

RISK FACTORS

You should carefully consider all of the information in this document and, in particular, the risks and uncertainties described below, before making an investment in our H Shares. We are affected materially by requirements and restrictions that arise under laws, regulations, judicial interpretations and government policies in nearly all aspects of our businesses in the jurisdictions where we operate.

The risks described below are not the only risks that may affect us or our [REDACTED]. Additional risks and uncertainties of which we are not aware or that we currently believe are immaterial may also adversely affect our business, results of operations, financial condition and growth prospects. If any of the possible events described below occurs, our business, results of operations, financial condition and growth prospects could be materially and adversely affected. The market prices of our H Shares could decline owing to any of these risks, and you may lose all or part of your investment.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Research and Development

If we fail to complete clinical development, obtain regulatory approvals and commercialize our product candidates, our competitiveness could be reduced and our business, financial condition and prospects could be materially and adversely affected.

Our long-term competitiveness depends on our ability to enhance existing products and to discover, develop and commercialize new pharmaceutical products that address significant unmet medical needs. The development of innovative drugs is inherently uncertain, lengthy and costly. There is no assurance that our research and development efforts will succeed, that our product candidates will demonstrate adequate safety and efficacy, that we will obtain regulatory approvals on the timelines we anticipate (if at all), or that any approved products will achieve commercial success.

As of the Latest Practicable Date, we had seven product candidates in clinical stage and eight in preclinical stage. Of these, three product candidates had been approved by the FDA to initiate clinical trials; three were in Phase III clinical trials; and four were in Phase II or Phase I clinical trials. Several product candidates were in preclinical stage. The scope, timing and outcome of these product candidates are inherently uncertain and subject to change, and we may delay, modify or discontinue development in response to emerging data, regulatory feedback, manufacturing considerations, resource allocation or other factors. Before obtaining required approvals, our product candidates must successfully complete preclinical studies and extensive clinical trials to demonstrate safety and efficacy in humans. Clinical trials are expensive, difficult to design and implement, time consuming and inherently uncertain, and results from preclinical studies, early stage trials or interim analyses may not be predictive of later phase or final outcomes. Regulators may also require additional studies or data, and product candidates that appear to perform satisfactorily in clinical trials may still fail to obtain regulatory approval. In particular, while we have not obtained regulatory approval for the commercialization of a proprietary self-developed product since 2001, when our product CLOBICO received regulatory approval, this primarily reflects our strategic prioritization of resource allocation, portfolio optimization and in-licensing opportunities during the relevant period. Drug discovery and development remain inherently complex and uncertain, and we continue to advance our pipeline with a view to achieving future regulatory approvals.

In addition, GB18 targets the same pathway and indication as certain competing product candidates, including Pfizer’s Ponesimab, which is currently in a later clinical phase. If Pfizer or other competitors obtain marketing approval for their GDF15-targeting therapies in China or the United States ahead of us, such earlier approvals may affect the competitive landscape for GB18,

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including the timing of market entry, potential market share, pricing expectations and commercial positioning. Although we expect such developments and do not anticipate any change to our internal development plan, there is no assurance that GB18 will achieve comparable clinical outcomes, regulatory progress or commercial acceptance. Any such approval by competitors ahead of GB18 could reduce the addressable market available to us at launch and may adversely affect our business, financial condition and prospects.

Achieving development milestones is critical to our ability to launch products and meet our strategic objectives, but the timing of these milestones may differ significantly from our plans due to factors beyond our control, including delays or failures in preclinical studies or clinical trials, challenges in maintaining or establishing relationships with research or co development partners, uncertainties inherent in the regulatory approval process, changes in regulations or government policies, and delays in production or marketing arrangements necessary for commercialization. If we fail to achieve one or more milestones as expected, we may incur additional expenses, experience delays in product launches, be required to recognize impairment charges on intangible assets, suffer reputational harm, and our market position, revenue and profitability could be materially and adversely affected.

The regulatory approval process for our product candidates with the NMPA and other comparable regulatory authorities is lengthy, expensive and unpredictable; any failure or delay in obtaining required approvals could materially and adversely affect our business, financial condition, results of operations and prospects.

Advancing our product candidates through the regulatory process requires substantial time, effort and financial resources, and there can be no assurance that any product candidate will obtain marketing approval. The timing of reviews by the NMPA and other comparable regulatory authorities is difficult to predict and depends on numerous factors, including the exercise of regulatory discretion. Our product candidates may not obtain timely approval, or approval at all, for reasons that include, among others: (i) inability to initiate or complete clinical trials due to disagreements with regulatory authorities; (ii) failure to adequately demonstrate safety, efficacy, or purity of the pipeline project for the intended indication; (iii) clinical trial results not meeting the statistical significance required for approval; (iv) issues with the integrity of clinical trial data; (v) regulatory authorities disagreeing with our interpretation of preclinical or clinical data; (vi) failure to strictly comply with regulatory requirements or trial protocols; or (vii) non-compliance, protocol deviations, or early withdrawal by clinical institutions, investigators, or other participants.

In addition, the NMPA or other comparable regulatory authorities may request additional information (including further analyses, reports, data, non-clinical studies, or clinical trial results) to support the approval process. This may lead to extended or delayed approval timelines, hinder commercialization, or even prompt us to terminate related R&D projects. Regulatory laws and guidelines may also change, requiring us to revise the submitted clinical trial protocols accordingly. Resubmissions may further increase trial costs, prolong timelines, or affect the successful completion of trials. Changes in regulatory policies may also introduce uncertainty, and failure to adapt to new requirements or maintain compliance may prevent us from obtaining or retaining regulatory approvals, thereby impacting profitability.

Moreover, clinical trial results obtained in one country may not be recognized by regulatory authorities in other countries, and approval in one jurisdiction does not guarantee approval elsewhere. Approval procedures may vary significantly across countries and often involve additional testing, inspections, and administrative reviews. We cannot guarantee that we will meet the requirements of different regulatory systems or that our pipeline projects will be approved for marketing in all target markets. Even if approval is granted, we may still need to invest additional time and resources to realize commercialization.

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Delays in, or termination of, clinical trials or regulatory reviews can increase development costs, postpone potential approvals and commercialization, narrow the window of market opportunity, and adversely affect our ability to generate revenue from the affected product candidate. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

Adverse events associated with our product candidates may lead to the interruption, delay or termination of clinical trials and delay or prevent regulatory approval; even after approval, such events may restrict commercialization and could adversely affect our business prospects.

If our product candidates, whether used alone or in combination with other products, cause adverse events, the consequences could include, among others: (i) regulatory authorities may interrupt, delay, or terminate the ongoing clinical trials; (ii) if trial results indicate that the severity or incidence of certain adverse events is unacceptably high, the regulatory authorities may require us to halt further development or delay or even deny approval for any or all intended indications; (iii) regulatory authorities may revoke or suspend marketing authorization for approved products, or we may voluntarily take such actions even without regulatory mandate; (iv) regulatory authorities may require additional warnings on product labels, issue safety announcements or other relevant information, or impose further restrictions; (v) we may be forced to suspend, delay, or revise development and commercialization plans for the product candidate; (vi) we may need to develop or revise risk assessment and mitigation strategies to meet updated regulatory requirements; (vii) we may be required to change the product's route of administration or conduct post-marketing studies; (viii) patient recruitment may be slower than expected, or dropout and loss-to-follow-up rates may exceed expectations; (ix) clinical trial costs for the product candidate may increase significantly; (x) if the product candidate causes harm to patients, we may be forced to recall the product and face lawsuits or regulatory investigations; or (xi) additionally, our corporate reputation could suffer serious damage. Any of the above circumstances could hinder market acceptance of our approved products or diminish their commercial potential, thereby having a material adverse impact on our operations, financial performance, and future development.

Results from preclinical studies and early-stage clinical trial results cannot guarantee the success in later-stage clinical trials.

Results from preclinical studies and early-stage clinical trials do not guarantee success in later-stage trials, and positive preliminary or mid-stage findings may not translate into favorable final results. Even if a product candidate advances beyond preclinical and early clinical stages, it may still fail to demonstrate the expected safety or efficacy in subsequent trials. Differences across trials may arise from protocol modifications; variations in sample size and patient characteristics (including genetic factors); differences in patient adherence; changes in trial design elements; varying dropout rates; or differences in trial sites and the number of participating countries. In addition, as drug development progresses through preclinical and clinical phases before approval and commercialization, elements of the development plan (such as manufacturing processes or formulation) are typically refined during the process, which may affect trial outcomes. Evolving standards of care may also alter patient characteristics or resistance profiles, affecting efficacy and increasing the risk that results will not meet expectations. Future clinical results may differ from early-stage findings and could be unfavorable; even where later trials show efficacy, not all patients may benefit. As a result, the results of planned or future trials may deviate significantly from expectations and may delay clinical development, regulatory approval or commercialization of a product candidate. We may already have invested substantial resources, and if a product candidate ultimately fails to obtain regulatory approval due to unsatisfactory trial results, we may be unable to generate any revenue from it and may not recover our investment. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

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We may not be able to respond sufficiently or in a timely manner to rapid scientific and technological changes, evolving clinical demand and market developments in the pharmaceutical industry.

