, including: (i) the size and nature of the patient population and disease severity; (ii) trial eligibility criteria and study design; (iii) the availability and competence of clinical sites and investigators; (iv) patient consent and perceptions of the drug versus other therapies; (v) physician referral practices; and (vi) external disruptions such as health epidemics or natural disasters. The complexity and severity of the diseases under investigation may further exacerbate enrollment difficulties. These factors significantly complicate subject recruitment and retention, which could potentially hinder the overall clinical trial progress. Even if we are able to recruit a sufficient number of eligible subjects for our clinical trials, any delays or difficulties encountered during the enrollment process could adversely impact our clinical development progress, resulting in increased costs, obstacles to trial completion, and disrupted timelines for planned trials, all of which would hinder our ability to advance our drug candidates.

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

Adverse events (“AEs”) and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of clinical trials involving our drug candidates could reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, such trials could be suspended or terminated by the NMPA, the FDA or other comparable regulatory authorities, who could also deny approval of our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, if we, our collaboration partners, or others identify undesirable side effects caused by our drug candidates after they receive regulatory approval, it may lead to potentially significant negative consequences, including (i) withdrawal of approvals, license revocation, or marketing suspension; (ii) additional label warnings, restrictions, or the imposition of risk mitigation strategies; (iii) stricter inspections, changes to administration methods, or mandatory post-marketing studies; (iv) litigation and liability for patient harm; and (v) reputational damage.

Further, combination therapy involving our drug candidates and third-party agents may give rise to AEs, some of which could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our collaboration partners from achieving or maintaining market acceptance of any approved drug candidate and could significantly harm our business, financial condition, results of operations and prospects.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time are subject to change.

From time to time, we may publicly disclose top-line or preliminary data from our preclinical studies and clinical trials, which is based on initial analysis of available data at the time. The related findings and conclusions remain subject to changes upon a more thorough and comprehensive review. As our analyses proceed, we may make assumptions, estimations, calculations and conclusions without having had the opportunity to fully assess all relevant data. Consequently, the top-line or preliminary results we disclose may differ from future results of the same studies, or additional data and full evaluations may lead to different interpretations or modify earlier conclusions. Furthermore, top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Accordingly, such top-line data should be interpreted and viewed with caution until the final, validated results are available.

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Interim data from clinical trials we may complete are subject to the risks that one or more clinical outcomes could change materially as subject enrollment progresses and additional participant data become available. Adverse discrepancies between preliminary or interim data and final data could significantly harm our business prospects. Moreover, the disclosure of interim data by us or our competitors could lead to volatility in the price of our Shares after the [REDACTED].

In addition, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the perceived value, likelihood for approval, and commercial potential of our drug candidates.

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

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

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

Our historical financial performance may not be indicative of our future performance. We cannot guarantee that we will be able to maintain profitability in the future.

We recorded revenue of RMB1,163.6 million, RMB1,254.9 million and RMB1,198.2 million for the years ended December 31, 2023, 2024 and 2025, respectively. During the same periods, our profit for the year amounted to RMB173.4 million, RMB141.3 million and RMB37.0 million, respectively. Our historical financial performance may not be indicative of our future performance. Projecting or estimating future financial performance based solely on past data carries inherent risk, as it reflects

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conditions that may no longer apply. The continued growth of our business depends on our ability to effectively manage and scale our operations while maintaining operational efficiency and financial stability.

Our revenue, expenses and operating results may be subject to period-to-period fluctuations driven by various factors beyond our control, such as market conditions in China’s pharmaceutical industry. In addition, our financial and operating results may not meet the expectations of [REDACTED] market analysts or [REDACTED] in the future, potentially causing our share price to decline. Consequently, there can be no assurance that our future revenue will increase or that we will be able to maintain profitability. [REDACTED] should not rely on our historical results as an indicator of our future financial or operating performance.

We may need to obtain substantial additional financing to fund our operations and expansion, and we cannot assure you that we will be able to obtain such financing on favorable terms or in a timely manner.

During the Track Record Period, we funded our operations and other capital requirements primarily through cash generated from our operations and bank borrowings. We expect to continue incurring significant costs and expenses to drive our R&D activities, particularly as we advance the development of our drug candidates, including conducting clinical trials of, and seek regulatory approval for, existing and future drug candidates. In addition, we expect to incur significant expenses relating to the manufacturing, marketing, sales and distribution of our marketed products, including fulfilling post-approval obligations to monitor the efficacy and safety of these products. We may also incur further costs as we enhance our overall capabilities to operate as a public company. Consequently, we may need to secure substantial additional funding in connection with our continuing operations.

We expect to fund our future operations primarily with our cash on hand, cash generated from operating activities, bank borrowings, and [REDACTED] from the [REDACTED]. Should we fail to generate sufficient cash flow for our operations or secure adequate external funds, our liquidity and financial health could be affected, which may in turn constrain business expansion. In addition, any alternative financing may involve higher costs, uncertain availability, or unfavorable terms. Such limitations may heighten our vulnerability to adverse economic and industry conditions, which could adversely affect our financial condition and results of operations.

Fair value changes and credit risk associated with our financial assets measured at FVTPL could adversely affect our results of operations and financial condition.

As of December 31, 2023, 2024 and 2025, we recorded financial assets at FVTPL of RMB322.3 million, RMB311.8 million and RMB435.1 million, respectively. Our financial assets at FVTPL during the Track Record Period represented wealth management products and other unlisted investments at fair value. We may continue to make such instruments as part of our cash management and treasury measures, thereby exposing us to fair value fluctuations in these FVTPL financial assets.

We cannot assure you that we will recognize comparable fair value gains in the future, and we may, on the contrary, recognize fair value losses, which would affect our result of operations for future periods. In addition, the valuation of financial assets at FVTPL is subject to uncertainties in estimations. Such estimated changes in fair values involve the exercise of professional judgment and the application of certain bases, assumptions and unobservable inputs, which are inherently subjective and uncertain. As such, these valuations have been, and will continue to be, subject to estimation uncertainties, which may not reflect the actual fair value of these financial assets and could lead to fluctuations in periodic profits or losses.

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

We are subject to credit risk in relation to our trade and bills receivables. As of December 31, 2023, 2024 and 2025, we had trade and bills receivables of RMB308.9 million, RMB339.5 million and RMB330.0 million, respectively. There is no assurance that we will be able to collect our trade and bills receivables in a timely manner, or at all. If any of our customers faces unexpected situations, such as financial difficulties or deterioration in creditworthiness, there may be challenges in collecting all or part of our receivables from them, and enforcing judgments against them, even if successfully obtained, could be difficult. Such unforeseen circumstances may also render our accounting judgments or estimations on impairment inaccurate, potentially resulting in higher losses than currently estimated. As a result of these factors, our profitability, working capital and cash flow may be adversely affected.

