

RISK FACTORS

You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our H Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and prospects depend substantially on the success of our drug candidates. Development of innovative drugs involves a lengthy and expensive process with uncertain outcomes. If we are not able to develop and commercialize new products, including our Core Products, our business prospects could be adversely affected.

We have systematically built a pipeline of drug candidates across multiple modalities that target major tumor types. As of the Latest Practicable Date, iza-bren was being evaluated in 14 ongoing Phase III clinical trials in China and three global pivotal Phase II/III registrational trials across multiple tumor types, and T-Bren was in eight pivotal Phase III registrational trials. As of the same date, our innovative drug pipeline featured 15 clinical-stage drug candidates, five of which were undergoing clinical development outside China. See “Business — Our Portfolio Assets” for details. The success of our drug candidates, including iza-bren and T-Bren, will depend on several factors, including: (i) generating favorable safety and efficacy data, successful patient enrollment, and data integrity; (ii) the performance and capabilities of our CROs and collaborators; (iii) obtaining necessary regulatory approvals and managing protocol modifications; (iv) securing sufficient clinical supplies and commercial manufacturing capabilities; (v) successful commercial launch, reimbursement, and competitive positioning; and (vi) obtaining, maintaining, and defending our intellectual property rights. There can be no assurance that our R&D activities will deliver the expected results and we will be able to develop drug candidates that are potentially first-in-class or best-in-class on a global basis. Our ADC drug candidates and other pipeline assets, given their novelty and differentiated features, may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. In addition, they may require additional preclinical and/or clinical development, regulatory approvals, and substantial investment and significant marketing efforts, before we are able to generate any revenue from product sales.

We may face intense competition, and 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 biopharmaceutical industry in which we operate is highly competitive and rapidly changing. Our drug candidates, upon potential marketing approval, will face competition from existing ADCs directed against the same molecular targets and approved for the same target indications. Our competitors primarily include large domestic and international pharmaceutical companies. Smaller or early-stage biopharmaceutical companies may also compete with us, particularly through collaborative or licensing arrangements with large and established companies. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better market acceptance. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates. To compete with an approved product, we will need to demonstrate compelling advantages in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status, in order to overcome price competition and to be commercially successful. Competition may further

RISK FACTORS

intensify as a result of advances in technologies and capital availability. Many of our competitors have substantially greater financial, technology and other resources, such as better access to capital, more advanced commercial infrastructure, larger research and development team and more established manufacturing facilities. Disruptive technologies and medical breakthroughs could render our current drug candidates or underlying technologies obsolete or significantly less competitive. If we fail to effectively compete with our competitors or adjust to structural changes in the pharmaceutical industry, our revenue and financial performance may be materially and adversely affected.

We may be unable to identify, discover, in-license, acquire or develop new drug candidates, or to expand the therapeutic opportunities for our drug candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential regulatory approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to continue to discover, develop, license, or commercialize additional drug candidates. There can be no assurance that we will be successful in identifying new drug candidates in the future. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We may also enter into strategic collaborations, licensing arrangements, acquisitions or other transactions with third parties, but such arrangements may not achieve their intended objectives or generate the anticipated benefits. Research programs to discover and develop new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

If we encounter difficulties in recruiting clinical trial subjects, our clinical development activities may 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. Participant enrollment 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. These factors significantly complicate participant recruitment and retention, which could potentially hinder the overall clinical trial progress and our ability to advance drug candidates.

Adverse events or undesirable side effects caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved drug, 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, delay or halt clinical trials, potentially resulting in narrowed scope of indications, restrictive labelling, protocol changes, or denial of approval. 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. Additionally, if we, our collaboration partners, or others identify undesirable side effects caused by our drug candidates after they receive regulatory approval, this 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

RISK FACTORS

using our drug candidates together with third-party agents may involve AEs, which in some cases could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our collaboration partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

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

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. For example, we are advancing iza-bren into earlier-line combination settings through immune-checkpoint-inhibitor-based (“ICI”) and TKI-based regimens across over 20 trials. If the regulatory agency revokes or denies the approval of a component therapeutic, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In the event that we encounter unstable supply of certain drugs that we use in trials for combination therapies, it could disrupt the clinical development of our drug candidates, delay regulatory approvals, and hinder our ability to meet market demand, thereby adversely affecting our business. In addition, it is common practice in the industry to use companion diagnostic tests to detect a predictive biomarker, such as PD-L1, EGFR and HER2, in patients to evaluate their likely response to certain treatment. In the U.S., the FDA generally requires pre-market approval for *in vitro* companion diagnostics intended to select patients for cancer treatment. In China, regulations governing companion diagnostics remain developing, which could impose additional restrictions on our drug development and commercialization.

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

The top-line or preliminary results may differ from the future results, 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 material differences. 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 [REDACTED] in the [REDACTED] 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.

Any failure to timely obtain relevant regulatory approvals could adversely affect our business prospects and profitability. Even after we obtain regulatory approval for the marketing of our drug candidates, they remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may expose us to liabilities and result in significant additional expenses.

The regulatory approval process is time-consuming, inherently uncertain, and subject to discretion. We may fail to receive the regulatory approvals for our drug candidates due to a number of reasons, including: (i) disagreements over clinical trial design or implementation; (ii) failure to demonstrate safety, efficacy or statistical significance; (iii) insufficient data or procedural errors; (iv) failure to pass Good Clinical Practice (“GCP”) inspections or data audits; (v) unexpected changes in regulations or approval policies; or (vi) manufacturing deficiencies, including failure to pass Good Manufacturing Practice (“GMP”) inspections. Even if we do obtain regulatory approvals, the process may take longer than expected, or such approvals may be subject to limitations, thereby restricting the market size and adversely affecting our business, results of operations and growth prospects. In addition, clinical trials conducted in one jurisdiction may not

RISK FACTORS

be accepted by regulatory authorities in other jurisdictions. Additional time, efforts and expenses may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes. Furthermore, even after we obtain regulatory approval for the marketing of our drug candidates, they remain subject to ongoing or additional regulatory requirements. If we are unable to maintain regulatory compliance, or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained, and we may not achieve or sustain profitability.