The pharmaceutical industry is characterized by rapid advances in science and technology and the continuous emergence of new treatment options. Our future success depends on our ability to develop and launch new products that meet evolving market demand, including products that are effective in treating or diagnosing emerging diseases. We cannot assure you that we will be able to respond to emerging or evolving trends by enhancing our product portfolio, technology platforms and R&D capabilities in a timely manner.

In addition, clinical demand for pharmaceutical products may change rapidly. Our success depends on our ability to adjust our R&D plans, production scale and schedules, product portfolio and inventory levels in response to clinical demand, customer preferences, sales trends and other market conditions in a timely manner. There can be no assurance that we will be able to respond sufficiently and promptly to changes in clinical demand and other market conditions in the future, and any such failure could have a material adverse effect on our business, financial condition, results of operations and profitability.

Data and information we gather in our R&D activities may be inaccurate or incomplete, which could affect the clinical development of our product candidates and harm our business, reputation, financial condition and results of operations.

We receive, collect and analyze data and information from our preclinical studies and clinical trials. Because data in the pharmaceutical industry are often fragmented in origin, inconsistent in format and incomplete, overall data quality is subject to challenges, and the extent of missing or omitted data, whether known or unknown, can be material. Consequently, we may discover issues or errors during data monitoring and auditing. Errors in the capture, entry, aggregation, analysis or interpretation of data could materially and adversely affect our ability to advance our product candidates, and our business, prospects and reputation could suffer.

We also manage and submit data to governmental agencies to obtain regulatory approvals. These processes and submissions are governed by complex data-processing and validation requirements. Notwithstanding such requirements, interim, top-line or preliminary clinical data that we release from time to time may change as additional patient-level data become available and as audit and verification procedures are completed. Such changes could expose us to claims, penalties or other liabilities if a patient, court or government agency concludes that our storage, handling, submission, delivery or presentation of data was improper or erroneous. Although we maintain clinical trial insurance, coverage may be inadequate. Even successful claims could result in substantial costs and the diversion of management time, attention and resources. A claim brought against us that is uninsured or underinsured could harm our business, financial condition and results of operations.

In addition, we engage certain third parties to monitor and manage data for our clinical trials. If any of these third parties do not perform to our standards in terms of data accuracy or completeness, data from those clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “— If we, our employees, affiliates or business partners engage, or are perceived to engage, in misconduct or other improper activities, including corrupt practices and non-compliance with regulatory standards and requirements, our business or reputation could be harmed, and we could be exposed to regulatory investigations, costs and liabilities.”

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Risks Relating to Market and Commercialization

Our current revenue and profits mainly rely on certain pharmaceutical products. Decreases in sales volume or pricing and changes in our cost structure could adversely affect our revenue and profitability.

During the Track Record Period, we derived a significant portion of our revenue and gross profit from certain of our pharmaceutical products. For details, see “Business — Our Products and Product Candidates — Major Commercialized Products.” If revenue or gross profit from any of these products declines materially, our financial condition and results of operations could be adversely affected.

In addition, our revenue and profitability depend largely on the commercial performance of these products, and we may be particularly susceptible to factors that adversely affect their sales volumes, pricing or costs, including, among others: (i) exclusion from, delayed inclusion in or reduced coverage under government-sponsored medical insurance programs; (ii) the impact of government pricing regulation; (iii) failure to win bids in centralized tender processes required for sales to public hospitals and other relevant medical institutions; (iv) weaker supply advantages relative to substitutes and competing products; (v) interruptions in, or increased costs of, raw-material supply; (vi) product-quality issues, adverse events or negative publicity; (vii) allegations of intellectual property infringement; (viii) adverse changes or disruptions in our distribution and sales network; (ix) failure to respond to changes in the needs and preferences of healthcare practitioners and patients; and (x) unfavorable changes in policy, regulation or enforcement. Many of these factors are beyond our control, and decreases in sales volume, pricing or margins of these products could cause our revenue and profitability to decline and could materially and adversely affect our business, financial condition, results of operations and prospects.

The commercial performance and profitability of our in-licensed products are subject to uncertainty.

Some of our products are in-licensed and rely on licensors and other external counterparties for intellectual property rights, technical support, registration data, manufacturing, and sales authorization. If any such in-licensed product fails to achieve expected sales, market penetration, pricing, or cost control during commercialization, our profitability and financial performance could be materially and adversely affected. Factors that could cause these products to fall short of commercialization expectations include, among others: (i) Real-world performance and post-approval requirements. Efficacy, safety, tolerability or convenience in real-world settings may differ from clinical trial conditions, and products may face stricter labeling, additional safety warnings or further review requirements; (ii) Pricing and reimbursement. Policy controls, reimbursement systems and centralized procurement/tendering may constrain pricing or limit coverage, reducing competitiveness; (iii) Competition. Similar or substitute products may be launched around the same time; competitors with more favorable pricing, broader indications or stronger brand recognition may limit market share; (iv) Distribution and promotion. Acceptance by hospitals and physicians, prescribing habits, and the level of promotional resources, academic support and market-education efforts may fall short of expectations; (v) Manufacturing and supply chain. Product-specific process, quality or raw-material requirements may drive higher-than-budgeted costs or expose the supply chain to delays or instability, compressing margins; (vi) Market access and timeline. Additional time may be required to complete registration or approval steps and to obtain regional or national market access, reimbursement coverage or sales licenses, which could delay revenue recognition and affect impact the profitability cycle; and (vii) External environment. Changes in laws and regulations, shifts in market demand, public-health events, macroeconomic deterioration, exchange-rate volatility or tariffs/trade barriers could reduce market expectations or increase operating costs. If one or more of the foregoing occur, our in-licensed products may not achieve targeted sales volumes, margins or market share, which could adversely affect our revenue, profitability, business and prospects.

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We are exposed to specific risks related to overseas commercialization.

We sell pharmaceutical products in overseas markets. We have established commercial relationships with several overseas partners and plan to further expand our international business. If we fail to obtain applicable licenses or to enter into strategic collaboration arrangements with third parties in our target overseas markets, or if such arrangements are unsuccessful, our revenue growth potential could be adversely affected.

Our global expansion may expose us to risks and uncertainties, including: (i) compliance with unfamiliar policies and procedures that may differ materially from those in the PRC or other jurisdictions where we operate, in order to obtain the permits, licenses and approvals necessary to manufacture or import, market and sell products in overseas jurisdictions; (ii) ongoing compliance with laws and regulations in foreign jurisdictions; (iii) changes in the political or cultural climate or economic conditions of specific countries or regions, such as political instability, inflation, currency fluctuations, unexpected changes in tariffs, trade barriers and regulatory requirements; (iv) challenges in commercializing products in new markets where we have limited experience with local dynamics and no established sales, distribution or marketing infrastructure; (v) increased expenses or diversion of management attention due to efforts to enter into collaboration or licensing arrangements with third parties for international sales, marketing and distribution; (vi) increased risk of product liability litigation and regulatory scrutiny arising from marketing and sales in overseas markets, the costs of responding to such matters, and potential limitations on the availability or scope of insurance coverage; (vii) potentially reduced protection for intellectual property rights and exposure to third-party infringement claims; (viii) compliance with tax, employment, immigration and labor laws; (ix) the possibility of parallel imports whereby local retailers, faced with higher domestic prices, may opt to import goods from lower-priced markets rather than purchasing locally; and (x) business interruptions resulting from geopolitical events such as war or terrorism, natural disasters including earthquakes, volcanic eruptions, typhoons, floods, hurricanes and fires, or epidemics. These and other risks could materially and adversely affect our ability to attain or sustain revenue from international markets. If we are unable to successfully implement our global expansion strategies, our business prospects could be adversely affected.

We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors, which could materially and adversely affect our revenue and profitability.

We operate in a highly competitive environment. Failure to compete effectively could result in lower sales, price reductions and loss of market share, any of which could materially and adversely affect our results of operations and prospects. Our products primarily compete on efficacy, safety, price and overall market acceptance. Our competitors include large domestic and international pharmaceutical companies, as well as smaller emerging pharmaceutical and biotechnology companies. We face intense competition in the development of innovative drugs. Some competitors have greater resources, experience and capabilities in R&D, regulatory affairs, manufacturing, commercialization and global partnerships. In light of the intense competition, we may not be able to compete effectively and obtain substantial market share even if we successfully complete the development and commercialization of our product candidates. We anticipate that we will face increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunities could be significantly reduced if competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than those drugs we develop or commercialize. Our competitors may also obtain approvals from the NMPA or other comparable regulatory authorities more rapidly than we do, establishing strong market positions before we are able to enter the market and putting our product candidates at a competitive disadvantage, potentially delaying or preventing recovery of our development and commercialization expenses.

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Our products may also face increased competition from substitute products manufactured overseas that seek to access or further penetrate the PRC market. To the extent such products are, or are perceived to be, more clinically or cost effective than ours, or if imported products are preferred over domestically manufactured products, our sales volumes, pricing and market share could be adversely affected, which could materially and adversely affect our results of operations and prospects.