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

We incurred equity-settled share-based payment expenses of nil and RMB6.3 million for the years ended December 31, 2024 and 2025, respectively, and recorded a reversal of RMB4.6 million for the year ended December 31, 2023. We consider the granting of share-based compensation to be of substantial significance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based payments may increase, which could affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective employee incentive plan from time to time. Any such reassessments could result in material fluctuation in our share-based payments in the reporting periods following this [REDACTED]. Moreover, the issuance of additional Shares with respect to such share-based payments could also dilute the shareholding of our existing Shareholders.

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

The property valuation report prepared by Jones Lang LaSalle Corporate Appraisal and Advisory Limited (“JLL”), an independent property valuer, set out as Appendix III to this document with respect to the appraised values of our properties is based on various assumptions, which are inherently subjective and uncertain and may differ from actual results. The assumptions used by JLL in the property valuation report include that the seller sells the property interests in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interests. Certain of the assumptions used by JLL in reaching the appraised value of our properties may be inaccurate or unreasonable. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the appraised value of our properties may differ materially from the price we could obtain in an actual market sale of the properties and should not be taken as their actual realizable value or an estimation of their realizable value. You should not place undue reliance on such values attributable to these properties as appraised by JLL.

If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

As of December 31, 2023, 2024 and 2025, we had intangible assets of RMB33.5 million, RMB41.3 million and RMB315.7 million, respectively. The value of intangible assets is based on a number of assumptions made by the management. If any of these assumptions fail to materialize, or if the performance of our business deviates from such assumptions, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. Furthermore, subsequent to initial recognition, we assess whether these intangible assets are impaired at the end of each reporting period when events or changes in circumstance indicate that the carrying amount of

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these assets may exceed their recoverable amount. Should the carrying amount exceeds its recoverable amount, our intangible assets could be deemed impaired. Any such impairment could have an adverse effect on our business, financial condition and results of operations.

We benefit from certain government grants and preferential tax treatments, which may be subject to discontinuation or changes.

We recorded government grants income amounting to RMB30.1 million, RMB29.8 million and RMB38.5 million for the years ended December 31, 2023, 2024 and 2025, respectively. These government grants primarily represent subsidies received from the local governments for expenses arising from research and development activities, rewards for financial contribution and capital expenditure incurred on certain projects. 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 Items — Other Income and Gains” for details.

The government grants and preferential tax treatments we receive are subject to the discretion of relevant government authorities, who may reduce or eliminate such incentives at any time, generally with prospective effect. Given this inherent uncertainty, our net income in a particular period may fluctuate relative to other periods beyond those attributable to our underlying business performance or operational factors. Consequently, the discontinuation or changes of such government grants, preferential tax treatments, and other related financial incentives currently available to us could have an adverse effect on our financial condition, results of operations, cash flows and prospects.

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

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our Shares in foreign currency. These factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

RISKS RELATING TO THE MANUFACTURING OF OUR DRUGS AND DRUG CANDIDATES

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

A substantial majority of our revenue has been, and in the near future will continue to be, generated by sales of products produced at our manufacturing facilities. See “Business — Manufacturing” for details. Manufacturing activities at these facilities could be substantially interrupted due to a range of factors, many of which are outside our control, including natural disasters, operational disruptions, security threats, land-related issues, and regulatory compliance issues. If the operation of any of our manufacturing facilities is severely disrupted, we may not be able to locate alternative facilities and equipment or a third-party contractor to continue our production in a legal, timely and cost-effective manner or at all. And in the event of a significant

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disruption to any manufacturing facility, our insurance coverage may be insufficient to cover the resulting losses. We may also encounter other issues in manufacturing, due to a variety of reasons, including equipment malfunctions, deviations from established protocols and procedures, deficiencies in raw materials, and delays in constructing new facilities or the expanding existing ones.

Failure to maintain proper quality control or produce products that satisfy necessary quality standards could harm our business and reputation, and our revenue and profitability could be adversely affected.

Our products and manufacturing processes are required to meet certain quality standards. We cannot eliminate the risk of errors, defects or failure in our quality control system and procedures. We may fail to detect or cure quality defects as a result of a number of factors, including but not limited to: (i) manufacturing error or malfunction; (ii) human error or malfeasance; (iii) mishandling by third parties; and (iv) quality issues with the raw materials. Any significant failure or deterioration of our quality control, quality assurance protocol, or standard operating procedures could render our products non-compliant and cause other consequences that could seriously harm our reputation and relationship with business partners.

If we fail to increase our production capacity to meet the increasing demand for our drugs and future approved drugs, our business and prospects could be adversely affected.

We are currently expanding our manufacturing facilities and production lines, and may continue to do so in the future. See “Business — Manufacturing — Manufacturing Facilities” for details. The financing and completion of such expansion of the manufacturing facilities and production lines involves regulatory approvals and reviews by various government authorities. We cannot assure you that we will be able to obtain all of the required approvals, permits and licenses, and expansions in production capacity also may fail to meet the anticipated timetable, exceed budget, or result in underutilized production capacity post-completion.

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

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. During the Track Record Period, we primarily produced APIs for sales or used in our marketed products and drug candidates in-house. We also sourced from independent third parties certain APIs and other raw materials for our products. See “Business — Quality Management — Supply Chain Quality Control” for details. See also “— Risks Relating to Dependence on Third Parties — We engage third parties to provide a stable and adequate supply of raw materials, products and equipment for our development and manufacturing needs. Any interruptions of or significant price increases in such supply could adversely affect our business.”

During the Track Record Period, we had not experienced material interruptions in our raw material supplies. However, we cannot guarantee that our suppliers will consistently provide sufficient quantities of raw materials of acceptable quality in the future. If they fail to do so, we may be unable to obtain substitute raw materials elsewhere in a timely manner, or at all. Furthermore, procurement from alternative suppliers could expose us to less favorable prices or materials of inferior quality. Any such potential interruption in our supply of raw materials could delay the production and delivery schedules of the relevant products, which may result in the loss of customers and revenue. In addition, the market prices of raw materials may be subject to significant fluctuations due to various factors. We cannot ensure our ability to pass on any increase in raw material costs to our customers, and any substantial fluctuation in market prices of raw materials may materially raise our costs and impair our profitability.

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Failure to manage our inventory effectively could materially and adversely affect our results of operations and financial condition.

Our inventory primarily consists of raw materials, work in progress and finished goods. We have adopted a series of measures to regularly monitor our inventory. We maintain our inventory levels based on our internal forecasts which are inherently uncertain due to rapid changes in product life cycles, evolving clinical demands, uncertainty of product development and launch, as well as the economic volatility in the markets where we operate. Further, demand for products could change significantly between the time when the products are ordered and the time they are ready for delivery. As a result, there can be no assurance that we can accurately predict these trends and events and avoid overstocking or understocking our products.