If we fail to obtain facilitated regulatory pathways from the NMPA, the FDA or comparable regulatory authorities in other jurisdictions, we may be required to conduct additional clinical trials, which would result in additional costs and expenses and delay our receipt of relevant approvals.

The NMPA, the FDA and the comparable regulatory authorities have implemented expedited review programs. As of the Latest Practicable Date, iza-bren had received breakthrough therapy designations for a total of eight indications, comprising seven indications under the CDE’s breakthrough therapy designation program and one indication under the FDA’s breakthrough therapy designation. As of the same date, one T-Bren indication had been included by the CDE in the breakthrough therapy designation program. There can be no assurance that our drug candidates will qualify for these programs, or that we will pursue or submit any applications for them. In addition, approvals granted under expedited registration pathways may be subject to 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 such approvals and/or any future changes to current policies and approvals with respect to the expedited registration pathways could delay our commercialization, increase development expenses and adversely affect our competitive position.

Compassionate use programs and off-label use of our products may expose us to liability and harm our business reputation, product brand and financial condition.

Currently, there is no unified regulatory approach to expanded access programs across different countries, leading to uneven patient entry criteria and protocols for compassionate use. In addition, as products in such programs are unapproved investigational drug candidates, patients with advanced disease or comorbidities face an increased risk of serious adverse events and adverse drug reactions. If we participate in compassionate use programs, these occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing. Separately, any of our innovative drug candidates that will receive marketing approval in the future may be subject to off-label drug use. This risk may be heightened where we obtain approval of a drug candidate for one indication while continuing to investigate it for others, as physicians may prescribe the approved product for such unapproved indications. Off-label use could render our drug candidates less effective or entirely ineffective and cause unexpected adverse drug reactions or serious adverse events, creating negative publicity, exposing us to liability, delaying our clinical trials, and potentially resulting in failure to obtain regulatory approval.

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.

We incurred research and development expenses of RMB1,442.8 million, RMB2,513.7 million, RMB494.9 million and RMB694.8 million for the years ended December 31, 2024 and 2025 and the three months ended March 31, 2025 and 2026, respectively. We may not be able to successfully develop or commercialize new drug candidates or marketed products with expanded indications in a timely or cost-effective manner, or secure adequate intellectual property protection. We prioritize research programs and drug candidates targeting selected indications. We may in turn

RISK FACTORS

forgo or delay other indications that may later prove to have greater commercial potential or a greater likelihood of success. If our current pipeline priorities do not yield the anticipated outcomes, we may need to adjust our strategy. Furthermore, if we inaccurately evaluate the commercial potential or target market for a particular drug candidate, we could relinquish valuable rights through collaboration or license arrangements where retaining sole development and commercialization rights would have been more advantageous. Conversely, we may allocate internal resources to a drug candidate where collaboration would have been preferable. Either scenario could adversely affect our future growth and prospects.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURING

Before we start to generate revenue from the commercialization of our innovative drug candidates, we rely on the sales of commercialized products. If we are unable to maintain the sales volume, pricing levels and profit margins of our existing marketed products, our operations, revenue and profitability could be adversely affected.

In 2024 and 2025 and the three months ended March 31, 2025 and 2026, our revenue generated from the sale of pharmaceutical products was RMB486.8 million, RMB380.1 million, RMB60.5 million and RMB92.0 million, respectively. Before we generate revenue from the commercialization of our innovative drug candidates, we expect that our revenue will continue to be concentrated in a limited number of marketed products in the near future. We may be particularly susceptible to factors adversely affecting the sales volume, price levels, or profitability of these products, including: (i) exclusion from, or reduction in, government insurance coverage; (ii) pricing regulations; (iii) competition from substitute products or alternative therapies; (iv) interruptions in raw material supply or associated cost increases; (v) issues with product quality or side effects; (vi) intellectual property disputes; (vii) adverse distribution network changes; and (viii) unfavorable policy or regulatory changes. Many of these factors are outside of our control, and any resulting adverse impact could hinder our ability to invest in and develop new products, thereby affecting our long-term growth prospects.

Pricing regulations or other policies such as volume-based procurement (the “VBP”) that are intended to reduce healthcare costs could adversely affect our operations, revenue and profitability.

The PRC government may reform the schemes of pricing control and statutory tender processes for pharmaceutical products or revise other policies affecting prices of pharmaceutical products over time. See “Regulatory Overview — Overview of Laws and Regulations in the PRC — Laws and Regulations in Relation to New Drugs — The Drug Centralized Procurement in Nationwide” for details. During the Track Record Period, a number of our products were subject to national or provincial VBP schemes. See “Business — Pricing — Centralized Tender Process and Volume-based Procurement” 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, the drug coverage of the VBP schemes may be updated from time to time, and there can be no assurance that any of our additional drugs 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.

RISK FACTORS

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

Insurance coverage is a critical factor in a patient’s ability to afford treatments. As of March 31, 2026, certain of our approved products were included in the NRDL. See “Business — Centralized Tender Process and Volume-based Procurement” for details. The selection of pharmaceutical products for listing in medical insurance catalogs is based on a variety of factors, including efficacy, safety and price. If we fail to have our products included or maintained in the NRDL, our products may become less attractive due to reliance on patient self-payment, and patients may choose alternatives with lower price which have been included in the NRDL. 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 over time, as we may be required to significantly lower their prices to secure such inclusion. In addition, inclusion in any national or provincial negative catalogs in China represents considerable risk. Further, considering that we may in the future commercialize our drug candidates in the U.S., the assignment of a black box warning by the FDA for our drug candidates may impose significant risks, leading to decreased physician prescribing, heightened liability concerns, and ultimately, a substantial reduction in sales. Moreover, it can negatively affect the perception of our commitment to safety, potentially harming our reputation and long-term business prospects.