Our ability to sell our products to public hospitals and other relevant medical institutions in China depends on centralized tender and VBP processes, and PRC pricing regulation and other policies intended to reduce healthcare costs may exert significant downward pressure on our product prices, which could adversely affect our revenue, profitability and market share.

Most pharmaceutical products sold to public hospitals and other relevant medical institutions in China are procured through competitive centralized tender processes, under which we submit bids to supply products at specified prices and are evaluated based on, among other things, bid price (including relative to substitute products), clinical value, and the quality of our products and services. Winning tenders generally determines the prices at which we sell to such institutions and often influences the prices at which we sell to distributors, and these processes may intensify price competition for products perceived to be substitutes. If we fail to win tenders in one or more regions due to factors such as uncompetitive pricing, reduced demand, failure to meet quality or service criteria, or perceived inferior efficacy or safety, we may be unable to sell the relevant products to public hospitals and other relevant medical institutions in those regions, and our sales volume, market share, revenue and profitability could be materially and adversely affected.

In addition, prices of pharmaceutical products typically decline over the product life cycle due to factors such as the centralized tender process, pricing regulation by the PRC government and increased competition from substitute products. The PRC government has continued to implement reforms and policies intended to reduce overall healthcare costs, including changes to tendering practices and the national and provincial volume based procurement, or VBP, schemes, which are designed to secure larger procurement quantities at lower prices. While successful bidding under VBP may increase sales volume, it can require significant price reductions and may also reduce the prices at which we sell to distributors. If competitors win VBP bids while we fail to do so for products with the same generic names, demand for our products may decrease. Even if we win, actual procurement volumes may differ from estimated volumes, and the impact on sales volume and revenue may be uncertain. We cannot predict or control future policy developments, tender rule changes or the scope of products covered by VBP, and any additional downward pricing pressure could materially and adversely affect our margins, profitability, business, financial condition, results of operations and prospects.

A number of our generic products have been included in the national VBP program, provincial VBP programs and/or other VBP initiatives. As of the Latest Practicable Date, our SINOGEN (赛若金®) Human Interferon α 1b for Injection, EPOSINO (依普定®) Human Erythropoietin Injection and WHITE-C (白特喜®) Human Granulocyte Colony-stimulating Factor Injection had been selected under provincial level and provincial alliance VBP programs. In 2025, the generic products that were not subject to VBP collectively accounted for approximately 71.3% of our total revenue and 67.7% of our gross profit. For further details on the impact of VBP programs on our business, please see “Business — Product Pricing — Centralised Bidding Processes and Volume-based Procurement.” If government pricing regulation or other policies aimed at reducing healthcare costs cause our product prices to decline, our margins and profitability could be materially and adversely affected, and our business, financial condition, results of operations and prospects could suffer.

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If we fail to effectively carry out promotional activities or maintain a professional and competitive sales team, our product sales performance, operating results, revenue, profitability and overall business outlook could be adversely affected.

Efficient sales and marketing efforts are essential to further expand the market penetration of existing products, increase coverage across hospitals and other medical institutions, and support the successful launch of future products. If we are unable to continuously improve the effectiveness and execution of our sales and marketing activities, or fail to leverage experience gained from marketed products to support the promotion of innovative biologic drugs, our growth may be constrained and our sales and commercial prospects may be negatively affected.

Our sales and marketing activities focus on enhancing awareness and trust among healthcare professionals, hospitals and related institutions regarding our products and, where permissible, our product candidates. Accordingly, our sales and promotional teams must possess strong technical backgrounds, be familiar with industry trends and possess specialized knowledge in relevant therapeutic areas, as well as strong communication and promotional skills. If we are unable to effectively train our internal sales representatives or scientific marketing teams, or fail to continuously evaluate and improve their performance, our promotional activities may fall short of expectations.

In addition, attracting, motivating and retaining experienced sales and marketing professionals is important because we primarily rely on our internal team to drive product sales. Competition for qualified sales and promotional talent is intense. If we fail to remain competitive in this area and cannot attract or retain a sufficient number of qualified professionals, our product sales, hospital coverage and market penetration may be adversely affected, which could materially and adversely affect our business, financial condition, results of operations and profitability.

We may face potential disputes regarding the use of the Chinese trade name “科興”, which could adversely affect our business, brand recognition and market position.

We use the Chinese trade name “科興” in our corporate name and in connection with the marketing and promotion of certain of our products in the PRC. Sinovac Biotech Ltd. (“Sinovac”), a biopharmaceutical company that also uses the Chinese trade name “科興”, may consider our use of the same Chinese trade name as infringing upon or conflicting with its rights.

We have been using the trade name “Kexing”(科興) since January 2000, prior to the establishment of Sinovac in 2001. Our Class 5 “Kexing” trademark was filed on July 17, 2000, prior to the registration date of Sinovac.

Although we are not currently involved in any legal dispute with Sinovac regarding the use of “科興”, we cannot assure you that Sinovac will not initiate administrative complaints, civil litigation, or other actions in the future asserting its rights over the trade name.

Any such dispute, regardless of its outcome, could result in negative publicity, increased legal and administrative expenses, and diversion of management attention. If Sinovac were to succeed in challenging our use of “科興”, we could be required to cease using the trade name, rebrand part or all of our operations or products, or take other remedial steps. These actions could materially and adversely affect our brand recognition, market reputation, sales and marketing activities, and our business and results of operations.

Furthermore, uncertainty arising from any perceived or actual conflict over the trade name may also affect our relationships with customers, distributors and business partners, particularly in overseas markets where the parties’ rights and recognition of the “科興” name may differ under applicable laws. As a result, our ability to expand internationally and leverage our brand may be adversely affected.

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If we fail to maintain, expand and optimize an effective distribution network for our pharmaceutical products, our sales and business prospects could be adversely affected.

We have established a network of distributors in China and overseas markets and rely on them to deliver our pharmaceutical products, meet market demand and drive sales. In 2023, 2024, and for 2025, revenue from our five largest customers, a substantial majority of whom were our distributors, accounted for 45.1%, 44.8% and 40.4% of our total revenue, respectively. For more details on our five largest customers, see “Business — Our Customers.” Our ability to maintain and grow our business and to satisfy demand for our products depends on maintaining, expanding and optimizing a distribution network that can deliver our products to our target markets on a timely basis. However, we have limited control over third-party distributors. They may not distribute our products in the manner we expect, which could impair the effectiveness of our distribution network. In addition, our distributors may distribute other products that are substitutes for, or have the same indications as, our products, thereby giving rise to direct competition with our products.

Moreover, we typically enter into distribution agreements with our distributors for a fixed term, which requires continuous renewal of these agreements to maintain our relationships with them. Our distributors might choose not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, including adverse impact from pricing regulations in China or other jurisdictions where we operate, or other factors that limit the margins our distributors can obtain through the resale of our pharmaceutical products to hospitals, other medical institutions and retail pharmacies.

Our strategies contemplate collaborating with leading pharmaceutical distributors to leverage their channel resources and marketing networks to swiftly penetrate key markets around the globe. However, we may not be able to establish relationships on commercially acceptable terms with new distributors to cover these areas. In the event that a significant number of our distributors terminate their relationships with us, or we are otherwise unable to maintain and expand our distribution network effectively, our sales volumes and business prospects could be adversely affected. Furthermore, if a significant number of our distributors cease or reduce their purchases of our products or fail to perform their obligations under the distribution agreements, our business, financial condition and results of operations may be materially and adversely affected.

Risks Relating to Manufacture and Products

If our quality control, quality assurance or manufacturing do not meet required 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 applicable quality standards. Despite our quality management systems and procedures, we cannot eliminate the risk of errors, defects or failures. We may fail to detect or remediate quality issues due to factors that may be beyond our control, including:

- production deviations;
- technical or mechanical malfunctions in the manufacturing process;
- human error or misconduct by quality or manufacturing personnel;
- product tampering or other third-party interference; and
- quality problems in purchased or internally produced raw materials.

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In addition, as we expand our manufacturing capacity, we may be unable to ensure consistent quality across existing and new facilities without incurring substantial costs. Failure to detect quality defects in our pharmaceutical products, or to prevent defective products from reaching patients, could result in patient injury or death, product recalls or withdrawals, license suspension or revocation, regulatory fines or other consequences. Any of these could seriously damage our reputation and brand, expose us to liability and adversely affect our business, financial condition, results of operations and profitability.

A substantial portion of the key raw materials for our products is sourced from overseas, exposing us to supply chain disruptions and cost volatility amid global economic and trade uncertainty.

Key raw materials used in our production, such as cell culture media, bovine serum and certain excipients, are currently procured mainly from overseas. Although we have initiated efforts to replace certain imported materials with domestic alternatives, overseas procurement is expected to remain our primary supply channel in the near term.

Amid global macroeconomic instability, our overseas supply may experience delivery delays or supply disruptions due to logistics congestion, capacity constraints, export restrictions or other unforeseen events, and may also increase prices. Any such developments could raise our production costs, disrupt normal production and operating schedules, lead to product shortages or delays and could materially and adversely affect our business, financial condition, results of operations and prospects.

Our products may be subject to contamination risks.