As of December 31, 2023, 2024 and 2025, we had inventories of RMB344.6 million, RMB364.6 million and RMB364.3 million, respectively. For the years ended December 31, 2023, 2024 and 2025, our inventory turnover days were 236 days, 270 days and 256 days, respectively. See “Financial Information — Description of Certain Consolidated Statements of Financial Position Items — Inventories” for details. Excess inventory levels may increase our inventory holding costs, obsolescence risks or potential impairment loss. On the other hand, if our forecasted demand is lower than actual level, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors.

RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain patent and other intellectual property protection for our drugs and drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected.

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the technology and drug candidates that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. See “Business — Intellectual Property” for details. The process of prosecution and maintenance is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biopharmaceutical companies generally involves complex legal and factual questions. Our current and future patent applications may not be granted with approvals. Even if the patent application is issued, it is still not conclusive as to its scope, validity or enforceability. Thus, we may not effectively prevent third parties from commercializing competitive technologies and drug candidates. Besides, we may not be able to prevent third parties from practicing infringing acts of our invention patents in all countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drugs and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

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Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance.

The China National Intellectual Property Administration (the “CNIPA”), the United States Patent and Trademark Office (the “USPTO”) and other applicable patent authorities require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits.

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

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. Patents for invention generally expire 20 years from the application or filing date in China and the U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. Manufacturers of generic or biosimilar drug products may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights. As a result, we may not be able to exclusively develop or market the relevant product, which would materially harm the potential sales of that product and, in turn, adversely affect our business and results of operations.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after commercialization, which may limit our ability to exclude others from commercializing technology and products similar or identical to ours. Although we may seek certain patent term extensions, there can be no assurance that such extensions will be granted, or that they will be granted for the full period requested, due to failure to satisfy applicable requirements or applicable deadlines. If we are unable to obtain a patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed.

We may not be able to protect intellectual property rights, or prevent unfair competition by third parties, throughout the world.

The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or to prevent third parties from engaging in unfair competition by using our technologies or proprietary information in jurisdictions where we lack strong protection, and exporting such competing products into jurisdictions where enforcement mechanisms are weaker. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a

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significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

We own a number of trademarks in China, the U.S. and other jurisdictions. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and may not be registered in all the necessary or desirable jurisdictions and categories in which we intend to sell our future products or provide our future services. Competitors may adopt similar trade names or trademarks, which could cause market confusion and impair our ability to build brand recognition. Meanwhile, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. In addition, misuse of our trademarks and trade names by business partners or licensees could diminish the goodwill associated with our brands. As a result, these risks could undermine our ability to establish meaningful name recognition through our trademarks and trade names and our business could be materially adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. In the course of collaborating with third parties for the development, our trade secrets could be misappropriated, disclosed, or discovered by competitors. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure, confidentiality and similar agreements with parties that have access to them, such as our employees, collaborators, and other third parties. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Such inappropriate or unauthorized use could have an adverse effect on our business and results of operations.

Our competitors may still gain access to our trade secrets. Enforcing a claim that a party has illegally disclosed or misappropriated a trade secret can be difficult, costly and time-consuming, and the outcome is unpredictable. Should we fail to prevent the unauthorized material disclosure or misappropriation of our trade secrets and confidential information by third parties, we would not be able to establish or maintain a competitive edge in our market, which could materially and adversely affect our business, financial condition, and results of operations. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using such technology or information to compete against us and our competitive position would be harmed. Furthermore, we may be subject to claims that we or our employees, consultants, advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer, which could also adversely affect our business and results of operations.

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.

Litigation relating to patents and other intellectual property rights in the pharmaceutical industry is common, including patent administrative proceedings, patent ownership and patent infringement lawsuits. The various markets in which we operate and plan to operate are subject to

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frequent and extensive intellectual property litigation, which could be expensive and time-consuming. We cannot guarantee that we will not become involved in such litigation, prevail in it, and its costs or adverse outcomes may adversely affect our business.

We may also fail to identify relevant patents or patent applications held by third parties that cover our drug products. We cannot assure you that our marketed products or drug candidates, or the sale or use of our future products, do not or will not infringe upon, misappropriate, or otherwise violate any third-party intellectual property rights. As a result, third parties could resort to litigation against us or other parties we have agreed to indemnify, and a court may determine that such third-parties' patents are valid, enforceable and infringed, which could prevent us from selling or using the relevant products unless we obtain a license or until such patents expire or are finally determined to be invalid or unenforceable. If we are found to be infringing a third party's patent rights, defending such claims would cause us to incur substantial expenses and potentially significant damages. We may need to seek a license from a third party, which may be costly, unavailable, or available on acceptable terms. If so, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations. Even if obtained, such licenses may be non-exclusive and could erode our competitive advantage, potentially leading to price pressures, or diminished market share for our offerings.

Our intellectual property rights could be challenged or invalidated or become subject to ownership disputes. For example, third parties may claim ownership of, or have filed competing patent applications covering, our drug products or similar inventions, which could result in our patent applications not being granted or our issued patents being limited or invalidated. Competitors or other third parties may also infringe or misappropriate our intellectual property rights, and enforcing or defending such rights may require litigation that is costly, time-consuming and unpredictable. Courts may determine that our patents are invalid or unenforceable, decline to grant injunctive relief, or interpret our rights narrowly, and enforcement actions may expose us to counterclaims, substantial damages, disclosure of confidential information and significant management distraction. If the public, securities analysts or [REDACTED] perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain product sales, it could have a substantial adverse effect on the price of our Shares.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our current and any future drug candidates.

Obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws and regulations, in the governmental bodies enforcing them, or in how such authorities interpret and enforce these laws across jurisdictions may diminish the value of our intellectual property, and weaken our ability to obtain new patents or to enforce our existing and future owned and licensed patents, while increasing the uncertainty and cost of prosecuting, enforcing or defending patents. We cannot predict the scope of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are proposals for changes to the patent laws in China, the U.S. and other jurisdictions that, if adopted, could limit our ability to enforce our proprietary technology.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We rely on third parties to support and conduct certain aspects of our business, and the inability of any of these parties to reliably carry out their contractual duties or meet expected timelines could adversely affect our business and prospects.

We cooperate with third parties, such as CROs, CDMOs, and third-party promoters, for the drug development, as well as sales and distribution of our products. If these parties, whom we cannot fully control, do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if our collaboration partners do not have the ability or the resources to

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successfully 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 may be delayed, impaired or terminated.

We have engaged third-party CROs and other third parties to assist us in conducting our preclinical studies and clinical trials. The CROs we engage may not always perform to our standards, devote sufficient time and resources, produce results in a timely manner or may fail to perform at all. We may engage third-party CDMOs to outsource certain manufacturing processes, which introduces additional risks, including potential deviations from our quality standards, inadequate oversight of the CDMOs’ facilities or processes, delays in production caused by the CDMOs’ operational issues or limited capacity, and misconduct by the CDMOs, such as misappropriation or violation of intellectual property rights of us or third parties. We may also face difficulties in enforcing strict compliance with regulatory requirements at outsourced facilities, which could expose us to penalties or disruptions in supply.