Our products and future approved products may fail to achieve or maintain the degree of market acceptance, and the actual market size of our drug candidates might be smaller than expected, which could render some drug candidates less profitable than expected even if commercialized.

The commercial success of our products, including existing or future products, is highly dependent on their continued market acceptance among patients, healthcare practitioners, and others in the medical community. The market acceptance of our products 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 and the prevalence and severity of side effects, if any; (iii) the pricing and cost effectiveness of our products; (iv) the effectiveness of our sales and marketing efforts; (v) publicity concerning our products or competing products; (vi) our ability to respond to changes in needs and preferences of healthcare practitioners and patients; and (vii) the inclusion of our products in key insurance or reimbursement schemes. 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, they may be rendered obsolete, and the demand for our products may decline. Furthermore, the actual market size of our drug candidates may not be as large as we anticipate, influenced by various factors such as market acceptance, pricing, and patient availability. Any of the above unfavorable developments could adversely impact on our business, financial condition and results of operations.

If we fail to maintain and optimize an effective distribution network for our products or encounter problems with our distributors, our operations, revenue and profitability could be adversely affected.

In 2024, 2025 and the three months ended March 31, 2025 and 2026, our sales to distributors accounted for 99.4%, 98.8%, 98.1% and 99.3%, respectively, of our revenue from the sale of pharmaceutical products during the respective period. Our ability to grow our business is significantly affected by our ability to maintain and manage a distribution network and to expand our distribution network effectively. See “Business — Sales and Marketing” for details. While the engagement of sub-distributors is not allowed for sales to public medical institutions in accordance with the two-invoice system, we generally allow our regional distributors to engage sub-distributors

RISK FACTORS

for products sold to pharmacies and private medical institutions. Our distributors and sub-distributors may fail to sell our products efficiently, manage inventory appropriately, comply with applicable laws and regulations, or adhere to our sales, pricing and marketing policies, and may engage in competition among themselves for market share of our products. Any of the foregoing could adversely affect our commercial operations and sales performance. In addition, in line with industry practice in China, we typically enter into distribution agreements for a prescribed term. Our distributors may elect not to renew their distribution agreements, cease or reduce their purchases of our products, or otherwise terminate their business relationships with us for various reasons. We may also not be able to establish business relationships with new distributors to support the continued growth of our business, which may adversely affect our business, financial condition and results of operations.

If we are unable to conduct effective promotion or maintain a qualified sales force, our business and results of operations could be adversely affected.

Successful sales and marketing efforts are crucial for us. 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 attract, motivate and retain a sufficient number of qualified sales professionals and develop our in-house sales force, our sales and marketing may be less successful than desired. See “Business — Sales and Marketing” for details.

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

We currently have five manufacturing facilities located in Sichuan Province and the Xizang Autonomous Region, China. See “Business — Manufacturing” for details. Manufacturing activities at these facilities may be substantially interrupted and adversely affected due to a number of factors, including natural disasters, operational disruptions, security threats, land-related issues, and regulatory compliance issues. In the event of a significant business disruption, we may not be able to locate alternatives to continue our production in a legal, timely and cost-effective manner, or at all. In addition, 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, among others.

If we fail to increase our production capacity in response to the increasing demand of our customers, our business prospects could be adversely affected.

We plan to expand our existing production facilities and production lines to meet the increasing demand for our products and prepare for the expected commercialization of our drug candidates following marketing approval. The financing and completion of such expansion of the production facilities and production lines involve regulatory approvals and reviews by various authorities in relevant jurisdictions, including, but not limited to, urban planning, construction and environmental protection authorities. For the expansion of production facilities and production lines, we cannot assure you that we will be able to obtain all of the required approvals, permits and licenses. Expansion of the production facilities also may not be completed on the anticipated timetable or within budget. We may also be unable to fully utilize the production capacity after the expansion of our production facilities. Any of the foregoing factors could materially and adversely affect our results of operations and prospects and result in loss of business opportunities.

RISK FACTORS

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

Our products and manufacturing processes are required to meet certain quality standards. Despite our quality control system and procedures, we cannot eliminate the risk of errors, defects or failure. We may fail to detect or resolve quality defects as a result of a number of factors, many of which are outside our control, including: (i) manufacturing error or malfunction; (ii) human error or misconduct; (iii) mishandling by third parties; and (iv) quality issues with raw materials. In addition, when we expand our manufacturing capacity in the future, we may not be able to ensure consistent quality throughout the upgrade process, or may need to incur substantial costs for doing so. Furthermore, if we acquire other pharmaceutical companies, we may not be able to immediately ensure that their manufacturing facilities and processes will meet our own quality standards. Failure to detect quality defects in our pharmaceutical products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other consequences that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenue and profitability.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net losses during the Track Record Period except for the year of 2024. We may continue to incur net losses and may fail to achieve or maintain profitability in the future.

We recorded net profits of RMB3,707.5 million in 2024, mainly attributable to the license fee income we received in that year. However, we had net losses of RMB1,053.6 million, RMB531.4 million and RMB774.6 million in 2025 and the three months ended March 31, 2025 and 2026, respectively. Our net losses recorded during the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities, reflecting the continued advancement of our iza-bren and T-Bren clinical programs, (ii) a decrease in license fee income as the milestone payment revenue recognized in 2025 was smaller in scale than the upfront payment revenue recognized in 2024, and (iii) the reduction of revenue from the sale of pharmaceutical products, mainly because certain of our major marketed generic and traditional Chinese medicine products are generic drugs subject to the impact of the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products. Our revenue, expenses and operating results may vary from period to period due to a variety of factors beyond our control. Accordingly, there can be no assurance that our revenue will continue at similar levels or increase as it did or that we will continue to record profits as we did in 2024. [REDACTED] should not rely on our historical results as an indication of our future financial or operating performance.

We have net cash outflows used in our operating activities in 2025 and the three months ended March 31, 2025 and 2026, and we may need to obtain additional financing to fund our operations. If we are unable to obtain sufficient financing on terms acceptable to us or at all, we may be unable to complete the development and commercialization of our drug candidates.