Our products, particularly our therapeutic biological products, may be exposed to contamination risks. The manufacture of therapeutic biological products typically involves cultivation steps (including growth of the relevant organism) and may use substances of animal origin, which can introduce contaminants and amplify low levels of contamination. Cross-contamination may also occur when manufacturing is conducted on shared equipment or in shared facilities. In addition, improper handling during long-distance transportation, storage or delivery may result in contamination.

In the event of injury resulting from such contamination, we could face product quarantines, batch rejections, recalls or destruction, as well as suspension or shutdown of manufacturing lines. We could also incur significant costs or liabilities, including regulatory investigations, civil or criminal fines and penalties, and product-liability claims. Contamination events may erode customer and counterparty confidence in our product quality and manufacturing reliability, disrupt supply and adversely affect our sales and profitability. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

If we become subject to product liability claims, we could be exposed to substantial costs and liabilities, which could adversely affect our operations, profitability and reputation.

We are exposed to product liability risk from the development, production, marketing, promotion and sale of pharmaceutical products in the PRC and other jurisdictions where our products are or may be marketed and sold. Claims may arise if any of our products are alleged or found to be unsafe, ineffective, defective or contaminated, or if we are alleged to have engaged in practices such as insufficient or improper labeling, inadequate warnings or insufficient or misleading disclosure of side effects. There can be no assurance that we will not become subject to product liability claims or that we would successfully defend against such claims.

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If a product liability claim is brought against us, it may, regardless of merit or outcome, strain our financial resources and divert the time and attention of management. Such claims may also result in damage to our reputation, product recalls, loss of revenue and an inability to commercialize our products. If we are unable to defend against a claim and our products are found to be defective, we may be subject to civil liability for physical injury, death or other losses, as well as criminal liability and revocation of business licenses. We may be required to recall the relevant products, suspend sales or cease sales altogether. Other jurisdictions in which our products are sold, or may be sold, including more developed markets such as Europe and the U.S., may have similar or more stringent product liability and pharmaceutical regulatory regimes and more litigious environments, which may further expose us to product liability risk. Even if we successfully defend against such claims, doing so may require significant financial resources and management attention.

Negative results from off-label use of our products could materially and adversely affect our business, reputation, brand and results of operations, and could expose us to liability.

Products distributed or sold in the pharmaceutical market may be prescribed for uses that are not consistent with the approved labeling, including unapproved indications, patient populations, dosages, dosage forms or routes of administration. The NMPA and other comparable regulatory authorities actively enforce laws restrictions on off-label use, and companies found to have improperly promoted off-label uses may face significant liabilities. Although we do not promote off-label uses and we maintain compliance policies and training, we cannot prevent physicians from prescribing our products off-label. Off-label use may render a product less effective or ineffective or, may result in adverse events, which could lead to negative publicity, reduced sales, product liability claims, regulatory inquiries or enforcement actions, fines or penalties, additional labeling or use restrictions, and reputational harm. Any of these events could materially and adversely affect our business, reputation, brand and results of operations.

Risks Relating to Policy and Regulations

If our products are not timely included in, or are removed or excluded from, national, provincial or other government-sponsored medical insurance programs, our revenue and profitability could be adversely affected.

Insurance coverage is a critical factor in a patient’s ability to afford treatments. If a pharmaceutical product is covered by medical insurance, whether provided by the government or a commercial insurer, patients may receive reimbursement for all or a portion of the cost. For instance, in the PRC, government-sponsored medical insurance programs reimburse patients for pharmaceutical products listed in the NRDL or relevant provincial medical insurance catalogs, or special drugs for critical illnesses included under provincial insurance programs. Consequently, the inclusion or exclusion of a pharmaceutical product in or from such programs, or any limitation on their coverage could significantly affect patient demand for our pharmaceutical products. Any delay in inclusion of our products in the NRDL or other government-sponsored medical insurance programs may adversely affect their market adoption and sales growth.

The decision to include pharmaceutical products in insurance coverage depends on various factors, including efficacy, safety and price, which may be beyond our control. Moreover, government authorities may, from time to time, review and adjust the scope of reimbursement for products that are listed in any medical insurance catalog. For example, in the PRC, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security, together with other government authorities, regularly review the inclusion or removal of drugs from the NRDL. If our products are not timely included in relevant government-sponsored medical insurance programs, or if they are removed from these programs, or if the scope of reimbursement is reduced, demand for our products may decrease, which could adversely affect our revenue and profitability. See “Business — Product Pricing — National Reimbursement Drug List” for more information on the NRDL’s impact on us.

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All material aspects of our operations are heavily regulated, and any failure to comply with these regulations could materially and adversely affect on our business.

We operate primarily in the PRC and have an increasing global presence, including sales to multiple EU and emerging markets, localized overseas operations and other international collaborations. The pharmaceutical industry in the PRC and certain overseas markets is strictly regulated across product development and approval, manufacturing and quality management, sales and marketing. For example, the NMPA or other relevant authorities may conduct announced or unannounced inspections of our facilities to monitor compliance, and we cannot assure you that we will pass all such inspections. Differences among regulatory regimes also increase complexity and compliance costs for a company expanding globally.

The pharmaceutical industry is subject to extensive government regulation and supervision that cover virtually all aspects of a pharmaceutical company’s operations. Violations of applicable laws, rules or regulations may constitute criminal offenses in certain circumstances. Specific laws, rules and regulations may affect the pricing, demand and distribution of our products, including those governing procurement, prescription and dispensing of essential and other drugs by hospitals and other medical institutions, retail pharmacies, government funding for private healthcare and medical services, and inclusion of products in national or provincial reimbursement catalogs. In addition, the pharmaceutical manufacturing, distribution and retail sectors, as well as healthcare services and medical devices, are subject to extensive and evolving regulation and supervision. Changes in these regulations could increase our compliance costs and could materially and adversely affect our business, profitability and prospects.

Obtaining regulatory approvals and maintaining ongoing compliance in different jurisdictions require significant time and financial resources. Failure to comply with applicable requirements in the jurisdictions where we operate or intend to operate at any stage of development, approval or post-approval may subject us to administrative or judicial sanctions, including refusal to approve pending applications, revocation of approvals, withdrawal of licenses, suspension of clinical trials, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusal of government contracts, restitution, disgorgement, and civil or criminal penalties. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

Any failure to comply with existing laws, regulations or industry standards could also result in fines or other penalties, termination of ongoing research, disqualification of data submitted to regulators, or bans on future product sales, each of which could have an adverse impact on our reputation, business, financial condition, results of operations and prospects. Even if we successfully defend against any action or investigation, we could incur significant legal expenses, management time and attention could be diverted from operations, and our reputation and financial results could be adversely affected.

Even after we obtain regulatory approval to market our product 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.

Our product candidates, once approved, will be subject to ongoing or additional regulatory requirements of the NMPA or other comparable regulatory authorities, including those relating to production, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and conduct of post-marketing studies. These requirements also include submissions of safety, efficacy and other post-marketing information and reports, registration, as well as continued compliance with the applicable GMP and GCP, for any clinical trials that we conduct post-approval.

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Any approvals that we receive for our product candidates may be subject to limitations on the indications approved for which the drugs may be marketed, which could adversely affect the drugs’ commercial potential. In addition, the approvals may contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidates. The NMPA or other comparable regulatory authorities may also require a post-approval risk evaluation and mitigation strategy program as a condition of approval of our product candidates.

Once a drug is approved by the NMPA or other comparable regulatory authorities for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including issues with production processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA or other comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. Accordingly, we must continue to expend time, costs and efforts in all areas of regulatory compliance, including production and quality management. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or other jurisdictions, especially when the regulatory environment is constantly evolving. 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.

Economic sanctions, export controls, anti-corruption, anti-bribery, anti-money laundering and other relevant laws and regulations may expose us to potential compliance risks.

During the Track Record Period, we generate an increasing portion of our revenue from overseas sales, which accounted for 11.0%, 16.0% and 23.9% of our total revenue relating to pharmaceutical products in 2023, 2024 and 2025, respectively. We are subject to economic sanctions, export controls, anti-corruption, anti-bribery, anti-money laundering and other relevant laws and regulations in the countries and regions where we have business operations. Any violation of these laws or regulations could result in governmental or regulatory investigations, civil or criminal fines or other sanctions, whistleblower complaints and adverse publicity, which could have an adverse effect on our reputation, business, operating results and prospects. In addition, responding to any enforcement action may result in a significant diversion of management’s attention and significant defense costs and other professional fees.

The U.S., the United Kingdom and other jurisdictions or organizations, including the EU and the United Nations, have, through executive orders, passing of legislation or other governmental means, implemented measures that impose economic sanctions or export control restrictions on certain countries or jurisdictions, persons or organizations within these countries or jurisdictions, or targeted industry sectors, groups of companies, or persons. There can be no assurance that we will be able to prevent or detect all inadvertent business dealings with sanctioned parties or the

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dispatch of freight to higher-risk or prohibited end-uses. We cannot predict the interpretation or implementation of government policies in the U.S. at the federal, state or local levels or any policy of the United Kingdom, the European Union, the United Nations and other applicable jurisdictions with respect to any current or future activities by us or our business partners in countries subject to international sanctions or otherwise sanctioned, or our business activities subject to export control restrictions. As a result, we cannot assure you that our future business will be free of risk under sanctions or export control restrictions implemented in these jurisdictions or that we will conform our business to the expectations and requirements of the authorities of the U.S. or any other government or organization that, with or without jurisdiction over our business, assert the right to impose sanctions or export control restrictions on an extraterritorial basis. Our business and reputation could be adversely affected if the authorities of the U.S., the United Kingdom, the European Union, the United Nations or any other government or organization were to determine that any of our activities constitutes a violation of the sanctions or export control restrictions. In addition, as many sanction programs are constantly evolving, new requirements or restrictions could come into effect, which might increase scrutiny of our business or result in additional compliance risks.