We have entered into license and collaboration agreements with third parties in the development, manufacturing and commercialization of our drug candidates, and may seek and enter into additional partnerships in the future. We may fail to identify suitable business partners or may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development, manufacturing and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. See “Business — Collaborations and Partnerships” for details.

Our results of operations have been, and may continue to be, affected by our collaboration and licensing arrangements. Collaboration and licensing agreements involving our drug candidates are subject to various risks, including (i) collaborators having significant discretion over the level of efforts and resources they devote to a collaboration, (ii) the possibility that such agreements may be terminated on short notice or that collaborators may elect to discontinue collaboration due to changes in strategic focus, acquisitions of competing products, funding constraints or other external factors, (iii) delays, suspension or discontinuation of clinical trials, insufficient funding, the need to repeat or conduct additional trials, or requirements for new formulations imposed by collaborators, (iv) milestone payments and royalties being contingent upon the achievement of specified regulatory, development and commercialization milestones, which may not be fully realized, (v) collaborators’ failure to properly maintain or defend our intellectual property rights or their use of our intellectual property or proprietary information in a manner that could give rise to actual or threatened litigation or potential liability, (vi) disputes with collaborators that may delay or terminate research, development or commercialization activities or result in costly litigation or arbitration and diversion of management attention and resources, (vii) collaborators independently developing, or developing with third parties, competing products, (viii) collaborators owning or co-owning intellectual property arising from the collaboration, in which case we may not have exclusive rights to such intellectual property, and (ix) adverse effects on collaboration and licensing relationships resulting from cross-border data transfer restrictions and geopolitical tensions, including trade policies and export controls.

For these and other reasons, we may not achieve the outcomes and synergies expected from our collaboration and licensing arrangements. Such arrangements are subject to uncertainties, and we may face operational and financial risks, including increased expenditures, exposure to unknown liabilities, business disruption and diversion of management time and attention. In addition, any material and adverse changes to our relationships with our collaborating partners or our inability to attract or retain suitable strategic partners due to competition or the complexity of negotiations, may reduce the technological and financial resources available to us and adversely affect our R&D activities and business operations. Our drug candidates may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our drug candidates as

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having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may be required to curtail, delay or reduce the scope of development or commercialization of our drug candidates, or incur increased expenditures by undertaking such activities ourselves. If we fail to enter into collaboration and licensing arrangements, face difficulties in securing adequate reimbursement from existing collaborators, or do not have sufficient funds or expertise to undertake the necessary development, manufacturing and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

We engage third parties to provide a stable and adequate supply of raw materials, products and equipment for our development and manufacturing needs. Any interruptions of or significant price increases in such supply could adversely affect our business.

During the Track Record Period, we and our CDMOs engaged third parties to supply certain raw materials, products and equipment used in our R&D and manufacturing activities, and may continue to do so in the future. Such third parties may fail to meet our increasing demand, maintain required licenses, or implement effective quality control. Therefore, reliance on third parties exposes us to certain risks, including: (i) production disruptions or inadequate supply; (ii) rising raw material and product costs; (iii) delays in our clinical trials or regulatory filings, and (iv) recalls of our products.

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

Our relationships with principal investigators, physicians and other industry experts play an important role in our research and development and marketing activities. These industry participants may leave their roles, change their business or practice focus, or choose to no longer cooperate with us and cooperate with our competitors instead. Should they continue to cooperate with us, their market insights and perceptions, which we factor into our research and development process, may be inaccurate and lead us to develop products with limited market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Any of the foregoing factors could materially and adversely affect our business, financial condition and results of operations.

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 logistic service agreements with third-party logistics service providers for the transportation of our products. Delivery delays may occur for various reasons beyond our control, including poor handling by our logistics service providers, labor disputes or strikes, natural disasters, and health epidemics, and could lead to delayed or lost deliveries. We have purchased cargo insurance policies for our finished drug products. For APIs and intermediates, we typically rely on our logistics management and contractual arrangements with transportation providers instead of purchasing separate cargo insurance. However, we cannot guarantee you that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. If products are not delivered on time or are delivered in a damaged state, our customers may refuse to accept products and claim refund from us, and may have less confidence in our services. Poor handling of our products could also result in product contamination or damage, which may in turn lead to product recalls, product returns or exchanges, product liability, increased costs and reputation damage.

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RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we operate or intend to operate our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products in great depth and detail. We intend to implement a global development strategy, with a focus on major markets including China, the U.S., Europe, Japan, South Korea, and key emerging markets. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ a broad range of strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

We are required to obtain and maintain certain licenses and permits for conducting our business, and the process of obtaining and maintaining such approvals require substantial time and financial resources. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or permits or we failed to timely comply with new laws, regulations or restrictions, it may have the discretion to levy fines, confiscate our income, revoke our business licenses, require us to discontinue our relevant business or impose restrictions on the affected portion of our business, among other actions. In particular, failure to comply with the applicable regulatory requirements at any time during the product development process and approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an 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, restitutions, disgorgements, or other civil or criminal penalties. Failure to comply with these laws, regulations and guidance could have a material and adverse effect on our business and prospects.

In China, the U.S. and other markets where we may sell our drugs, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of pharmaceutical products, as well as strict rules, regulations and industry standards on how we develop such products. For example, we may need to obtain clearance from the NMPA, the FDA or other regulatory authorities to seek authorization to begin clinical trials, and file an NDA or similar application to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management’s attention from the operation of our business, and adversely affect our reputation and financial results.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain timely regulatory approvals for our drug candidates in the target markets, our business may be subject to actual or perceived harm.

The regulatory approval process is inherently uncertain, time-consuming, and subject to discretion. The authorities may, for example, raise concerns about the materials submitted, request additional efficacy or safety data, question study design or statistical analyses, request modifications to study protocols, or interpret study results differently than anticipated. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes. We may fail to receive

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the regulatory approvals due to a number of reasons, including: (i) disagreements over clinical trial design or implementation; (ii) failure to demonstrate safety and efficacy or meet statistical significance; (iii) insufficient data or procedural errors; (iv) failure to pass GCP inspections or data audits; (v) unexpected changes in regulations or approval policies; or (vi) manufacturing deficiencies, including failure to pass GMP inspections.

Regulatory authorities may require more information to support approval, which may result in delay in regulatory approval and commercialization plans or denial of regulatory approval. Even if approved, our candidates may be restricted to fewer indications or require post-marketing trials. Therefore, our commercial prospects and reputation might be harmed. If any of our drug candidates fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities, we may not be able to realize any revenue on such drug candidate despite the significant amount of resources we would have spent on its development.