We had net cash used in operating activities of RMB977.1 million, RMB539.2 million and RMB778.4 million in 2025 and the three months ended March 31, 2025 and 2026, respectively. The reasons of our cash flows used in operating activities in the foregoing periods primarily include our loss for the year/period, which is in turn primarily attributable to our cost of sales, R&D expenses, distribution and selling expenses, and administrative expenses. Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. We cannot guarantee that we will not experience net operating cash outflows in the future, whether as a result of our business expansion, intensified market competition, unfavorable changes in the

RISK FACTORS

macroeconomic environment or other factors beyond our control. If we are unable to generate sufficient operating cash inflows on a sustained basis, we may not have adequate working capital to fund our operations, which could adversely affect our business, financial condition, results of operations and prospects.

We are uncertain about the recoverability of our deferred tax assets, which may affect our financial position in the future.

As of December 31, 2024 and 2025 and March 31, 2026, our deferred tax assets amounted to RMB179.2 million, RMB38.2 million and RMB53.6 million, respectively. For details, see Note 20 to the Accountants’ Report in Appendix I to this document. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets are not recognized if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit. As such, this requires significant judgment on the tax treatments of certain transactions and also assessment on the probability that adequate future taxable profits will be available for the deferred tax assets to be recovered. In this context, we cannot guarantee the recoverability or predict the movement of our deferred tax assets, and to what extent they may affect our financial position in the future.

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

During the Track Record Period, we have incurred indebtedness, including borrowings and lease liabilities. As of December 31, 2024 and 2025 and March 31, 2026, our indebtedness amounted to RMB2,068.5 million, RMB3,714.2 million and RMB4,318.3 million, respectively. See “Financial Information — Indebtedness” for details. Our ability to generate sufficient cash to satisfy our debt obligations depends on our operating performance, which will be affected by many factors beyond our control. We may not generate sufficient cash flow to pay our anticipated operating expenses and to service our debt, forcing us to consider reducing capital expenditures, disposing of our assets, restructuring or refinancing our indebtedness or seeking equity capital. If we fail to repay borrowings or breach loan covenants, we could default. In the event of default, the lenders may accelerate debt repayment or seize collateral. If any of these events occur, we cannot assure you that our assets and cash flow would be sufficient to repay all of our indebtedness, or that we would be able to obtain alternative financing on terms that are favorable or acceptable to us. As a result, our cash flow, financial condition and results of operations may be materially and adversely affected.

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

Our trade receivables consisted of amounts due from our customers which include distributors who on-sell our products to hospitals and, to a lesser extent, pharmaceutical retail chains. We generally grant credit terms of 30 to 120 days to our customers. As of December 31, 2024 and 2025 and March 31, 2026, we had trade receivables of RMB106.7 million, RMB67.8 million and RMB62.0 million, respectively. In 2024 and 2025 and the three months ended March 31, 2026, trade receivables turnover days were 6.4 days, 12.6 days and 62.0 days, respectively. See “Financial Information — Discussion of Major Items of Consolidated Statements of Financial Position — Trade and Other Receivables.” Our customers may not be able to make timely payment, due to their adverse operating conditions or financial conditions and their inability to pay as a result of the delays in payment from end customers. In addition, as our business continues to develop, our trade receivables may continue to grow and would increase our credit risk. If our customers delay or default on their payments to us, we may need to make impairment provisions and write off the relevant receivables. This would have a negative impact on our liquidity and financial condition.

RISK FACTORS

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

Our inventory consists of raw materials, consumables, work-in-progress, goods in transit and finished goods. As of December 31, 2024 and 2025 and March 31, 2026, we had inventories of RMB149.9 million, RMB146.3 million and RMB144.7 million, respectively. In 2024 and 2025 and the three months ended March 31, 2026, our inventory turnover days were 182.5 days, 202.7 days and 273.4 days, respectively. For details, see “Financial information — Discussion of Major Items of Consolidated Statements of Financial Position — Inventories.” To operate our business successfully and meet our customers’ demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We cannot assure you that we will avoid overstocking or understocking. Further, demand for products could change significantly between order and delivery. Excess inventory levels may increase our inventory holding costs, obsolescence risks or potential impairment losses. Conversely, underestimating demand may cause stock shortages and we may lose sales and market share to our competitors.

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

Our other income related to the government grants amounted to RMB44.7 million, RMB42.5 million and RMB8.8 million in 2024, 2025 and the three months ended March 31, 2026, respectively. We also enjoyed preferential tax treatment during the Track Record Period. See “Financial Information — Results of Operations — Other Income” and “— Income Tax (Expense)/Credit” for more 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.

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

During the Track Record Period, our financial assets at FVTPL primarily consisted of our investment in wealth management products and foreign currency forward contracts. Our financial assets at FVTPL amounted to nil, RMB2,170.0 million and RMB2,167.8 million as of December 31, 2024 and 2025 and March 31, 2026. We may continue to make such investment as part of our cash management and treasury measures and therefore may face exposure to fair value change for the financial assets at FVTPL. We cannot assure you that we will not recognize fair value losses, which would adversely affect our result of operations for future periods. In addition, the valuation of financial assets at FVTPL, which relies to a certain extent on subjective assumptions and unobservable inputs, is subject to estimation uncertainties, potentially leading to fluctuations in periodic profits or losses.

We may be affected by exchange rate fluctuations.

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,

RISK FACTORS

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.

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

Since 2014, SystImmune, a wholly-owned subsidiary of our Company in the United States, entered into share option arrangements with certain eligible employees to recognize their contributions and to strive for the future development of the Group’s overseas operations. For details, see Note 43 to the Accountants’ Report in Appendix I to this document. Expenses incurred with respect to such share-based payment may increase our operating expenses and therefore have an adverse effect on our financial performance. Issuance of additional shares by SystImmune with respect to such share-based payment may also dilute the shareholding interest of our Company in SystImmune.