Risks Relating to Collaboration, Licensing, and Intellectual Property

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

We are required to obtain, maintain and renew various licenses and permits to develop, produce, promote, and sell our pharmaceutical products. Our business partners, such as suppliers, distributors, licensing collaboration partners, and other third-party contractors, on whom we may rely to develop, produce, promote, sell and distribute our products, may be subject to similar requirements. For details, see “Business — Legal and Compliance — Licenses, Permits and Certificates.” We and our business partners may be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of, permits, licenses and certifications may change from time to time, and there can be no assurance that we or parties whom we cooperate with will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties whom we cooperate with fail to maintain or renew material permits, licenses and certifications, it could materially impair our ability to conduct our business. While we have always been able to maintain and renew our material permits, licenses and certificates, there is no assurance that we will be able to continue doing so in the future.

Any changes in the standards used by government authorities in considering whether to renew or reassess our licenses, permits and certificates, as well as any enactment of new regulations that may restrict the conduct of our business, may decrease our revenue and increase our costs, which in turn could materially and adversely affect our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws and regulations changes, or any new regulation comes into effect, so as to require us or parties whom we cooperate with to obtain any additional licenses, permits or certificates that were previously not required to operate our business, there can be no assurances that we or parties whom we cooperate with will successfully obtain such permits, licenses or certificates.

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If we are unable to adequately protect our intellectual property, or if the scope of our intellectual property fails to sufficiently protect our proprietary rights, our competitors could compete against us more effectively, 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 valuable innovations, including our products, product candidates and proprietary technologies, by obtaining, maintaining and enforcing our intellectual property rights, such as patent rights. We seek to protect our intellectual property that we consider commercially important by filing patent and trademark applications, securing pharmaceutical regulatory protection, enforcing contractual confidentiality obligations, relying on trade secrets, or employing a combination of these methods. For details of our intellectual property rights, see “Business — Intellectual Property” and Appendix VI to this document. If we fail to adequately protect our intellectual property, competitors may be able to imitate or copy our products, use our technologies and erode or negate any competitive advantage we may have, which could adversely affect our business and results of operations.

However, there are a number of risks and uncertainties related to the patent application process. Filing, prosecuting and maintaining patents or patent applications on our products or product candidates worldwide could be time-consuming and expensive, and there is no assurance that any of our pending patent applications will lead to issued patents, or that such patents, if issued, will provide us with adequate proprietary protection or competitive advantages. In addition, the patentability requirements across countries and regions vary and the laws of different countries or regions do not provide patent protection to pharmaceutical inventions to the same extent. Therefore, our patent applications may not be granted in all countries and regions, and the scope and strength of issued patents can vary globally. Moreover, different countries and regions may provide varying regulatory exclusivities to pharmaceutical products, and some countries or regions provide no regulatory exclusivities at all. Consequently, we may not be able to achieve uniform protection or exclusivities for our products or product candidates. Furthermore, given the lengthy process required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with an adequate exclusivity period for our products or product candidates.

Moreover, the patents that we hold are for a finite duration. Following the expiration of the relevant patents, our existing or future competitors may be able to develop and introduce substitute products to ours which may be identical in formulation. In the event that our competitors introduce substitutes for these products post-patent expiration, it could have an adverse impact on the sales volume and pricing levels for such products. Although extensions may be available, there is no guarantee that we will be able to secure such extensions, or that they will be extensive as requested. This might allow our competitors to obtain approval for competing products following our patent expirations. Furthermore, there are a number of factors that could cause our existing patents or other intellectual property to become invalid or unenforceable, including known or unknown prior art, deficiencies in patent applications and lack of originality in the underlying technologies. If the patents relevant to our products or product candidates were to be declared invalid or unenforceable, it could have an adverse impact on the sales volume and pricing levels for our products and our ability to successfully commercialize the product candidates.

Certain of our patents and patent applications, including those developed under our collaboration and licensing agreements, may from time to time be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in relevant patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors. In addition, we may need the cooperation of such co-owners to enforce these patents or patent applications against third parties, while these co-owners may not be willing to cooperate with us. Any of these factors could adversely affect our competitive position and results of operations.

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In addition, our employees or partners might disclose our proprietary information or trade secrets. We may be unsuccessful in securing confidentiality agreements with our employees or business partners. Our employees or partners may also breach the confidentiality clauses and disclose our trade secrets to third parties, which could adversely affect our competitive position.

We may be subject to intellectual property infringement claims, which could divert our management's attention, expose us to substantial liability, harm our reputation, limit our R&D or other business activities and impair our ability to sell our products or commercialize our product candidates.

Our success depends significantly on our ability to develop, manufacture, market and sell our products and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. We may from time to time become party to, or threatened with, adversarial proceedings or litigation in the PRC and overseas regarding intellectual property rights with respect to our technology and any products or product candidates we may develop. As the pharmaceutical industry expands and more patents are issued, the risk increases that our products or product candidates or technologies that we develop may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert infringement claims against us based on patents or other proprietary rights that we currently hold or may be granted in the future, regardless of their merit. The risk of being subject to intellectual property infringement claims will increase as we continue to expand our operations and product offerings. Additionally, as patent applications can take many years to issue, there may be pending patent applications which might eventually lead to issued patents which our products or product candidates could inadvertently infringe. Moreover, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid. As such, we may be unable to determine whether any of our products, product candidates, processes and other related matters infringe upon the intellectual property rights of others. We may from time to time receive, notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused third parties' intellectual property rights. Whether or not third-party intellectual property claims have merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. Defending against these claims, regardless of their merit, would also involve substantial litigation expenses and create a significant diversion of resources from our business. A court of competent jurisdiction could hold that these third-party patents or other intellectual property rights are valid and enforceable and infringed by us, which could materially and adversely affect our ability to commercialize product candidates we may develop and any other products or technologies covered by the asserted third-party patents or other intellectual property rights.

If we are found to have infringed on a third party's intellectual property, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party, which may not be available on commercially reasonable terms, if at all;
- acquire any necessary licenses from third parties, which could be non-exclusive, give our competitors and other third parties access to the same technologies licensed to us, and require us to make substantial licensing and royalty payments;
- defend litigation, arbitration, or administrative proceedings;
- reformulate our product or product candidate so that it does not infringe the intellectual property rights of others, which may not be possible or could be costly and time-consuming;

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- cease developing, manufacturing and commercializing the infringing products, product candidates or technologies; or
- pay such third party significant monetary damages, if we are found to have willfully infringed a patent or other intellectual property rights.

Some of our competitors may have substantially greater resources, and therefore are likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

Claims that we or our employees have misappropriated the confidential information or trade secrets of third parties could have a material adverse effect on our business, financial condition, results of operations, and prospects. Certain of our employees were previously employed at medical institutions and pharmaceutical companies, including our competitors or potential competitors. Although we endeavor to ensure that our employees do not use proprietary information or know-how of other companies during their employment with us, we may 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 employers. Litigation may be necessary to defend against these claims, and even if we are successful in litigation or administrative proceedings, such litigation and proceedings may be costly and could result in a substantial diversion of management resources.

We engage with third parties for certain aspects of our business, and any failure to perform or unsuccessful collaborations could adversely affect our business.

We rely on third parties, such as qualified medical institutions and contract research organizations (“CROs”), in certain aspects of our business, including the design and conduct of clinical trials for our product candidates as well as commercialization of our products or product candidates in specific regions. Our business will be adversely affected if business or economic conditions or future developments in applicable laws and regulations negatively impact the operations of these third parties and, consequently, result in a reduction in their provision of services to us. If these third parties, whom we do not control, do not successfully fulfill 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. In addition, if the quality or accuracy of the data we obtain from these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical activities could be delayed, and we may not be able to obtain regulatory approvals for our product candidates.

In addition, we will continue to pursue opportunities for, collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements that we believe would advance our business development. For details, see “Business — Collaboration and Licensing.” Proposing, negotiating and implementing these opportunities may be a lengthy and complex process. Our competitors, including those with substantially greater financial, marketing, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not be able to identify, secure, or complete any such transactions or arrangements in a timely manner, on acceptable terms, or at all.

Certain transactions or arrangements may also require consents, approvals or cooperation from regulators, government authorities, creditors, licensors or other stakeholders, and there is no assurance that such consents, approvals or cooperation will be obtained, in which case we may be unable to carry out the relevant transactions or arrangements.

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If we, our employees, affiliates or business partners engage, or are perceived to engage, in misconduct or other improper activities, including corrupt practices and non-compliance with regulatory standards and requirements, our business or reputation could be harmed, and we could be exposed to regulatory investigations, costs and liabilities.