Our current and future approved drugs are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. We may face penalties and other negative consequences if we fail to comply with these regulatory requirements or experience unanticipated problems with our drugs and drug candidates.

Our marketed products and future approved candidates are subject to extensive ongoing regulatory obligations and continued regulatory review covering R&D, manufacturing, and marketing. These include CMC adherence, continuous compliance with current cGMPs, GCPs and post-approval studies for license renewal. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including, if applicable, phase 4 trials for the surveillance and monitoring of the safety and efficacy of the drug. Furthermore, approvals may be limited to specific indications or conditioned on costly post-marketing studies, such as Phase IV trials, to monitor safety and efficacy. Even after approval, subsequent discovery of previously unknown problems with the drug, such as manufacturing or regulatory compliance, could lead to severe consequences, including: (i) restrictions on marketing or manufacturing, product withdrawals, or recalls; (ii) fines, warning letters, or clinical trial holds; (iii) refusal to approve pending applications or supplements, or suspension or revocation of licenses; (iv) refusal to accept new INDs, NDAs or similar applications; (v) drug seizure, detention, or import/export bans; and (vi) injunctions or the imposition of civil, administrative, or criminal penalties.

If we or any of our business partners fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences that could have a material and adverse effect on the success of our business.

We and certain third parties we work with, such as our CROs, CDMOs and business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We generally contract with third parties for the disposal of solid waste and wastewater, and we cannot guarantee their continuous compliance. We cannot eliminate the risk of contamination or injury from these materials. We do not maintain insurance for environmental liability or toxic tort claims and our coverage for employee injuries may be inadequate. In the event of contamination or injury we may face liabilities exceeding our resources and could incur significant costs associated with fines and penalties. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations and impair our research, development or production efforts.

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

We and the CROs we engage may routinely receive, collect, generate, store, process, transmit and maintain medical data and treatment records of subjects enrolled in our clinical trials, but do not collect the personal information irrelevant to our trials or our enrolled subjects. In recent years, the PRC authorities have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC.

Regulatory requirements are evolving and subject to varying interpretations, resulting in uncertainties regarding our responsibilities. We may also face new laws and regulations regarding personal information and privacy concerning our data collection, analysis, storage and use. Such developments may result in ever-increasing public scrutiny enforcement and sanctions and compliance costs. Failure to comply with any of these laws or effectively address data privacy and protection concerns could result in enforcement action against us, including and without limitation to fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material and adverse effect on our business, financial condition, and results of operations or prospects.

The personal information of patients or subjects which might be involved in our clinical trials could be highly sensitive and subject to strict privacy and data protection regulations. Data leakage and abuse and other misconduct related to data and personal information protection might not be completely avoided. We also cooperate with third parties for our clinical trials and marketing operations. Any security breach, failure or perceived failure to comply with data/privacy policies or data/privacy-related legal obligations, whether by us or our partners, could result in the unauthorized data release, legal claims, and a loss of customer trust.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), and if and to the extent any data collected or generated in connection with our R&D of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China.

The Personal Information Protection Law of the PRC specifies the circumstances in which data processors providing data export shall apply for outbound data transfer security assessment with the CAC, including, among others, the outbound data transfer containing important data. The Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》) specifies that data handlers that are not critical information infrastructure operators and sets out detailed requirements for outbound transfers of personal information. See “Regulations in Relation to Information Security and Data Privacy — Data Security and Export” for details.

In addition, use of or collaboration involving China’s human genetic resources may require approvals or filings under the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) (the “**HGR Regulation**”), and failure to comply may adversely affect our R&D of drug candidates. Further, the PRC Biosecurity Law (《中華人民共和國生物安全法》), reaffirms the regulatory requirements stipulated by the HGR Regulation and potentially increases the administrative sanctions. see “Regulatory Overview — Laws and Regulations in Relation to New Drugs — Gathering, Collection and Filing of Human Genetic Resources” for details.

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

The pharmaceutical industry and healthcare system in China, the U.S. and other jurisdictions has witnessed a series of legislative and regulatory changes, including measures that may reduce or limit coverage and reimbursement and affect our ability to profitably sell our products. See also “Regulatory Overview” and “— Risks Relating to Our Business and Industry — National or other government-sponsored medical insurance programs may have a material impact on our sales, profitability and business prospects.” Such new regulations and rules, along with other potential future measures, may lead to stricter requirement and standards for our business and operations, which could increase our compliance burden and operating expenses.

These legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our marketed products and drug candidates in the future. Moreover, these laws and regulations are subject to updates, and their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

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

A substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources; however, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations may also be amended from time to time, and the application, interpretation and enforcement of such evolving laws, rules and regulations may affect our business operations. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR OPERATIONS

Our future success depends in part on our ability to attract, retain and motivate senior management, key personnel, and other qualified professionals.

We are highly dependent on the expertise of our senior management, key personnel, and other qualified professionals. We believe that there is, and will continue to be, intense competition for skilled management, technical, sales and other personnel with experience in our industry. Recruiting, retaining and motivating qualified management, scientific, clinical and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

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

Our future performance will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. Any failure to do so may materially and adversely affect our ability to capitalize on new business opportunities, which in turn may have a material and adverse effect on our business, financial condition, results of operations, and prospects. Managing our growth and executing on our growth strategies will require continuous innovation, and the ability to identify and develop promising drug candidates in a highly competitive market. We may also need to effectively develop new facilities and teams, recruit and train talent, and maintain robust financial, management and quality controls. All of these endeavors will require substantial management attention and efforts and significant additional expenditures. We cannot assure you that we will be able to execute our business strategies and manage any future growth effectively and efficiently.

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

From time to time, we may be involved in inspections, claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, privacy protection, environmental and safety matters, breach of contract, employment or labor disputes and intellectual property rights. Any inspections, claims, disputes or legal proceedings initiated by us or brought against us, our management or Directors, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, inspections, claims, disputes or legal proceedings against us, our management or Directors may be due to actions taken by our business partners, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

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

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. In addition, we may engage various third parties to expand our sales and distribution network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrongdoing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

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

Our operations depend in part on the skills and know-how of our employees. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further increase in labor cost, which may adversely affect our operations and financial condition. In addition, share options and other share-based incentives granted under our existing or future share-based incentive

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arrangements and scheme could adversely affect our costs and our results of operations. See also “— Risks Relating to Our Financial Position and Need for Additional Capital — Share-based payments may impact our financial performance and cause shareholding dilution to our existing Shareholders.”

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

We are exposed to changing international economic, regulatory, social and political conditions, as well as local conditions in the foreign countries and regions in which we operate or with which we conduct business. Rising trade and political tensions may reduce cross-border trade, investment and other economic activities between China and other countries and regions. For example, in February 2025, the U.S. government issued the “America First Investment Policy” memorandum, signaling possible additional restrictions on U.S. investment in China in certain sensitive sectors, including biotechnology, and in April 2025, the U.S. Department of Commerce announced investigations into the national security implications of semiconductor and pharmaceutical product imports. These developments underscore the uncertainty of the cross-border policy environment and may adversely affect our business, financial condition and results of operations.

Furthermore, the BIOSECURE Act was signed by President Trump on December 18, 2025, which aims at prohibiting the U.S. government from procuring biotechnology equipment or services from designated “biotechnology companies of concern,” and would prohibit government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated “biotechnology company of concern.” If our suppliers or business partners were to be listed as “biotechnology companies of concern,” our ability to engage in business with the U.S. government or with companies that engage in business with the U.S. government may be limited. The timing and substance of enabling regulations remain subject to uncertainty and may differ materially from current expectations.

Tariff policies and other trade measures affecting cross-border trade have been subject to changes, particularly in the United States. In early 2025, the United States imposed increased tariffs on certain imports from China across multiple sectors, and China responded by imposing retaliatory tariffs on certain U.S. goods. Although the United States and China subsequently announced temporary trade arrangements, including partial tariff reductions, the future development of such measures remains uncertain. Notwithstanding the foregoing, the direct impact of such tariff measures on our business was limited. Our revenue generated from sales to the U.S. market were RMB109.9 million, RMB219.1 million and RMB144.5 million in 2023, 2024 and 2025, respectively. The decrease from 2024 to 2025 was primarily attributable to the fluctuations in customer demand in connection with their R&D and product launch preparation processes, including higher procurement associated with validation and related pre-commercial activities in 2024, and was not primarily driven by tariff measures. See also “Financial Information — Year to Year Comparison of Results of Operations — Year ended December 31, 2025 Compared to Year ended December 31, 2024 — Revenue.” In addition, our procurement from the United States or of U.S. origin represented only a small portion of our total procurement during the Track Record Period and accounted for less than 1.5% of our total procurement in 2025, and such measures did not result in any significant supply chain disruption. Nevertheless, we cannot assure you that further changes in U.S. tariff policies and related trade measures will not adversely affect our business, financial condition, results of operations and prospects.

Any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. We cannot predict how tariff policies may evolve or anticipate any potential impacts of

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subsequent developments in such policies on our business. If we, our customers, suppliers or other business partners become subject to these measures, our business, financial condition, and results of operations could be materially and adversely affected.

We could be adversely affected by the sales we make to certain countries that are, or may become subject to, sanctions administered by the United States, the European Union, the United Nations, Australia and other relevant sanctions authorities.

Economic sanction regimes imposed by the United States and other jurisdictions or international organizations, including the European Union, the United Nations and Australia, restrict dealings with certain countries or territories, as well as designated entities, sectors, and individuals. These measures are dynamic and subject to frequent amendments, and the interpretation and enforcement practices of the relevant authorities may evolve over time.

During the Track Record Period, we sold certain non-U.S. origin API products to certain customers or end-users located in countries/regions subject to International Sanctions, including Iran, Cuba, Russia and Belarus (collectively, “**Relevant Sanctioned Countries**”). Revenue attributable to such direct and indirect sales was immaterial, which involved an insignificant portion of our customers and constituted less than 2.7% of our total revenue during the Track Record Period. These sales were conducted in our ordinary course of business, where our APIs were used by customers for the manufacturing of pharmaceutical products, with no involvement of U.S. persons, no products subject to the EAR, and no U.S. dollar payments made to us. As advised by our International Sanctions Legal Advisors, our direct and indirect sales of API products to Iran, Cuba, Russia and Belarus did not represent a violation to primary U.S. sanctions on the bases that (i) all of these direct and indirect sales were conducted in RMB with non-sanctioned counterparties, and the products sold did not involve 10% or more of U.S.-origin controlled content and thus are not subject to the EAR under the applicable *de minimis* rule; and (ii) the nature of the products sold are API products, which are the essential components in drug medications, and can be viewed as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and hence potentially are eligible for applicable general licenses for sales to Relevant Sanctioned Countries.

The United States also has enacted secondary sanctions targeting non-U.S. persons who have engaged in certain sanctionable activities related to the Relevant Sanctioned Countries, or sanctioned entities designated on the SDN List. As advised by our International Sanctions Legal Advisors, given that (i) none of our customers are designed on the SDN List, based on standard sanctions screening procedures; (ii) the humanitarian nature of the products we provide, including the sales of API products to the Relevant Sanctioned Countries, and (iii) the general policy objectives to authorize sales of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals (i.e., products that we sold to Russia, Iran and Cuba were “medicine or medical devices” within the definition of General License 6D and General licenses for the exportation or re-exportation of medicine and medical devices under subpart E of the Iranian Assets Control Regulations and the Cuban Assets Control Regulations), our sales to the Relevant Sanctioned Countries are unlikely to be viewed as Secondary Sanctionable Activities that would result in U.S. secondary sanctions designations risk during the Track Record Period.

During the Track Record Period, we made procurement from two suppliers (“**Relevant Suppliers**”) who were designated on the BIS Entity List and the OFAC Chinese Military-Industrial Complex Companies (“**CMIC**”) List, respectively. Sales of products subject to the EAR to the Relevant Suppliers designated on the BIS Entity List are prohibited unless authorized, and United States persons are prohibited from the purchase or sale of any publicly traded securities, derivatives of such securities or those designed to provide investment exposure to such securities, of entities designated on the CMIC List unless licensed. As advised by our International Sanctions Legal Advisors, given that (i) our activities with the Relevant Suppliers were limited to procurement of products and did not involve any purchase or sale of any publicly traded securities, or restricted financial activities in relation to certain Relevant Supplier designated on the CMIC List; and (ii)

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such transactions did not involve transfer of any items subject to the EAR from us to the Relevant Suppliers, our activities with the Relevant Suppliers did not represent a violation of any of the applicable International Sanctions and the U.S. export controls.

Based on the reasons above, as advised by our International Sanctions Legal Advisors, (i) our direct and indirect business dealings in the Relevant Sanctioned Countries are unlikely to result in the violation of, or sanctions designation under, applicable sanctions laws administered by the United States, the European Union, the United Nations and Australia; and (ii) our business activities did not constitute Primary Sanctioned Activities that represent a violation to the applicable International Sanctions and are unlikely to be viewed as Secondary Sanctionable Activities during the Track Record Period. Based on a thorough review of our internal control policies and procedures for sanctions compliance (which encompass screening of customers, suppliers and business partners against applicable sanctions lists, ongoing monitoring of changes in sanctions laws and regulations, and employee training) in consultation with our International Sanctions Legal Advisors, and having considered that we had not been the subject of any sanctions-related investigations, claims, proceedings or penalties during the Track Record Period and up to the Latest Practicable Date, our Directors are of the view, and the Sole Sponsor concurs, that our internal control measures are adequate and effective to manage its exposure to sanctions risks, and that we are not subject to any sanctions risks that would materially and adversely affect our business operations and financial performance.

As of the Latest Practicable Date, neither we nor our Directors had received any notice of penalties or enforcement action related to our historical sales to the Relevant Sanctioned Countries. We have ceased all transactions with, and do not intend to undertake any future business with, any Comprehensively Sanctioned Countries and Sanctioned Targets that could cause us to violate the applicable International Sanctions. The interpretation and implementation of International Sanctions can be uncertain. If regulatory authorities were to determine that our business activities violated International Sanctions, we could face sanctions or penalties that could adversely affect our business, results of operations, reputation and prospects. Additionally, sanctions programs constantly evolve with new restrictions and interpretations that could increase scrutiny of our business. We cannot ensure full compliance with evolving regulations or the absence of resulting adverse consequences.

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

Overseas markets are an important component of our growth strategy. We plan to explore market opportunities overseas, where we believe there is substantial demand for our drug candidates, and we intend to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our drug candidates. We will also continue to seek licensing and co-development opportunities with global MNCs, and expand our global clinical programs. For more details, see “Business — Our Business Strategies.” However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including (i) increased expenses or diversion of management time and attention in connection with efforts to enter into collaboration or licensing arrangements with third parties, (ii) changes in political or cultural environments or economic conditions in specific countries or regions, (iii) differing and evolving regulatory requirements for drug approvals and marketing across international markets, (iv) difficulties in effectively enforcing contractual provisions in local jurisdictions, (v) reduced or uncertain protection of intellectual property rights, (vi) unexpected changes in tariffs, trade barriers and regulatory requirements, (vii) compliance with tax, employment, immigration and labor laws applicable to employees traveling or working abroad, and (viii) business interruptions resulting from geopolitical events, mainly war and terrorism, or natural disasters.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

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

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat including (i) natural disasters such as floods, earthquakes, sandstorms, snowstorms, fires or droughts, (ii) outbreaks of widespread health epidemics or other public health events, including swine flu, avian influenza, severe acute respiratory syndrome (SARS), COVID-19, Ebola or Zika, (iii) shortages or failures of power, water or fuel supplies, (iv) malfunctions or breakdowns of information management systems, (v) unexpected maintenance requirements or technical problems, and (vi) ongoing and potential wars or terrorist attacks. The occurrence of such disaster, epidemic or other adverse public health or geopolitical development could materially disrupt our business and operations including adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners.

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 industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. Our insurance policies cover adverse events in our clinical trials, liability insurance for workplace safety and general insurance for properties and machinery damage. In line with general market practice, we have elected not to maintain certain types of insurance, such as business interruption insurance or key personnel life insurance. Our existing insurance coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Our information technology systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

Our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.

We have leased certain properties in China primarily used as our offices, manufacturing, warehousing and R&D facilities, and also leased out certain properties to third parties. See “Business — Properties — Leased Properties” for details. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases.

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As of the Latest Practicable Date, four lease agreements for our leased properties in China, each with a GFA of over 1,000 square meters, which are used for R&D, manufacturing and office purposes, had not been registered with the relevant PRC authorities. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. Therefore, the maximum potential fine for these leased properties would be RMB40,000. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of leases. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. If any of our leases is terminated or becomes unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. Any relocation could lead to disruptions to our operations and adversely affect our business, financial conditions and results of operations. As our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

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 applicable PRC regulations, we are required to participate in the employee social welfare plan administered by local governments. See “Regulatory Overview — Regulations in relation to Employment and Social Securities” for details. Such plan consists of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. We were in compliance with applicable laws and regulations related to social insurance and housing provident funds in all material aspects during the Track Record Period. Any failure to make timely and full social welfare contribution for our employees could trigger an order of correction from competent authority. Such an order would require us to make up the full amount of such overdue social welfare contribution within a specified period of time and pay an overdue charge equal to 0.05% of the outstanding amount for each day of delay. Failure to comply within the stipulated deadline, we may be liable to a fine of one to three times the amount of the overdue payment. In addition, if we fail to pay the full amount of housing provident fund as required, the housing provident fund management center may order us to make the outstanding payment within a prescribed time limit. In the event of non-payment within such time limit, an application may be made to the PRC courts for compulsory enforcement.

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 acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including (i) increased operating expenses and cash requirements, (ii) the assumption of additional indebtedness or contingent liabilities, (iii) dilution to existing Shareholders resulting from the issuance of additional equity securities, (iv) diversion of management time and attention from existing product programs and initiatives, (v) loss of key personnel and uncertainty in maintaining key business relationships, (vi) risks and uncertainties related to the integration of operations, corporate culture, intellectual property, products and personnel of the acquired business, (vii) risks and uncertainties associated with the counter party to the transaction, (viii) the inability to generate revenue from acquired technologies or products

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sufficient to achieve our objectives or offset acquisition and ongoing costs, and (ix) changes in accounting principles or standards applicable to the recognition and measurement of our investments that could materially affect our financial results.

Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Further, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions of the State Council on Thresholds for Prior Notification of Concentrations of Undertakings (《國務院關於經營者集中申報標準的規定》), or the “Prior Notification Rules” issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the SAMR when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

RISKS RELATING TO THE [REDACTED]

Our A Shares are listed on the Shanghai Stock Exchange. The characteristics of the A Share and H Share markets may differ. We will be concurrently subject to [REDACTED] and regulatory requirements of the Chinese Mainland and Hong Kong.

Our A Shares are listed and traded on the Shanghai Stock Exchange. Following the [REDACTED], our A Shares will continue to be [REDACTED] on the Shanghai Stock Exchange and our H Shares will be [REDACTED] on the Stock Exchange of Hong Kong Limited (the “**Stock Exchange**” or “**Hong Kong Stock Exchange**”). Under the current PRC laws and regulations, our H Shares and A Shares are neither interchangeable nor fungible, and there is no [REDACTED] or settlement between the H Share and A Share markets. Specifically, the H Share and A Share markets have different trading characteristics, each have different trading volumes, liquidity and [REDACTED] bases, as well as different levels of retail and institutional [REDACTED] participation. As a result, the [REDACTED] performance of our H Shares and A Shares may not be comparable, and the historical prices of our A Shares may not be indicative of the prices of our H Shares. Nonetheless, fluctuation in the price of our A Shares may adversely affect the price of our H Shares, vice versa. Therefore, you should not place undue reliance on the trading history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

As we are listed on the Shanghai Stock Exchange and expect to be [REDACTED] on the Main Board of the Hong Kong Stock Exchange, we will be required to comply with the listing rules (where applicable) and other regulatory regimes of both jurisdictions, unless an exemption is available. Accordingly, we may incur additional costs and resources in continuously complying with all applicable listing rules and other regulatory regimes in the two jurisdictions.