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

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including, but not limited to: (i) valuation risks associated with the acquired targets; (ii) increased operating expenses and cash requirements; (iii) assumption of indebtedness or liabilities; (iv) shareholder dilution; (v) diversion of management attention; (vi) loss of key personnel and business relationships; (vii) integration risks relating to acquired businesses, brands, operations, culture, intellectual property, and products; (viii) counterparty risks, including prospects of their products and regulatory approvals; (ix) inability to generate revenue sufficient to offset costs; (x) accounting principle impacts, such as significant future amortization expenses related to acquired intangible assets; and (xi) failure to achieve the anticipated synergies, cost savings or revenues, enhancing opportunities resulting from the acquisition of new businesses and operating those businesses at a level of profitability acceptable to us. 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.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Failure to adequately protect our intellectual property throughout the world, or if the scope of our intellectual property fails to sufficiently protect our proprietary rights, other pharmaceutical companies could compete against us directly or indirectly, which may have a material adverse impact on our business and results of operations.

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect our drug candidates and technologies that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. See “Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Material Intellectual Property Rights” 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,

RISK FACTORS

we or our business partners may fail to identify third-party infringement in a timely manner and take necessary actions to defend and enforce our rights. The patent position of biopharmaceutical companies generally involves complex legal and factual questions. Our current and future patent applications may be rejected or may otherwise fail to result in granted patents. Even if a patent is granted, its scope, validity or enforceability may still be challenged. 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 our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. 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.

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 and, following grant, with applicable requirements to maintain patents in force. Although an inadvertent lapse in making payment of such fees or complying with such provisions can in many cases be cured, 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. In any such event, our competitors might be able to enter the market, which would have an adverse effect on our business.

Patent expirations and uncertainty of patent term extensions may expose us to premature 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, are limited. For instance, in China, the statutory term of an invention patent is 20 years from the filing date, subject to any applicable patent term compensation. 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 generic, biosimilar or other competing products, as applicable. Manufacturers of generic 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 patent term extensions or other term adjustments, as applicable, 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 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.

RISK FACTORS

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

We own a number of trademarks in Chinese Mainland and Hong Kong. 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 and confidential information, our business and competitive position would be harmed.

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drugs and drug candidates. Despite non-disclosure, confidentiality and similar agreements with parties that have access to our trade secrets and confidential information, any of these parties may breach their obligations and we may not be able to obtain adequate remedies. 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. We may also be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of their former employer.

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

Obtaining and enforcing patents in the pharmaceutical industry is costly, time-consuming and inherently uncertain due to a high degree of technological and legal complexity. 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, future changes to patent laws in China, the U.S. and other jurisdictions, and changes in their interpretation and enforcement, could limit our ability to enforce our proprietary technology.

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, and could be expensive and time-consuming. Third parties could assert claims of patent infringement against us. If we are found to be infringing, we may be forced to modify or cease business operations, seek a license which may not be available on acceptable terms, or pay substantial damages, including enhanced damages for willful infringement. We may also fail to identify relevant third-party patents that cover our products due to the lag in publication of the scientific or patent literature. Any FTO search or analysis commissioned by us is necessarily limited to patent information publicly available as of the relevant search date and the specific product

RISK FACTORS

configurations provided to the relevant adviser, and does not constitute a guarantee of non-infringement. Such analysis may not identify unpublished or later-published patent applications, subsequent changes to patent claims or legal status, or matters outside its express scope, including manufacturing processes, formulations, therapeutic uses, dosage regimens, combination therapies, independent intermediates or other commercialization activities. Our intellectual property rights could be challenged or invalidated. To counter infringement, we may be required to file infringement claims, the outcomes of which are unpredictable and could provoke counterclaims that may invalidate our patents or interpret them narrowly. Even if we establish infringement, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages. Furthermore, disclosure of adverse litigation developments or even the perception of uncertainty could have a substantial adverse effect on the price of our Shares.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We rely on certain industry partners for part of our business, and any deterioration in our relationships with such partners could materially and adversely affect our business, financial condition and results of operations.

We collaborate with industry partners under various strategic collaboration, licensing, co-development and commercialization arrangements as part of our business strategy. The success of these arrangements depends in part on our partners’ performance of their respective obligations and continued commitment of sufficient resources. Our partners may fail to perform their obligations in full or on a timely basis, change their strategic priorities, experience financial or operational difficulties, disagree with us regarding the relevant programs, or exercise contractual rights that delay, reduce or terminate the collaboration. If any collaboration is delayed or terminated, we may be unable to identify a suitable replacement partner on acceptable terms or at all, which could adversely affect the development, regulatory approval, manufacturing or commercialization of the relevant products. In addition, payments under certain collaboration arrangements may depend on the achievement of clinical, regulatory, sales or other milestones, many of which are outside our control. If the relevant milestones are not achieved or are delayed, we may not receive the related payments when expected or at all. Any deterioration in our relationships with industry partners, or any failure of such arrangements to achieve their intended objectives, could materially and adversely affect our business, financial condition, results of operations and prospects.

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

We rely on third parties, such as collaboration partners, medical institutions, clinical investigators, and contract laboratories, in the development of our drug candidates and in the conduct of clinical trials for our drug candidates. We are also dependent upon third parties for the commercialization or distribution of products or drug candidates. Our business will be harmed if business, economic conditions or future developments in laws and regulations in the PRC, the U.S. or other jurisdictions result in deteriorations in our service providers’ operations and consequently a reduction in the services they provide to us. If these parties, which we do not 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 successfully complete their objectives, or choose not to continue their relationship with us, our development and commercialization efforts could be delayed, suspended or terminated. If the quality or accuracy of the data obtained by these third parties is compromised due to non-compliance with our clinical protocols, regulatory requirements or other factors, our preclinical or clinical activities could be delayed and we may not be able to obtain regulatory approval for our drug candidates.

RISK FACTORS

We depend on a limited number of customers for a substantial portion of our revenue, and the loss of, or a significant reduction in sales to, one or more of our major customers would materially and adversely affect our business, result of operations and financial condition.