We are subject to risks in relation to improper actions taken by us, our employees, affiliates or business partners. Misconduct by these individuals and institutions could include intentional, reckless or negligent conduct that violates applicable laws and regulations, including on the reporting of true, complete and accurate information and data to regulatory authorities, data privacy and security, product quality and production standards. For example, we are subject to the anti-bribery and corruption laws of China, which generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also required to comply with the U.S. Foreign Corrupt Practice Act (FCPA), which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. As our business expands globally, our exposure to the FCPA and other anti-bribery and corruption laws relevant to our operations is expected to increase. In addition, sales, marketing, and business arrangements in the pharmaceutical industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Any allegations of such behavior against us, our employees, affiliates or our business partners or even the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects.

We do not and cannot fully control the conduct of our employees, affiliates or business partners. Our employees, affiliates or business partners may conduct their sales and marketing or other activities in violation of the applicable anti-corruption, anti-fraud and other related laws. If our employees, affiliates or business partners engage in corruption, fraud or other improper conduct that result in violation of these laws in the PRC or other jurisdictions, our reputation could be harmed. While we have implemented protocols against fraud, corruption and bribery, there can be no assurance that we have been and will be able to entirely prevent our employees, affiliates or business partners from engaging in such activities. We may be held liable for actions taken by our employees, affiliates or business partners, which could expose us to regulatory investigations and penalties. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, reputational harm and divert the attention of management in defending ourselves against any of these claims or investigations. These factors could have a material adverse impact on our business, financial condition and results of operations.

We will continue to pursue collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investments or arrangements, which may fail to produce the anticipated benefits and adversely affect our operations.

We will continue to pursue opportunities for, collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements that we believe would advance our business development. For details, see “Business — Collaboration and Licensing.” Proposing, negotiating and implementing these opportunities may be a lengthy and complex process. Our competitors, including those with substantially greater financial, marketing, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not be able to identify, secure, or complete any such transactions or arrangements in a timely manner, on acceptable terms, or at all.

To the extent that we are successful in entering into such commercial arrangements, the management and integration required in relation to a licensing arrangement, collaboration, joint venture or other strategic arrangements may disrupt our current operations and divert management resources that otherwise would be available for our existing business. We may not realize the anticipated benefits of any or all of our collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements in the time frame

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expected or at all. In addition, valuations supporting our acquisitions and strategic investments could change rapidly. Following any such transaction, there could be impairments of our investments or assets we acquired, which could materially and adversely affect our business, financial condition and operating results.

Moreover, partners, collaborators, or other parties to such transactions or arrangements may fail to fully perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons and subject us to potential risks, including situations where partners, collaborators, or other parties:

- may have significant discretion in determining the efforts and resources that they will apply to a transaction or arrangement;
- could independently develop, or develop with third parties, services and products that compete directly or indirectly with the product candidates developed under the collaboration with us;
- may stop, delay or discontinue clinical trials or repeat clinical trials or conduct new clinical trials by using our intellectual property or proprietary information;
- may not properly maintain or defend our intellectual property rights, or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information, or expose us to potential liabilities;
- may have disputes with us that cause the delay or termination of the research, development, or commercialization of the product candidates developed under the collaboration with us, or result in costly litigation or arbitration that diverts management’s attention and resources; and
- may own or jointly own the intellectual property pertaining to the product candidates developed under the collaboration with us, and in such cases, deny us the exclusive right to commercialize such intellectual property.

Any such transactions or arrangements may also require actions, consents, approval, waiver, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders, or other stakeholders or interested parties. There is no assurance that such third parties will be cooperative as we desire, or at all, in which case we may be unable to carry out the relevant transactions or arrangements.

Other Risks Relating to Our Business and Industry

We incurred a loss in a certain year during the Track Record Period, and we may incur losses in future periods.

During the Track Record Period, our revenue was RMB1,259.0 million, RMB1,406.9 million and RMB1,534.0 million in 2023, 2024 and 2025, respectively. After incurring loss of RMB195.5 million in 2023, we achieved profits of RMB27.0 million and RMB152.7 million in 2024 and 2025, respectively. However, you should not rely on the revenue growth of any prior period as an indication of our future performance, as our operational and financial growth is not necessarily indicative of results that we may achieve in the future. There is a wide array of factors that will affect our performance and growth, including the overall economy, market acceptance of our products, competitive products and technologies, and pricing pressures, many of which are beyond our control. We cannot assure you that we will be able to maintain our growth at the same rate as we did in the past, or avoid any decline in the future.

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In addition, we will continue to develop new products and technologies in the future, but we cannot assure you that our efforts will be successful or generate results that meet our expectations. In 2023, 2024, and 2025, our R&D expenses was RMB344.8 million, RMB168.1 million and RMB199.6 million, respectively. As we carry on the development of new product candidates, our R&D expenses as a percentage of our total revenue may fluctuate, which may impact our results of operations. Furthermore, the pharmaceutical market, as well as applicable laws and regulations governing the pharmaceutical market, in China and other jurisdictions where we operate, are subject to further changes. As market conditions and the regulatory environment continue to evolve, we cannot assure you that our operations will continue to deliver the expected business results.

We have net cash outflows used in our operating activities in 2023, 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 RMB119.6 million in 2023. The reasons of our cash flows used in operating activities in the foregoing periods primarily include our loss for the year, which is in turn primarily attributable to our R&D 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 will need to expend substantial resources on the R&D and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to: (i) the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials; (ii) the outcome, timing and costs of regulatory approvals of our drug candidates; (iii) the progress, timing, scope and costs related to discovery and early development of additional drug candidates; (iv) the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch; (v) the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates; (vi) our effective management of our CROs and other collaboration partners and associated costs; (vii) selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities; (viii) the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights; (ix) the amount and timing of any profit sharing, milestone and royalty payments we receive from our future collaborators; (x) cash requirements of any future development of other pipeline drug candidates; (xi) our headcount growth and associated costs; and (xii) the costs of operating as a public company and our need to implement additional internal systems and infrastructure, including but not limited to financial and reporting systems.

We expect our cash operating costs to increase significantly in light of our business expansion strategies. If the financial resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us. If we were unable to obtain additional capital to meet our cash requirements in the future, our business, results of operations and prospects could be materially and adversely affected.

Our business depends on our senior management members and other key personnel, including core technical personnel. If we fail to retain our key senior management members or to attract, retain and train qualified personnel, our business prospects could be adversely affected.

Our success depends heavily upon the continued services of our senior management members, key R&D personnel and key sales and marketing personnel. In particular, the industry experience, management expertise and contributions of our Directors and other members of our senior management are crucial to our success. They play a crucial role in the development and commercialization of our products and realization of the potential benefits of our intellectual

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property. In addition, success in the pharmaceutical distribution and pharmaceutical retail of our products depends on the dedication and skills of our sales and marketing personnel. Accordingly, our ability to attract and retain key personnel is a critical factor in our competitiveness.

Although we have employment agreements with each of our senior management members, these agreements do not prevent our executives from terminating their employment with us at any time. If we lose the services of any key personnel, we may be unable to recruit a suitable or qualified replacement and may incur additional expenses to recruit and train new personnel, which could disrupt our business and growth. In addition, if any of our key personnel joins a competitor or forms a competing business, we may lose know-how, trade secrets and customers.

Furthermore, as we expect to continue expanding our operations and product portfolio, recruiting, retaining and training qualified R&D, production and quality management, and sales and marketing personnel will be critical to our success. We will need to continue attracting and retaining personnel with extensive experience and industrial knowledge. We may also need to hire, train and manage individuals with expertise that is separate, supplemental or different from expertise that we currently have. Competition for these individuals in the pharmaceutical industry is intense and could cause us to offer higher compensation and other benefits in order to attract and retain them, thereby increasing our operating costs and in turn, materially and adversely affecting our financial condition and results of operations. If we are unable to attract, motivate, train and retain these key personnel required to achieve our business objectives, our business prospects could be adversely affected.

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

We manufacture substantially all of our products through our own production facilities in China. The continued operation of our production facilities and our production safety may be substantially interrupted and materially and adversely affected due to a number of factors, many of which are beyond our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, epidemics, terrorist attacks and wars, or other natural disasters; loss of licenses, permits or certificates; and changes in governmental planning for land used for these facilities or their vicinity, and other regulatory changes.

If the operation of any of our production facilities is substantially disrupted, we may not be able to replace the equipment or replenish the inventories at such facilities, or use alternative sites or third-party contractors to continue our production in a legal, timely and cost-effective manner, or at all. Although we maintain property insurance for our production facilities and equipment, we do not maintain business interruption insurance, and the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production facilities.

Additionally, we may experience disruptions to our supply chain, such as shortages in supplies of raw materials and other products from our suppliers, whether due to dependency on single-source or a few major market players or otherwise, or industry-wide disruptions in the supply chain for reasons beyond our control, such as pandemics, regional conflicts, global crises and destruction of transportation infrastructure or routes. Should any of these occur, it could materially and adversely affect our manufacturing operations, negatively impacting our business and results of operations.