There has been no prior [REDACTED] market for our H Shares, and their liquidity and market price may be volatile, which could lead to substantial losses to [REDACTED].

Prior to the completion of the [REDACTED], there has been no [REDACTED] market for our H Shares. We cannot assure you that a [REDACTED] market for our H Shares with adequate liquidity and [REDACTED] will develop and be sustained following the completion of the [REDACTED]. The [REDACTED] for our H Shares to the public will be the result of negotiations between us and [REDACTED] (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of our H Shares following the completion of the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares. A [REDACTED] on the Stock Exchange, however,

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does not guarantee that an active and liquid [REDACTED] market for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of our H Shares will not decline following the [REDACTED].

Furthermore, the [REDACTED] of our H Shares may be volatile. Various factors, among others, may affect the [REDACTED] and [REDACTED] at which our H Shares will [REDACTED], including (i) variations in our revenue, earnings and cash flows, (ii) announcements of new investments, business collaborations, strategic alliances or acquisitions, (iii) unexpected business interruptions resulting from epidemics, natural disasters or power shortages, (iv) material changes in our Directors, senior management or other key personnel, (v) our inability to obtain, maintain or renew regulatory approvals for our operations, (vi) our inability to compete effectively with competitors, (vii) political, economic, financial and social developments, and (viii) fluctuations in market prices for our products or raw materials. Moreover, shares of other biopharmaceutical companies [REDACTED] on the Stock Exchange have experienced significant price volatility in the past. It is possible that our H Shares may be subject to changes in [REDACTED] not directly related to our performance and as a result, [REDACTED] in our H Shares may suffer substantial losses.

Future sales or perceived sales of substantial amounts of our Shares in the [REDACTED] market could have a material adverse effect on the prevailing [REDACTED] of our H Shares and our ability to raise additional capital in the future.

Substantial future sales or the expectation of substantial sale of our Shares in the [REDACTED] market following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares. Future sales of a significant number of our Shares by our Controlling Shareholders or other existing shareholders in the [REDACTED] market after the [REDACTED], or the perception that these sales could occur, could cause the [REDACTED] of our H Shares to decline and could materially impair our future ability to raise capital through [REDACTED] of our Shares. We cannot assure you that our Controlling Shareholders will not dispose of Shares held by it or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors or otherwise. We cannot predict the effect, if any, that any future sales of Shares by our Controlling Shareholders, or the availability of Shares for sale by our Controlling Shareholders, or the issuance of Shares by the Company may have on the [REDACTED] of the H Shares. Sale or issuance of a substantial number of Shares by our Controlling Shareholders or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing [REDACTED] of the H Shares.

As the [REDACTED] of our H Shares is higher than our consolidated net tangible asset per Share, [REDACTED] of our H Shares in the [REDACTED] may experience immediate dilution upon such purchases.

As the [REDACTED] of our H Shares is higher than the consolidated net tangible assets per Share immediately prior to the [REDACTED], purchasers of our H Shares in the [REDACTED] may experience an immediate dilution. Our existing Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible asset value per Share of their Shares. In addition, holders of our H Shares may experience further dilution of their interest if we issue additional H Shares in the future to raise additional capital.

Our Controlling Shareholders may have substantial influence over the Company and their interests may not be aligned with the interests of other Shareholders.

Our Controlling Shareholders may have substantial influence over our business. Immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no other changes are made to the issued share capital of our Company between the Latest Practicable Date and the [REDACTED]), our Controlling Shareholders will control approximately [REDACTED]% of voting rights in our Company (excluding the 560,332 A Shares held by our Company as treasury Shares as of the Latest Practicable Date). This concentration of ownership may discourage, delay or prevent a change in control of the Company, potentially depriving other

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Shareholders of a takeover premium and reducing the price of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interest of our Controlling Shareholders may differ from the interests of our other Shareholders and potentially our Controlling Shareholders may exercise their influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

You may experience difficulties in effecting service of process upon or enforcing foreign judgments against us or our Directors or officers.

Most of our assets are situated in the PRC and most of our directors and officers reside in the PRC. Therefore, it may be difficult to effect service of process outside the PRC upon most of our directors and officers, including those arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the United States and many other countries which may further limit your ability to enforce such judgments against us or our directors and officers in the PRC.

On July 14, 2006, Chinese Mainland 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 Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese Mainland court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《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》), which has come into effect on January 29, 2024 and superseded the Arrangement, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Chinese Mainland and Hong Kong. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

Our historical dividends may not be indicative of our future dividend policy, and there can be no assurance whether and when we will declare and pay dividends in the future.

We have declared dividends in the past. However, we cannot make any assurance that dividends of any amount will be declared or distributed by us in any period in the future. Under the applicable PRC laws and regulations, the payment of dividends may be subject to certain limitations, and the calculation of our profit under the Accounting Standards for Business Enterprises may differ in certain respects from the calculation under the IFRS. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, taking into account various factors such as our results of operations, financial condition, cash flows, capital expenditure requirements, market conditions, our strategic plans and prospects for business development, regulatory restrictions on the payment of dividends and other factors as our Directors may deem relevant, and subject to the approval at Shareholders’ meeting. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the applicable PRC laws and regulations. No dividend may be declared or paid except out of profits and reserves

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lawfully available for distribution, and our historical dividends should not be regarded as indicative of our future dividend policy. For further details of our dividend policy, see “Financial Information — Dividends.”

Under the existing foreign exchange regulations of the PRC, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior SAFE approval by complying with certain procedural requirements. However, approval from or registration with competent government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. If we fail to obtain sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, we cannot assure you that new regulations will not be promulgated in the future that could affect the remittance of Renminbi into or out of China.

This document contains certain facts, forecast and other statistics derived from various government resources, which have not been independently verified.

Certain facts, forecast and other statistics in this document are derived from various government resources, which has not been independently verified by us, the Sole Sponsor, [REDACTED], any of the [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED] and, therefore, we make no representation as to the accuracy of such facts and statistics. In all cases, our [REDACTED] should consider carefully how much weight or importance should be attached to or placed on such facts or statistics.

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 sources regarding us or the [REDACTED].

We may be subject to press and media coverage prior to the publication of this document, and subsequent to the date of this document but prior to the completion of the [REDACTED]. The press and media may include certain financial information, industry comparisons, profit forecasts and other information about us that does not appear in this document. You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your [REDACTED] decision regarding the H Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding ourselves or the [REDACTED]. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information, reports or publications, and prospective [REDACTED] should not rely on them in making their [REDACTED] decisions regarding the [REDACTED]. In making their decisions as to whether to [REDACTED] in our H Shares, prospective [REDACTED] should only rely on the financial, operational and other information included in this document, the [REDACTED] and any formal announcements made by us in Hong Kong. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed accordingly.