In 2024, 2025 and the three months ended March 31, 2026, revenue generated from our five largest customers for each period during the Track Record Period accounted for 95.1%, 91.5% and 50.7% of our total revenue, respectively, and revenue generated from our largest customer for each period during the Track Record Period accounted for 91.6%, 84.8% and 19.2% of our total revenue for the respective period. For more information about our top five customers, see “Business — Customers.” We cannot assure you that we will be able to maintain or strengthen our relationships with our major customers, or that our major customers will continue to transact with us. If there is any significant reduction in spending on our products and services by our major customers due to industry consolidation, deterioration of their financial conditions, budget cuts, pending regulatory approvals or other reasons, and we are unable to obtain suitable contracts or purchase orders of a comparable size and terms in substitution, our business, financial condition and results of operations may be materially and adversely affected. In addition, any deterioration of our key customers’ ability to settle their trade receivables in a timely manner will have a material adverse effect on our results of operations.

Our operations are dependent on the supply of certain raw materials. Any disruption in the supply of raw materials or significant increase in the prices of raw materials could materially and adversely affect our business, financial condition and results of operations.

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. For details, see “Business — Quality Control and Assurance — Supply Chain Quality Control.” We typically do not enter into long-term supply agreements with raw material suppliers, and as a result, we are vulnerable to supply shortages and fluctuations in market prices. We may be unable to renew existing agreements or secure new suppliers to support our growth, and overseas procurement is additionally subject to geopolitical and cross-border risks. If our suppliers fail to supply sufficient, acceptable-quality materials, we may be unable to identify suitable substitutes in a timely manner. Any resulting supply interruptions could delay our production and delivery, and we may be unable to pass increased costs on to customers, any of which 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, acts of war or terrorism, health epidemics, earthquakes and other natural disasters, and could lead to delayed or lost deliveries. We cannot guarantee that our 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 refunds 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, thereby adversely affecting our business, financial condition and results of operations.

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

Our relationships with principal investigators, KOLs, and leading hospitals play an important role in our R&D and marketing activities. 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 could materially and adversely affect our business, financial condition and results of operations.

RISK FACTORS

RISKS RELATING TO GOVERNMENT REGULATIONS

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

We operate in the pharmaceutical and biopharmaceutical industries in China and the U.S. The industries we operate in are subject to comprehensive government regulation and supervision. See “Regulatory Overview” for details. Changes in government regulations or in practices, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business and results of operations. In addition, we are subject to periodic inspections of our facilities to monitor our regulatory compliance. Failure to comply with the applicable regulatory requirements in any of the jurisdictions where we operate at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

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

We are susceptible to constantly changing international economic, regulatory, social and political conditions. Tensions between China and other countries may adversely affect our business, financial condition, and results of operations. Changes to trade policies, treaties and tariffs — or the perception that such changes could occur — could adversely affect our operations, demand for our products, and trade, investment and technological exchange between China and other countries.

In February 2024, U.S. lawmakers called for investigations into, and possible economic sanctions against, certain Chinese biopharmaceutical companies over alleged ties to the Chinese military. The enacted BIOSECURE Act prohibits federal agencies from contracting with or funding companies that are designated “biopharmaceutical companies of concern.” The BIOSECURE Act’s final definition of “biopharmaceutical companies of concern” includes (i) entities on the Department of Defense’s section 1260H list of Chinese military companies operating in the United States (known as the “**1260H List**”), and (ii) entities that will be named through a process headed by the Office of Management and Budget (“**OMB**”), who must supplement the list of biopharmaceutical companies of concern within one year of enactment. If our suppliers or business partners were to be listed as “biopharmaceutical 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. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized. The timing and substance of such enabling regulations remain subject to uncertainty and may differ materially from current expectations. We are of the view that the BIOSECURE Act would not have a material and adverse impact on our business, primarily because we, or any of our subsidiaries, are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future.

Furthermore, 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. We cannot predict how tariff policies may further evolve or anticipate any potential impacts of subsequent developments in such policies on our business. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

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 receive, collect, generate, store, process, transmit, and retain medical data and treatment records of clinical trial subjects in accordance with applicable laws and regulations and the requirements of ethically approved clinical trial protocols. In recent years, the PRC authorities have promulgated certain laws and regulations in respect of information security, data collection and privacy protection, which impose stricter requirements on the protection of personal information. See “Regulatory Overview — Overview of Laws and Regulations in the PRC — Regulations in Relation to Information Security and Data Privacy” for details. We may also face new laws and regulations regarding personal information and privacy, which could potentially result in ever-increasing public scrutiny, enforcement and sanctions, and compliance costs. The personal information of patients or subjects involved in our clinical trials could be highly sensitive and subject to strict privacy regulations. Data leakage, abuse, and other misconduct may occur, due to hacking activities, human error, employee misconduct or negligence or system breakdown, among other reasons. We also cooperate with third parties including principal investigators, hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any security breach, failure, or perceived failure to comply with privacy obligations, whether by us or our partners, could result in unauthorized data release, legal claims, and a loss of customer trust.

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

We may be required to complete regulatory filings, obtain government approval or undergo security assessments to transfer data abroad, particularly if it involves personal information, state secrets or government-funded research. See “Regulatory Overview — Overview of Laws and Regulations in the PRC — Regulations in Relation to Information Security and Data Privacy” for details. Failure to comply with relevant requirements, such as obtaining authorization from subjects, completing regulatory procedures, and implementing safeguards to ensure data safety, may lead to restrictions on the cross-border transfer of our data. In addition, under the Regulations of the 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 PRC Biosecurity Law (《中華人民共和國生物安全法》), and other relevant laws and regulations, entities are restricted from directly collecting human genetic resources and must cooperate with local institutions, subject to specific approvals or filings. For details, see “Regulatory Overview — Laws and Regulations in Relation to New Drugs — Gathering, Collection and Filing of Human Genetic Resources.” Any non-compliance may expose us to fines and other administrative penalties and hinder the R&D of our drug candidates.