Furthermore, problems may also arise during production for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of our existing production facilities (including changes in production sites and limits to production capacity due to regulatory requirements), changes in the types of products produced, physical limitations that could inhibit continuous supply, and man-made or natural disasters and environmental factors. As a result

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of disruption to our manufacturing facilities or any problems in producing our products, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be adversely affected.

Failure to maintain optimal inventory levels could increase our operating costs or lead to unfulfilled customer orders, either of which could have a material adverse effect on our business and results of operations.

As of December 31, 2023, 2024 and 2025, we had inventories of RMB191.4 million, RMB141.8 million and RMB139.2 million, respectively. We seek to maintain optimal inventory levels to fulfill orders coming from our extensive distribution network and successfully meet our customers’ demand. However, we are exposed to inventory risk as a result of rapid changes in product lifecycles, changing clinical demands, uncertainty of product developments and launches as well as the volatile global economic environment. Further, demand for products could change significantly between the time when the products are approved for market introduction and the time they are ready for sale and delivery. When we begin to sell a new product, it is particularly difficult to forecast product demand accurately.

There can be no assurance that we can accurately predict customer demand and market trends and avoid over-stocking or under-stocking our products. Inventory levels in excess of demand may result in inventory impairment, expiration of our products or an increase in inventory holding costs, and a potential negative effect on our liquidity. On the contrary, if we underestimate demand, we may experience inventory shortages, which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships and loss of sales opportunities and revenue. There can be no assurance that we will be able to maintain proper inventory levels of our products, and any such failure may have a material adverse effect on our business and results of operations.

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

As of December 31, 2023, 2024 and 2025, we had trade and bills receivables of RMB285.7 million, RMB500.6 million and RMB638.8 million, respectively. We are subject to credit risk in relation to our trade and bills receivables. We recognized impairment for trade and bills receivables of RMB24.9 million, RMB26.3 million and RMB27.1 million as of December 31, 2023, 2024 and 2025, respectively. If any of our customers faces unexpected situations, such as financial difficulties or deterioration in creditworthiness, there may be challenges in collecting full or part of our receivables from them, and enforcing judgments against them could be difficult. Such unforeseen circumstances may also render our accounting judgments or estimations on impairment inaccurate, potentially resulting in higher losses than currently estimated. As a result of these factors, our profitability, working capital and cash flow may be adversely affected.

We may incur impairment losses for intangible assets, which may adversely affect our results of operations.

Our intangible assets comprised primarily licensing and development cost. As of December 31, 2023, 2024 and 2025, our intangible assets amounted to RMB138.9 million, RMB236.8 million and RMB293.5 million, respectively. Intangible assets not ready for use are tested annually for impairment or more frequently if indicators of impairment exist. This requires an estimate of the recoverable amount, which is the higher of value in use and fair value less costs of disposal. The estimation is based on key assumptions such as the expected achievement of drug development milestones, the outcome of new drug development, estimated revenue to be generated from the drug under development, and the discount rate. If any of these assumptions do not materialize, or if the performance of our business is not consistent with our assumptions, we may need to record an impairment loss. We did not recognize any impairment on intangible assets as of December 31, 2023, 2024 and 2025. However, any significant impairment losses charged against our intangible assets could have a material adverse effect on our financial condition and results of operations.

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If our preferential tax treatments and government grants become unavailable or otherwise change or terminate, it could adversely affect our profitability.

Historically, we have benefited from a number of preferential tax treatments and tax allowances. During the Track Record Period, the Company and its subsidiary Kexing Pharmaceutical were qualified as High and New Technology Enterprises (HNTEs) and are eligible for a preferential income tax rate of 15%, compared to the 25% income tax rate generally applicable to PRC resident enterprises under the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “EIT law”). In addition, during the Track Record Period, we also received additional deductible allowance for qualified R&D costs, which resulted in tax savings of RMB48.6 million, RMB24.2 million and RMB28.9 million in 2023, 2024 and 2025, respectively.

The preferential tax treatments and tax allowances applicable to the Company and our subsidiaries may be changed, terminated, or otherwise become unavailable due to many factors, including changes in government policies or administrative decisions by relevant government authorities. Our post-tax profitability may be adversely affected as a result of one or more of these or other factors. For example, HNTE qualifications are subject to review by the relevant PRC tax authority every three years. There is no guarantee that we will be able to renew these qualifications. If we fail to do so, the affected subsidiaries and us will no longer enjoy the 15% preferential income tax rate, and will be subject to the 25% income tax rate, unless eligible for other preferential tax treatments.

Furthermore, we have historically received government grants in the form of subsidies received from the government. In 2023, 2024 and 2025, our government grants were recognized as other income, which amounted to RMB8.6 million, RMB25.5 million and RMB6.4 million, respectively.

Any change, suspension or discontinuation of these preferential tax treatment and government grants to us could adversely affect our financial condition, results of operations and cash flows.

The implementation of our strategies and other aspects of our business will require significant funding. If we do not have access to sufficient funding on terms acceptable to us, or at all, it could adversely affect our business prospects.

The implementation of many aspects of our strategies will require significant funding, including:

- the costs of drug development programs for the expansion of our portfolio in our key therapeutic areas;
- the expenses related to the introduction and commercialization of drugs;
- the expenses associated with expanding our sales and distribution network;
- the funding required to conduct localized operations overseas; and
- the capital expenditure required to increase our production capacity and to make upgrades and enhancements.

In addition, many aspects of our general business operations have ongoing funding requirements that may increase over time. Over the longer term, we expect that the implementation of our strategy and business plans may require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms will depend on a number of factors, many of which are beyond our control, including our financial condition, results of operations and cash flows, China’s and global economic condition, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government

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policies on lending. If we cannot obtain sufficient funding on commercially acceptable terms, or at all, to implement our strategies and business plans as currently contemplated, we could be required to revise our strategies and business plans, which could adversely affect our business prospects.

We may seek additional funding through a combination of equity and debt financing. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, the beneficial ownership interest of existing Shareholders could be diluted. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as incurring additional debt, making capital expenditures, or declaring dividends.

RISKS RELATED TO DOING BUSINESS IN THE JURISDICTIONS WHERE WE OPERATE

Changes in the economic, political and other policies of the jurisdictions where we operate could have a material adverse effect on our business, financial condition and results of operations.

A substantial portion of our assets and operations are located in the PRC, and we also operate our business in several other jurisdictions. We have obtained authorization for marketing or achieved sales in over 70 countries and regions. As a result, our business, financial condition, results of operations and prospects are substantially affected by political, economic and legal developments both in the PRC and overseas markets where we operate or sell our products. Economic growth in these markets has been uneven.

Government authorities in China and other jurisdictions implement various measures to encourage economic growth. These measures may include differential policies towards specific groups of pharmaceutical companies, such as the promotion of traditional medicines or investments in competing pharmaceutical companies, which may have an adverse effect on us. In addition, the overall economic growth in jurisdictions where we operate is influenced by government regulations and policies related to capital investments, monetary policies, regulation of financial services and institutions, preferential treatment to particular industries or companies. Any changes in these regulations and policies could affect the business environment in the jurisdictions where we operate changes, thus impacting our business and its growth prospects.

Furthermore, any economic downturn could create an uncertain economic outlook in markets where we currently operate or may operate in the future, which may adversely affect our business, financial condition and results of operations. Changes in the political environment could also increase our costs, heighten our exposure to legal and business risks, disrupt our operations and affect our results of operations. For example, the global trade tension since 2025, particularly the tensions between China and the United States, could intensify and last for an extended period. As a result, the global trade patterns and economic growth in China, the United States, and globally could be materially and adversely affected, which could harm our business prospects and results of operations.

We are subject to laws and regulations in jurisdictions where we operate, and any failure to respond to future changes in the regulatory environment in these jurisdictions could have an adverse effect on our business, results of operations and financial condition.

We are subject to various laws and regulations in jurisdictions where we operate. For example, companies operating in the PRC have to participate in various employee benefit schemes required by the government, including certain social insurance, housing provident funds and other welfare-oriented payment obligations. The requirement and implementation of employee benefit schemes may vary considering the different levels of economic development in different locations in the PRC, and the relevant government authorities may examine whether an employer has made adequate payments of the requisite employee benefit payments, employers who fail to make adequate payments as required may be subject to late payment fees, fines and/or other penalties.

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During the Track Record Period and up to the Latest Practicable Date, we had not received any administrative penalty imposed by the relevant regulatory authorities regarding PRC social insurance and housing provident funds. However, there is no assurance that our historical and current practice with respect to the contribution of social insurance schemes and housing provident fund will at all times satisfy the government authorities in China mainly due to the evolving interpretation and implementation of these laws and regulations. In the event of any such non-compliance, we may be required to pay any shortfall in the contribution of social insurance plans and housing provident fund within a prescribed period and to pay penalties if we fail to do so. In addition to the above, if we fail to comply with any other relevant labor laws and regulations in China, we may be exposed to penalties or be required to compensate employees.

In addition, we are subject to evolving laws and regulations governing the pharmaceutical industry in China and other markets where we operate. Laws and regulations that are recently enacted in our industry may not comprehensively cover all aspects of economic activities within pharmaceutical markets. In particular, the interpretation and enforcement of these laws and regulations may be subject to future implementations. We cannot predict the effect of future legislative developments in the PRC and other jurisdictions on the pharmaceutical industry, including the enactment of new laws, amendments to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws.

Changes to laws and regulations applicable to our industry could lead to new and unexpected challenges. The history of prior enforcement activity cannot be predictive of future enforcement actions. Therefore, our business operations are subject to increased uncertainties and risks. Any enforcement actions against us could have a material adverse effect on us. Any litigation or governmental investigation or enforcement proceedings may be protracted and may result in substantial cost, diversion of resources and management attention, negative publicity, and damage to reputation. As a result, our business, results of operations and financial condition may be adversely affected.

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

In our business operations, we or our business partners (such as clinical trial institutions and medical institutions) may need to collect and store non-personally identifiable data and information of clinical trial subjects. This requires us and our business partners to maintain effective control systems to protect such data and information, and comply with relevant data privacy and protection laws and regulations that apply to our data activities in the jurisdictions where we operate and conduct our clinical trials. For details, see “Business — Data Privacy and Protection” and “Regulatory Overview — Regulations on Information Security and Data Privacy”.

In recent years, privacy and data protection has become an increasing regulatory focus of government authorities across the world. Particularly in China, where we operate substantially all our businesses, the PRC government has enacted a series of laws and regulations in respect of information security, data collection, privacy and protection, including the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), the Cybersecurity Review Measures (《網絡安全審查辦法》), the Data Security Law of the PRC (《中華人民共和國數據安全法》), the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), and the Measures for the Security Assessment of Data Outbound Transfers (《數據出境安全評估辦法》). In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), or the HGR Regulation, was promulgated by the State Council in May 2019, which was last amended and became effective from May 1, 2024. In October 2020, the Standing Committee of the National People’s Congress (the “SCNPC”) promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》), which was last amended and became effective from April 26, 2024. The Biosecurity Law of the PRC reaffirms the regulatory requirements

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stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China’s human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. In addition, the Implementation Rules for the Regulations on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》), or the HGR Regulation Implementation Rules, was promulgated in May 2023 and came into effect on July 1, 2023, which provide further detailed implementation regulations for the administration of human genetic resources in the PRC. Although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot guarantee that we will be deemed at all times in full compliance with the HGR Regulation, the HGR Regulation Implementation Rules, the Biosecurity Law of the PRC and other applicable laws in our utilizing of and dealing with China’s human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC. For details of the HGR Regulation and the Biosecurity Law of the PRC, see “Regulatory Overview — Principal Regulatory Provisions — Laws and Regulations on Drugs — Gathering, Collection and Filing of Human Genetic Resources.”

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We are subject to restrictions on transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. To the extent our R&D of drug candidates are subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, if we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

On July 7, 2022, the Cyberspace Administration of China (the “CAC”) issued the Measures for the Security Assessment of Data Outbound Transfers (《數據出境安全評估辦法》), which took effect on September 1, 2022. The Measures for the Security Assessment of Data Outbound Transfers require that data processors who provide important data collected and generated during operations within the territory of the PRC or personal information that shall be subject to security assessment according to the relevant law to overseas recipients shall conduct security assessment. On March 22, 2024, the CAC issued the Regulations on Promoting and Regulating Cross Border Information Exchange (the “Promotion Regulations”), which came into effect on the same day. The Promotion Regulations indicate that in case of any conflict with the Measures for the Security Assessment of

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Cross-border Data Transfer, the Promotion Regulations shall prevail. The Promotion Regulations list a number of exemptions from the obligations of cross-border data transfer, including passing the security assessment of cross-border data transfer, entering into a standard contract for cross-border transfer of personal information or obtaining personal information protection certification. See “Regulatory Overview — Principal Regulatory Provisions — Regulations on Information Security and Data Privacy — Data security and data export” for more information. To the extent that any of our cross-border data transfers fall under the category of requiring a security assessment and fail to complete this assessment, we may not be able to carry out such transfers, which could adversely affect our ability to conduct out-licensing transactions or obtain overseas regulatory approvals and other aspects for our drugs in a timely manner, or at all.

We are subject to risks relating to some of the properties we use.

Under PRC laws and regulations, lease agreements in general are required to be registered with local housing authorities. As of the Latest Practicable Date, the lease registration for our leased properties in China had not been completed. Although failure to do so does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed timeframe after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority.

RISKS RELATED TO THE [REDACTED]

We will be concurrently subject to listing and regulatory requirements of the PRC and Hong Kong.

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

Our A Shares are listed on the Shanghai Stock Exchange. The characteristics of the A Share and H Share markets may differ.

Our A Shares are listed and traded on the Shanghai Stock Exchange. Following the [REDACTED], our A Shares will continue to be traded on the Shanghai Stock Exchange, and our H Shares will be traded on the Stock Exchange. Under the 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. The H Share and A Share markets have different trading characteristics, each have different trading volumes, liquidity and investor bases, as well as different levels of retail and institutional investor participation. As a result, the trading performance of our H Shares and A Shares may not be comparable, and the historical prices of our A Shares may not be indicative of the prices of our H Shares. Nonetheless, fluctuations in the price of our A Shares may adversely affect the price of our H Shares, vice versa. Therefore, you should not place undue reliance on the trading history of our A Shares when evaluating the investment decision in our H Shares.

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

Prior to the completion of the [REDACTED], there has been no public market for our H Shares. We cannot assure you that a public market for our H Shares with adequate liquidity and trading volume will develop and be sustained following the completion of the [REDACTED]. The [REDACTED] for our H Shares to the public will be the result of negotiations between us and the Overall Coordinators (for themselves and on behalf of the [REDACTED]), and the [REDACTED]

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may differ significantly from the market price of our H Shares following the completion of the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to deal in, our H Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of our H Shares will not decline following the [REDACTED]. Furthermore, the price and trading volume of our H Shares may be volatile. The following factors, among others, may affect the volume and price at which our H Shares will trade: (i) variations in our revenue, earnings and cash flow; (ii) announcement of new investments, business collaborations, strategic alliances or acquisitions; (iii) any unexpected business interruptions resulting from epidemics, natural disasters or power shortages; (iv) any major changes in our Directors, senior management or other key personnel; (v) our inability to obtain or maintain regulatory approval for our operations; (vi) our inability to compete with our competitors effectively; (vii) political, economic, financial and social developments; or (viii) fluctuations in market prices for our products or raw materials. Moreover, shares of other companies listed on the Stock Exchange with operations and assets in China have experienced significant price volatility in the past. It is possible that our H Shares may be subject to changes in price not directly related to our performance and as a result, investors in our H Shares may suffer substantial losses.

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

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

In addition, while investors subscribing shares in the [REDACTED] are not subject to any restrictions on the disposal of the H Shares they subscribed (except as disclosed in “Cornerstone Investors”), they may have existing arrangements or agreement to dispose part or all of the H Shares they hold either immediately, or within certain period upon the completion of the [REDACTED] for legal and regulatory, business and market, or other factors. Any sale of the H Shares subscribed by such investors pursuant to such arrangement or agreement could adversely affect the market price of our H Shares and any sizeable sale could have a material adverse effect on the market price of our H Shares and could cause substantial volatility in the trading volume of our H Shares.

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

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

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

Our Controlling Shareholders have substantial influence over our business, including matters relating to our management, policies and decisions regarding mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no additional Shares are issued pursuant to our 2024 Restricted Share Incentive Plan), our Controlling Shareholders will be collectively entitled to control the exercise of [REDACTED]% voting rights at general meetings of our Company. This concentration of ownership may discourage, delay or prevent a change in control of the Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of the Company and might reduce the price of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interest of our Controlling Shareholders may differ from the interests of our other Shareholders. It is possible that our Controlling Shareholders may exercise their influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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

Although we have declared dividends in the past, we cannot make any assurance that dividends of any amount will be declared or distributed by us in any period in the future. Under the applicable PRC laws and regulations, the payment of dividends may be subject to certain limitations, and the calculation of our profit under the Accounting Standards for Business Enterprises may differ in certain respects from the calculation under the IFRS. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, after taking into account various factors, including our results of operations, financial condition, cash flows, capital expenditure requirements, market conditions, our strategic plans and prospects for business development, regulatory restrictions on the payment of dividends and other factors as our Directors may deem relevant, and subject to the approval at the shareholders’ meeting. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the applicable PRC laws and regulations. For further details of our dividend policy, see “Financial Information — Dividend Policy.” No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Our historical dividends should not be taken as indicative of our dividend policy in the future.

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

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

As our A Shares are listed on the Shanghai Stock Exchange, we have from time to time released information pursuant to PRC regulatory requirements, industry standards and market practices, which differ from those applicable to the [REDACTED]. In addition, the press and media may include certain financial information, industry comparisons, profit forecasts and other information about us that does not appear in this document. Such information may not be directly comparable to, or consistent with, the information contained in this document, and we do not accept responsibility for its accuracy, completeness, fairness or appropriateness. Accordingly, you should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your investment decision regarding the H Shares. By applying to purchase 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.