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

Dividends payable to non-PRC [REDACTED] and gains realized on the sale of our H Shares are subject to PRC tax obligations. Non-PRC individuals are generally subject to a tax rate of 20% on dividends or gains under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》). While we generally withhold 10% from dividends paid to H Share holders, this rate may vary based on applicable tax treaties or increase to 20% if no treaty applies where the holder’s identity is known. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax. Non-PRC resident enterprises without establishments or premises in the PRC, or those whose income is unrelated to their establishments or premises, are subject to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“the EIT”) at the rate of 10% on dividends and gains, unless reduced or eliminated under special arrangements or applicable treaties. Enterprises entitled to lower treaty rates will be required to apply for a refund subject to regulatory verification. The interpretation and application of the relevant PRC tax laws are subject to evolution. If any such tax is collected, the value of our H Shares may be affected accordingly.

RISK FACTORS

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

A substantial part of our assets, and a majority of our Directors and senior management, are located in China. Additionally, as the PRC does not have reciprocal treaties with many countries, you may face difficulties enforcing foreign judgments against us or our management in the PRC. On January 29, 2024, 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》) came into effect, which stipulates that 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 they remain subject to case-by-case examination by relevant courts.

Any uncertainties embedded in the legal systems of certain geographic markets where we operate could affect our business, financial condition and results of operations.

We are subject to certain uncertainties embedded in the legal systems of some geographic markets where we operate. Some jurisdictions have a civil law system based on written statutes and others are based on common law. Laws and regulations that are recently enacted may not sufficiently cover all aspects of economic activities in such markets. It may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we have in many of the geographic markets where we operate. Local courts where we operate may have discretion to reject enforcement of foreign awards or arbitration awards. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or claims. In addition, the regulatory uncertainties in different jurisdictions may be exploited through unmerited or frivolous legal actions, claims concerning the conduct of third parties, or threats in attempt to extract payments or benefits from us. Furthermore, many of the legal systems in the geographic markets where we operate are based in part on their respective government policies and internal rules, some of which are not published on a timely basis or at all and may have retroactive effects. There are other circumstances where key regulatory definitions are unclear or not published. As a result, we may not be aware of our violation of certain policies or rules until sometime after the violation. In addition, administrative and court proceedings in certain of our geographic markets may be protracted, resulting in substantial costs and diversion of resources and management attention.

OTHER 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 pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

RISK FACTORS

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

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees. In recent years, the average labor cost in the global pharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. In addition, share-based compensation granted under our existing or future share-based incentive arrangements and scheme could adversely affect our costs and our results of operations. See also “— Risks Relating to Our Financial Position and Need for Additional Capital — Share-based payments may impact our financial performance and cause shareholding dilution to our existing Shareholders.” We may also face labor shortages, higher employee turnover rates, or labor disputes, which could materially adversely affect our results of operations.

[REDACTED]

Our legal right to certain properties may be challenged.

Pursuant to the applicable PRC laws and regulations, property lease contracts must be registered with the local branches of the Ministry of Housing and Urban Development. As of the Latest Practicable Date, eight lease agreements of our leased properties which are leased from third parties and used for production or office use had not been registered and filed with relevant land and real estate management departments in China. As advised by our PRC Legal Advisor, failure to register does not in itself invalidate the leases, but 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. 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 condition and results of operations. In addition, as of the Latest Practicable Date, we had not obtained the real estate ownership certificates for two properties occupied by us used for dormitories and warehouses, with an aggregate GFA of approximately 279.52 sq.m., representing around 0.2% of the total GFAs of our owned properties. These properties are primarily used for dormitories and warehouses and are not directly related to our production and operations. Our

RISK FACTORS

Controlling Shareholder has committed to compensating us for any losses incurred in connection with these properties. Based on the above, we believe that the title defect will not have a material adverse impact on production and business operations.

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

We maintain insurance policies that are required under relevant laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. See “Business — Insurance” for details. However, our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

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.

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

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, are 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. We may fail to promote our brands effectively to remain competitive. In addition, we may engage various third parties, such as distributors, 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 misconduct by us, our business partners or our affiliates, could harm our reputation 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.

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

The manufacturing of therapeutic biological products usually involves cultivation steps, including growth of the appropriate organism and the use of substances of animal origin, which increases the risk of introducing and amplifying contaminants. In addition, cross-contamination could result from manufacturing activities at shared equipment and facilities, or from linked diagnostic and research activities. Furthermore, improper actions during the long-distance transportation, storage and delivery services may also result in contamination. In the event of contamination or injury resulting from such contamination, we could be subject to liabilities for any

RISK FACTORS

resulting damages to patients, product recalls, confiscation and/or destroy. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with laws and regulations. In addition, contamination of our products could cause customers or other third parties with whom we conduct business to lose confidence in our products’ quality and the reliability of our manufacturing procedures, which could adversely affect our sales and profits.

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

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of: (i) natural disasters such as floods, earthquakes, or fires; (ii) widespread health epidemics; (iii) power, water, or fuel shortages; (iv) information system malfunctions or unexpected technical problems; and (v) wars or terrorist attacks. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in the regions where we operate could materially disrupt our business and operations, resulting in, among other things, adverse effects on the economy, potential delays to our ongoing and future clinical trials, and disruptions to the operations of our business partners.

RISKS RELATING TO THE [REDACTED]

Our A Shares were listed in China in January 2023, and the characteristics of the A share and H share markets may differ.

Our A Shares were listed on the SSE STAR Market in January 2023. Following the [REDACTED], our A Shares will continue to be traded on the SSE STAR Market and our H Shares will be [REDACTED] on the Stock Exchange. Under current PRC laws and regulations, our H Shares and A Shares are neither interchangeable nor fungible, and there is no trading or settlement between the H Share and A Share markets. With different trading characteristics, the H Share and A Share markets have divergent [REDACTED], [REDACTED] and [REDACTED] bases, as well as different levels of retail and institutional [REDACTED] participation. As a result, the trading performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the [REDACTED] of our H Shares, and vice versa. The fluctuations in the price of our A Shares may also affect our [REDACTED] in Hong Kong. Due to the different characteristics of the H Share and A Share markets, the historical prices of our A Shares may not be indicative of the performance of our H Shares. You should therefore not place undue reliance on the trading history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

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

Prior to the completion of the [REDACTED], there has been no [REDACTED] for our H Shares. The [REDACTED] for our H Shares to [REDACTED] will be the result of negotiations between us and the [REDACTED] (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the post-[REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares. We cannot assure you that a [REDACTED] for our H Shares with adequate [REDACTED] and [REDACTED] will develop and be sustained, or that the [REDACTED] will not decline following the [REDACTED]. The [REDACTED] and [REDACTED] of our H Shares may be volatile due to a number of factors, including: (i) variations in our financial results; (ii) new investments, collaborations or acquisitions; (iii) unexpected business interruptions; (iv) changes in management and key personnel; (v) regulatory or competitive issues; (vi) political, economic and social developments; and (vii) fluctuations in market prices for our products or raw materials. Moreover, pharmaceutical stocks have experienced significant [REDACTED] volatility unrelated to corporate performance in the past, and our H Shares may be similarly affected.

RISK FACTORS

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

The [REDACTED] of our H Shares may be highly volatile and could be subject to significant fluctuations. In addition, the [REDACTED] of our H Shares may fluctuate, which may cause significant [REDACTED] variations. Some of the factors that could negatively affect the [REDACTED] of our H Shares, or result in fluctuations in the [REDACTED] or [REDACTED] of our H Shares following the [REDACTED] include: (i) variations in our financial results or failure to execute our strategies; (ii) business interruptions or loss of key personnel; (iii) intellectual property disputes, litigation, or governmental investigations; (iv) adverse regulatory changes affecting our operations; and (v) broader macroeconomic conditions, market reactions to our financing activities, or fluctuations in peer valuations.

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value. In order to expand our business, we may consider [REDACTED] and [REDACTED] additional Shares in the future. [REDACTED] of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we [REDACTED] additional Shares in the future at a [REDACTED] which is lower than the net tangible asset value per Share at that time. Furthermore, we may [REDACTED] Shares pursuant to the share incentive schemes, which would further dilute Shareholders’ interests in our Company.

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

The [REDACTED] of our H Shares could decline as a result of substantial future [REDACTED] of our H Shares or other securities relating to our Shares in the [REDACTED]. Such a decline could also occur with the [REDACTED] of new Shares or other securities relating to our Shares, or the perception that such [REDACTED] or [REDACTED] may occur. Future [REDACTED], or perceived [REDACTED], of substantial amounts of our Shares could materially and adversely affect the [REDACTED] of our H Shares.

Our Controlling Shareholder has significant influence over our Company and his interests may not be aligned with the interest of our other Shareholders.

Immediately following the completion of the [REDACTED], our Controlling Shareholder will directly hold approximately [REDACTED]% of our total [REDACTED] Shares. Through voting power and Board representation, they have significant influence over our business and affairs, including decisions on mergers or other business combinations, acquisition or disposition of assets, [REDACTED] of additional shares or other equity securities, timing and amount of dividend payments, and our management. Their interests may not align with minority Shareholders, and they could block beneficial transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, potentially depriving Shareholders of a takeover premium and reducing our H Share [REDACTED].

Our historical dividends may not be indicative of our future dividend policy, and there can be no assurance that we will declare and distribute any amount of dividends in the future and you may have to rely on price appreciation of our H Shares for return on your [REDACTED].

During the Track Record Period, we did not distribute dividends. Our historical dividends may not be indicative of our future dividend policy. There can be no assurance that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors depending on, among other considerations, our business and financial

RISK FACTORS

performance, cash requirements and availability, capital and regulatory requirements and general business conditions. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you [REDACTED] the H Shares. You may not realize a return on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

Certain facts, forecasts and statistics in this document derived from third-party reports or publicly available sources may not be fully reliable.

Certain facts, forecasts, and other statistics in this document relating to the economy and the industry in which we operate our business are obtained from official government sources. The information from official government sources has not been prepared or independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], or any of our or their respective affiliates or advisors or any other parties involved in the [REDACTED], and, therefore, we cannot assure you as to the accuracy of such facts and statistics from official government sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon. Further, there can be no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as may be the case in other jurisdictions. You should consider carefully how much weight or importance you should attach to or place on such information or statistics from official government sources.

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

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

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

As our A Shares are listed on the SSE STAR Market, we publicly release information relating to us based on PRC requirements on the Shanghai Stock Exchange or other media outlets designated by the CSRC. However, these standards may differ from those applicable to the [REDACTED], and previously disclosed financial and operational information may not be directly comparable to this document. Therefore, prospective [REDACTED] in our H Shares should rely only on the financial, operating and other information included in this document. By applying to [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and any formal announcements made by us in Hong Kong with respect to the [REDACTED].

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

This document contains certain statements and information that are forward-looking and uses forward-looking terminology such as “aim,” “anticipate,” “believe,” “could,” “predict,” “going forward,” “intend,” “plan,” “project,” “seek,” “expect,” “may,” “should,” “would” or “will” and the negative of these terms as well as similar expressions. Reliance on any forward-looking statements involves risks and uncertainties and assumptions could prove inaccurate and as a result, the

RISK FACTORS

forward-looking statements based on those assumptions could also be incorrect. These statements should not be regarded as representations or warranties by us that our plans will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the Listing Rules, we do not intend publicly to update or otherwise revise these forward-looking statements. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

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

We may be subject to press and media coverage prior to the completion of the [REDACTED]. This coverage may include certain financial information, industry comparisons, profit forecasts and other information about us that does not appear in this document. We do not accept any responsibility for the accuracy or completeness of such media reports, nor the fairness or appropriateness of any forecasts or views expressed. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their [REDACTED] decisions regarding the [REDACTED]. You should rely only 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 [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong.