

## RISK FACTORS

*An [REDACTED] in our H Shares involves a high degree of risk. You should carefully consider all of the information about risks, together with other information contained in this document, including our consolidated financial statements and related notes below, before you decide to buy our H Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material and adverse effect on our business, financial condition and results of operations. In any such case, the [REDACTED] of our H Shares could decline, and you may lose all or part of your [REDACTED]. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section titled “Forward-Looking Statements” of this document.*

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business and industry; (ii) risks relating to our financial position; (iii) risks relating to laws and regulations; and (iv) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

### **RISKS RELATING TO OUR BUSINESS AND INDUSTRY**

*Certain of our products are subject to pricing regulation or other policies that are intended to reduce healthcare costs.*

In China, prices of pharmaceutical products are currently determined mainly by market competition, without being subject to price ceilings set by the NDRC. However, for a pharmaceutical product to be included on the NRDL, a ceiling of such product’s reimbursable amount under the national medical insurance will be determined based on negotiation with the government. Moreover, there is no assurance that such market-based pricing mechanism will result in higher product pricing compared to government-controlled pricing, as competition from other manufacturers, particularly those offering the same products at more competitive prices may force us to lower price of our existing marketed products and may also impact the prices of our drug candidates once commercialized in China. Increased competition may further intensify pricing pressure. Any changes in price control or reimbursement policies, which we may not be able to predict or control, could create uncertainties affecting our product prices, revenue and profitability.

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PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products, including the centralized volume-based procurement (VBP) scheme. For further details, see “Business — Pricing — Centralized Tender Process and Volume-based Procurement Scheme.” As of the Latest Practicable Date, more than 40 of our marketed products are subject to the centralized VBP scheme. In addition, if PRC government authorities implement other reform on the current centralized procurement system for pharmaceutical products or revise other policies affecting pharmaceutical prices, the retail prices of our marketed products may be subject to further downward adjustments, and our retail prices, our revenue and profitability could be adversely affected.

***If we are unable to compete effectively, we may lose market share and our revenue and profitability could be materially and adversely affected.***

The majority of the pharmaceutical products we sell to our distributors are ultimately sold to public hospitals and other medical institutions in China. Our bids are generally evaluated based on factors such as price relative to substitute products and their clinical effectiveness, as well as the quality of our products and services, among other things. If we are successful in winning bids, the relevant products will be sold at the bid prices, which is a primary determinant of the prices at which we sell such products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. See “Business — Pricing” for details.

Our sales and profitability depend on our ability to successfully differentiate our products and price our bids in a manner that enables us to succeed in centralized tenders at profitable levels. If we are unable to do so, our revenue associated with the sale of the affected pharmaceutical products to relevant public hospitals may be adversely affected, which may negatively impact our market share and results of operations. If our products are not selected in centralized tenders in one or more regions, our sales of the relevant products to public hospitals in those regions may encounter difficulties, and our market share, revenues and profitability could be adversely affected.

In addition, we operate in a highly competitive and rapidly changing industry. Large multinational pharmaceutical companies, specialty pharmaceutical companies and other research institutions have commercialized or are commercializing, or are pursuing the development of, drugs for the treatment of CNS, cardiovascular and digestive and other diseases and other indications for which we are developing our drugs and drug candidates.

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***We are largely dependent on sales of our marketed products. If we are unable to maintain or increase the sales volume, pricing levels and profit margins of our main products, our revenue and profitability could be adversely affected.***

As of October 31, 2025, we had a diversified portfolio of marketed products across three principal therapeutic areas, namely CNS, cardiovascular and digestive, as well as other therapeutic areas. During the Track Record Period, our products were primarily sold in the PRC. Our revenue generated from the PRC accounted for 82.6%, 79.7%, 80.1% and 78.6% of our total revenue in 2023, 2024 and the ten months ended October 31, 2024 and 2025, respectively. If we are unable to maintain the sales volumes, pricing levels or profit margins of these marketed products, our revenue and profitability could be materially and adversely affected.

If the performance of our existing marketed products declines, our revenue could decrease materially, which may limit our ability to invest in new product development and adversely affect our long-term growth. Our sales volumes, pricing and profitability may be negatively impacted by reduced medical insurance coverage, government pricing controls, intensified competition and centralized procurement outcomes for PRC public hospitals, competitor substitute products, raw material supply disruptions or cost increases, product quality or safety issues. Many of these factors are outside our control, and any such adverse change could materially and adversely affect our operations, revenue and profitability.

***If we fail to maintain or expand an effective distribution network for our products, or if we are unable to further expand our distribution channel, our business and sales of the relevant products could be adversely affected.***

We rely on our network of distributors to sell our products. Our distributors may, among other things, fail to distribute our products as contemplated, breach contractual restrictions, including selling expired products, selling outside designated territories or hospitals, fail to maintain required licenses or comply with regulatory requirements, or violate anti-corruption, anti-bribery, competition or other laws.

Any such violation could harm our reputation, expose us to liabilities and disrupt our distribution network, materially and adversely affecting our business, financial condition, results of operations and document. In addition, as our distributors are generally non-exclusive and our agreements are typically for one year, we must continually renew these arrangements and face risks that distributors may not renew or may terminate their relationships, and any disruption or inability to build or maintain distributor relationships could negatively affect our ability to sell our products.

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***Failure to attain market acceptance among the medical community would have a material adverse impact on our operations and profitability.***

The commercial success of our existing and future products depends on the level of market acceptance among the medical community, particularly medical professionals and hospitals. Such acceptance will depend on various factors, including the candidate’s safety and efficacy, cost, the effectiveness of our marketing efforts, and the product’s perceived advantages and disadvantages (including side effects) relative to competing products or treatments.

In addition, market acceptance of a product is also affected by whether it is included in the national and provincial medical insurance drug catalogues. See “— Certain of our products are subject to pricing regulation or other policies that are intended to reduce healthcare costs.” If our products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are perceived more favorably by healthcare practitioners and patients, are more cost-effective or otherwise render our products obsolete, the demand for our products may decline and our business and profitability may be materially and adversely affected.

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

Successful sales and marketing are crucial for us to increase the market penetration of our launched products, expand our coverage of hospitals and other medical institutions and promote new products in the future. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales volumes and business prospects could be adversely affected.

Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales professionals is especially important because we primarily rely on our in-house sales force to market and sell our products. Competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

***If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our drugs or drug candidates, or experience significant delays in doing so, our business will be materially harmed.***

Our long-term growth will depend on the successful development, regulatory approval and commercialization of our drugs and drug candidates, in which we have invested and expect to continue investing our financial resources. The success of our programs depends on, among other things, (i) the successful completion of preclinical and clinical studies and generation of favorable safety and efficacy data, (ii) obtaining regulatory approvals, (iii) the ability of contract research organizations and other third parties to conduct clinical trials in compliance with our protocols and applicable laws and to preserve the integrity of trial data, (iv) obtaining, maintaining, protecting and enforcing intellectual property and regulatory exclusivity, and avoiding infringement or misappropriation of third-party rights, (v) successfully launching and commercializing any approved products and achieving market acceptance, and (vi) obtaining sufficient supplies of any competitor products needed for use in clinical trials.

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If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain approval for and/or to successfully commercialize our drugs and drug candidates, which could materially and adversely affect our revenue growth and future profitability.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to products under development or failure to demonstrate safety and efficacy of our drug candidates to the satisfaction of regulatory authorities could have a material adverse effect on our prospects.***

Clinical testing is expensive, may take many years to complete, and is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Any failure to complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects.

The successful and timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrolment for a variety of reasons, such as the size and nature of the patient population, the design of the trial, our ability to recruit investigators with the appropriate competencies and experience, the availability of approved therapies or other competing drug candidates. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrolment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Clinical trial failure can occur at any stage, and results from preclinical studies, early-stage trials or interim analyses may not predict later-stage or final outcomes. Safety and efficacy results may also vary across trials of the same drug candidate due to differences in protocols, patient populations and participant dropout. To obtain regulatory approval, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drugs and drug candidates in humans. If trial results are negative or only modestly positive for proposed indications, raise safety concerns, or if our drug candidates cause adverse events, we may face delays in, or failure to obtain, regulatory approvals, be required to conduct additional trials or testing, or be required to include enhanced labeling, medication guides, or risk evaluation and mitigation measures. We may also fail to obtain approval for all intended indications, be subject to restrictions on distribution or use, face product liability claims, and be unable to obtain reimbursement for the drug.

If our drugs or drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would have expended a significant amount of capital to progress the relevant drugs or drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

## RISK FACTORS

***We invest substantial resources in research and development in order to develop our drugs and drug candidates and enhance our technologies, which we may not be able to do successfully.***

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. We expect to continue to invest significant amounts of capital resources to develop our drug candidates and enhance our technologies that will allow us to advance our pipeline drugs and enhance the scope and quality of our products. We intend to continue to strengthen our technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient patent or other intellectual property protection for such new or enhanced products or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may render our efforts obsolete, which could significantly reduce demand for our products and harm our business and prospects.

***We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success. The market opportunities for our drug candidates may be smaller than we anticipate, which could render some drug candidates ultimately unprofitable even if commercialized.***

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. In addition, our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products and the market opportunities for our drug candidates may be smaller than we anticipate. The total potential market opportunity will depend on, among other things, acceptance of the drug by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected and patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access. Any of the above unfavorable developments could materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

***Our relationships with principal investigators, leading hospitals and strategic partners may not generate the expected benefits and could adversely affect the clinical development and commercialization of our products.***

We maintain relationships with certain principal investigators, leading hospitals and academic institutions to support our R&D activities and to better understand clinical needs and practice trends. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators and leading hospitals and academic institutions, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. In addition, the clinical or market insights we obtain may prove inaccurate or may not translate into commercially viable products.

We have entered into collaborations and may pursue additional collaborations, in-licensing or out-licensing arrangements. These arrangements may require significant expenditures, involve non-recurring charges, dilute existing Shareholder if financed through equity issuances, divert management attention, and require us to relinquish some control over development and commercialization. They also entail risks that may delay, impair or prevent progress, including collaborators' discretion over priorities and resources, delays or termination of development activities, development of competing products, inadequate or contested intellectual property protection, and disputes that lead to delays, termination or costly proceedings.

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If we are unable to maintain effective relationships or achieve the expected benefits from collaborations or licensing arrangements, we may need to curtail or delay development programs, increase our expenditures, or undertake development or commercialization activities independently, which may require additional expertise and capital that may not be available on acceptable terms, or at all. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

***If our products are not manufactured to the necessary quality standards, it could harm our business and reputation, and our revenue and profitability could be adversely affected.***

Product safety and quality is critical to our business. Our products and manufacturing processes are required to meet certain quality standards. See "Business — Manufacturing and Quality Control" for further details. Despite our quality control system and procedures, we cannot eliminate the risk of errors, defects or failure, and product contamination. In addition, the mere publication of information or speculation asserting that any of our products contains or has contained any contaminants, over which we have no control, could damage our reputation and have a material adverse effect on us, regardless of whether such information or speculation has any factual basis. We may fail to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including: (i) manufacturing errors; (ii) technical or mechanical malfunctions in the manufacture process; (iii) human error or malfeasance by our quality control personnel; (iv) tampering by third parties; and (v) quality issues with the raw materials we purchase or produce.

***Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts.***

We operate ten manufacturing sites in China and one manufacturing site in Korea. As of the Latest Practicable Date, the construction works of our new production base in Shandong had passed completion inspection. The installation of process equipment at the Shandong facility will be implemented in phases. Our manufacturing facilities and our manufacture process will be subject to ongoing, periodic inspection by the NMPA or other comparable regulatory agencies to ensure compliance with GMP, which is usually the pre-requisite to obtain marketing approval in the respective jurisdictions. Failure to comply with applicable regulations could lead to increased expense and result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of products or drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

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

The operation of our production sites and production safety may be interrupted by events largely outside our control, including fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks, wars and other natural disasters, as well as loss of licenses, certifications or permits, changes in governmental planning for the relevant land or surrounding areas, and regulatory changes.

If any production site is materially disrupted, we may be unable to replace equipment or inventory, or shift production to alternative sites or third-party contractors in a legal, timely or cost-effective manner, or at all. While we maintain property insurance for our facilities and equipment, we do not maintain business interruption insurance, and our coverage may be insufficient to cover losses from significant disruptions. In addition, manufacturing issues may arise due to equipment malfunctions, failure to follow protocols, raw material problems, delays in constructing new sites or expanding existing sites, regulatory constraints on capacity, changes in product mix, physical limitations, and environmental or other external factors. Any such disruption or manufacturing problem could prevent us from meeting market demand or fulfilling contractual obligations, and materially and adversely affect our business, revenues and profitability.

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

Our products and manufacturing processes are required to meet certain quality standards. We have established a quality control management system and standard operating procedures to help prevent quality issues in respect of our products. See “Business — Quality Control”. However, despite these measures, we cannot eliminate the risk of errors, defects or failures. We may fail to detect, remediate or prevent quality defects for various reasons, many of which are outside our control, including manufacturing errors, technical or mechanical malfunctions in the manufacturing process, human error or misconduct by our quality control personnel, third-party tampering, and quality issues with raw materials that we purchase or produce.

In addition, when we expand our production capacity in the future, we may not be able to ensure consistent quality between products manufactured in the existing and new facilities, or need to incur substantial costs for doing so. Furthermore, if we acquire other pharmaceutical companies, we may not be able to immediately ensure that their production facilities and processes will meet our own quality standards. Failure to detect quality defects in our products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenues and profitability.

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

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. During the Track Record Period, we sourced raw materials, including but not limited to chemical raw materials, traditional Chinese medicinal materials, and specialized intermediates, ancillary materials and packaging materials from qualified suppliers. See "Business — Quality Control — Supply Chain Quality Control." We typically do not enter into long-term supply agreements with raw material suppliers and as a result are vulnerable to supply shortages and fluctuations in market prices. Should any of our suppliers fail to supply sufficient quantities of raw materials of an acceptable quality in the future, we may be unable to obtain substitute raw materials elsewhere in a timely manner, or at all. We may also be forced to obtain raw materials from different suppliers, who may require us to pay prices that are not commercially reasonable or may provide us with raw materials that are not of an acceptable quality. Although we have not experienced material interruptions in our supply chain or raw material supplies in the past, any potential interruption could delay the production and delivery schedules of the relevant products, which may result in the loss of customers and revenue. In addition, the market prices of raw materials may be subject to significant fluctuations due to various factors. We cannot assure you that we would be able to pass on any increase in raw material costs to our customers, and any substantial fluctuation in market prices of raw materials may materially increase our costs and impact our profitability. Potential disruptions to the supply chain, such as natural disasters, geopolitical tensions, transportation issues, or other unforeseen events, could further exacerbate these challenges and result in delays, increased costs, or interruptions in our production processes.

***Real or perceived incidents of severe side effects caused by our products could materially and adversely affect our reputation, results of operations and financial condition.***

Our products may cause undesirable or unintended side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical testing, unusual but severe side effects in isolated cases, defective products not detected by our quality management system, misuse of our products by end-users, or use of our products for an indication, dosage or in a dosage form that is not in accordance with regulator-approved usage and labeling. Our products may also be perceived to cause severe side effects when a conclusive determination as to the cause of such severe side effects is not obtained or is unobtainable. Further, our products may be perceived to cause severe side effects if other pharmaceutical companies' products containing the same or similar active pharmaceutical ingredients, raw materials or delivery technologies as our products cause or are perceived to have caused severe side effects, or if one or more regulators, such as the NMPA or the FDA, or an international institution, such as the WHO, determine that products containing the same or similar pharmaceutical ingredients as our products could cause or lead to severe side effects. If our products cause, or are perceived to cause, severe side effects, we may face, among other consequences, patient injury or death, a significant decline in demand for and sales of the affected products, and damage to our product brands and corporate reputation. As a result, our revenue and profitability could be materially and adversely affected.

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

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

***Counterfeits of our products could negatively affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.***

Certain products distributed or sold in the pharmaceutical markets may be manufactured without proper licenses or approvals or fraudulently mislabeled with respect to their content or manufacturer. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products, including those imitating our products. Consequently, certain pharmaceutical products sold in the PRC and other markets may be counterfeit products.

Since counterfeit pharmaceutical products are generally sold at lower prices than authentic pharmaceutical products and are in some cases very similar in appearance to authentic pharmaceutical products, counterfeit products imitating our own pharmaceutical products can quickly erode our sales volume of the relevant product. Moreover, counterfeit products may or may not have the same chemical composition as our products, which may make them less effective than our products, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. As a result of these factors, the continued proliferation of counterfeit pharmaceutical products in the market could affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims. Although we have not encountered instances of counterfeit version of our products in the past, there can be no assurances that we will be able to prevent future occurrences of counterfeit version of our products or instances of counterfeit version of our products in the future will not have a material adverse effect on us.

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***We do not maintain product liability insurance for certain of our products to cover potential damages arising from product liability claims. If we become subject to such claims, we may be exposed to significant costs and liabilities, which could adversely affect our reputation, revenues and profitability.***

We are exposed to product liability risks as a result of developing, producing, marketing, promoting and selling drugs, APIs and medical devices, in the jurisdictions in which our pharmaceutical products may be marketed and sold. Such claims may arise if any of our products are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects.

If a product liability claim is brought against us, it may, regardless of merit or outcome, strain our financial resources and consume the time and attention of our management, which might incur substantial costs and lead to diversion of resources. It may also result in damage to our reputation, product recalls and loss of our revenue and capability to commercialize our products. If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our pharmaceutical products are found to be defective. In addition, we may be required to recall the relevant pharmaceutical products, suspend sales or cease sales. We do not maintain product liability insurance for certain of our products to cover potential damages that may arise from product liability claims. PRC laws and regulations currently do not require us to, nor do we, maintain liability insurance to cover product liability claims. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we develop. See “— We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources” for details.

***We are subject to risks associated with international trade policies, geopolitics and trade protection measures, and our operations could be adversely affected.***

Several of our distributors are located outside of China and deteriorating geopolitical or geoeconomic relations may disrupt supply chains, limit market access, or increase compliance burdens. Certain foreign jurisdictions and intergovernmental organizations impose sanctions and other trade restrictions that directly or indirectly affect China-based companies based on product origin, ownership, or other factors. Such trade-related restrictions frequently change and are subject to uncertain interpretation and enforcement. These measures could therefore be costly or burdensome to satisfy and may limit our ability, and that of suppliers and customers, to obtain raw materials, technologies or components that are critical to our infrastructure and offerings and may constrain sales in certain foreign markets.

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We believe applicable sanctions and export controls do not impose material limitations on our operations, and we are committed to compliance. Nonetheless, we cannot assure you that regulators will not take the view that our past, current, or future activities are sanctionable, or that new or expanded restrictions will not increase scrutiny of our business. If competent authorities determine that any of our or any customer's, end user's, or supplier's activities violate applicable sanctions or export control laws or otherwise provide a basis for the designation of our group, our business and reputation could be materially and adversely affected.

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

We depend on the continued contributions of our senior management, especially the executive officers listed in the section headed "Directors and Senior Management" in this document, and other key employees, many of whom are difficult to replace. The loss of the services of any of our executive officers or other key employees could materially harm our business.

Our future success is dependent on our ability to attract a significant number of qualified employees and retain existing key employees, especially our product development and technology professionals. We believe that there is, and will continue to be, intense competition for highly skilled management, technical, sales and other personnel with experience in our industry in the cities where our offices are located. Our need to significantly increase the number of our qualified employees and retain key employees may cause us to materially increase compensation-related costs, including share-based compensation. We must provide competitive compensation packages and a high-quality work environment to hire, retain and motivate employees. In addition, our senior management team has limited experience in running H share listed public companies, which will require us to expend additional resources in hiring additional support staff and incur additional costs and expenses. To the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or divulged proprietary or other confidential information. If we are unable to retain and motivate our existing employees and attract qualified personnel for important positions, we may be unable to manage our business effectively, including the development, marketing and sale, which could adversely affect our business, operating results and financial condition, and the price of our [REDACTED] could suffer.

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***Our internal information technology systems, or those used by our CROs, partners, other independent contractors or consultants, may fail or suffer security breaches, which may require us to expend additional resources to protect our information technology systems and could materially and adversely affect our business, financial condition, results of operations and prospects.***

Our systems and those of our vendors, collaborators, consultants, clinical sites and, in certain cases, regulatory authorities are vulnerable to computer viruses and malicious code, unauthorized access, phishing and other cyber-attacks, industrial espionage, insider threats, natural disasters, terrorism, and telecommunications or power failures. While we have not experienced any material system failure or security breach to date, any such event could disrupt our operations and drug development activities, including through loss of trade secrets or other proprietary information. For example, loss or corruption of clinical trial data could delay regulatory approvals and increase costs to recover or reproduce such data. Any breach resulting in theft, destruction, misuse or disclosure of intellectual property, confidential information or personal data could harm our competitive position, delay development and commercialization, and cause financial, legal and reputation harm.

We may also be subject to regulatory actions or private litigation relating to data privacy and security, including claims for misuse or inappropriate disclosure of data. Although we maintain systems, controls and processes designed to prevent and mitigate these risks, they are costly and require continuous monitoring and updating as threats become more sophisticated. Moreover, as we increasingly rely on third-party vendors, electronic transactions and cloud-based systems, our exposure to these risks may increase, and there can be no assurance that our safeguards will prevent service disruptions, data loss, or data theft or corruption.

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

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

As our production process requires skilled technical workers in design, operating and quality control, we cannot guarantee that we can retain and attract sufficient qualified employees on reasonable employment terms. In the event that we cannot keep the existing skilled workers or recruit sufficient skilled workers to replace the departing skilled workers, or to cope with our expansion plan on a timely basis at reasonable costs, or that the turnover rate of our workers is high and we do not have time to train up the workers to cope with our standards, our production process can be severely affected or interrupted. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused by labor disputes.

## RISK FACTORS

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

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

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

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of natural disasters, such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

As a result, international political relationships among jurisdictions where we operate and conduct business may affect our cost structure, the demand for our products and our collaboration with business partners. Any such relationship tensions and political concerns may adversely affect our business, results of operations and prospects. In addition, any economic downturn, decrease in economic growth rates and other uncertain economic outlook in the market that we operate in could also affect our business, financial condition and results of operations.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

## RISK FACTORS

### RISKS RELATING TO OUR FINANCIAL POSITION

***We are subject to credit risks of our customers. If we experience delays in collecting or if we are unable to collect payments from customers, our cash flow and operations could be adversely affected.***

We generally grant credit terms of up to 30 to 120 days to our customers. The average turnover days of our trade receivables in 2023, 2024 and the ten months ended October 31, 2025, were 47.7 days, 57.9 days and 70.7 days, respectively. As of December 31, 2023, 2024 and October 31, 2025, our trade receivables were RMB571.5 million, RMB747.8 million and RMB808.5 million, respectively. As a result, we may be exposed to credit risks. We cannot assure you that we can properly assess and respond in a timely manner to changes in their credit profile. If our customers’ cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with our customers in a manner that may adversely and materially affect our cash flows and operations.

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

Our inventory consists of raw materials, work-in-progress and finished goods. To operate our business successfully and meet our customers’ demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We regularly monitor our inventory to ensure timely supply and reduce the risk of overstocking. We are exposed to inventory risk as a result of rapid changes in product life cycles, changing clinical demands, uncertainty of product developments and launches as well as the volatile economic environment in jurisdictions where we operate. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our products. Further, demand for products could change significantly between the time when the products are ordered and the time they are ready for delivery. We may be exposed to increased inventory risks due to accumulated excess inventory. This may result in a heightened risk of inventory obsolescence, declines in inventory values, inventory write-downs, product expiry, increased inventory holding costs and, in turn, potential adverse impacts on our liquidity. On the other hand, if our forecasted demand is lower than actual level, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors.

Furthermore, as we will not be able to recoup our cash paid for raw materials during the production process until the finished products are sold to customers and the purchase price is settled, our business is subject to working capital requirements. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

## RISK FACTORS

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

Our trade receivables consisted of outstanding receivables from our customers during our ordinary course of business. We generally grant credit terms of 30 to 120 days to our customers. See “Financial Information — Discussion of Selected Items from the Consolidated Statements of Financial Position — Trade and Other Receivables.”

We are exposed to the risks that our customers or other business partners may delay or even be unable to pay us in accordance with the payment terms included in our agreements in a timely manner, or at all. Although we closely monitor our outstanding trade receivables, we cannot assure you that we will be able to fully recover the outstanding amounts in a timely manner, or at all. In addition, as our business continues to scale up, our trade receivables may continue to grow, which may increase our credit risk. Any substantial delay in or default of payments from our customers could materially and adversely affect our cash flows. Moreover, we could be required to terminate our relationship with distributors in a manner that will impair the effective distribution of our products. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

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

During the Track Record Period, we have benefited from government grants and subsidies. During the Track Record Period, our other income related to the government subsidies amounted to RMB42.8 million, RMB97.1 million and RMB31.2 million in 2023 and 2024 and October 31, 2025, respectively. We also enjoyed preferential tax treatment during the Track Record Period. See “Financial Information — Description of Key Statements of Profit or Loss Items — Other Income”. The incentives to some extent are subject to the discretion of the relevant government authorities, which could determine at any time to eliminate or reduce these financial incentives or preferential treatments, generally with prospective effect. Since our receipt of the financial incentives or preferential treatments is subject to periodic time lags and inconsistent government practice, as long as we continue to receive these financial incentives or preferential treatments, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these financial incentives in addition to any business or operational factors that we may otherwise experience. Therefore, the discontinuation of financial incentives currently available to us could have a material adverse effect on our financial condition, results of operations, cash flows and prospects.

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

During the Track Record Period, our financial assets at FVTPL comprised structured deposits and unlisted equity investments. We recorded financial assets at FVTPL of RMB700.7 million, RMB1,322.2 million and RMB814.4 million as of December 31, 2023 and 2024 and October 31, 2025. The valuation of fair value changes of financial assets at FVTPL is subject to uncertainties in estimations. Such estimated changes in fair values involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the financial assets at FVTPL valuation has been, and will continue to be, subject to uncertainties in estimations, which may not reflect the actual fair value of these financial assets and result in significant fluctuations in profit or loss from period to period.

## RISK FACTORS

*Our international operations may be subject to transfer pricing adjustments by competent authorities.*

During the Track Record Period, we engaged in intra-group transactions within our Group. Our intra-group transactions and arrangements between our subsidiary in Korea and Hong Kong and other members of our Group primarily consisted of transfers of ownership of tangible assets. Please see “Business — Transfer Pricing”. We cannot assure you that our intra-group transactions will not be challenged by the relevant authorities in the future, or that the relevant regulations or standards will remain unchanged. If our transfer arrangements are later adjudged not in line with arm’s length principles by relevant authorities or disagree with our assessment and determine that our intra-group transactions do not comply with the relevant transfer pricing laws and regulations, we may be required to re-assess the transfer prices, re-allocate the income, or adjust the taxable income. Any such re-allocation or adjustment could result in higher tax liabilities for us and may adversely affect our business, results of operations, and financial condition. Also, we may face adverse tax consequences, such as the payment of outstanding tax, statutory interest or tax penalty. Moreover, failure to rectify within the timeframe prescribed by the relevant authorities may result in late payment interest, surcharge, or other penalties for any unpaid taxes. Any such circumstances could result in a higher overall tax liability for our Group and may adversely affect our business, financial condition and results of operation. Additionally, if relevant authorities challenge the intra-group transactions, it could give rise to tax recoverable in certain jurisdictions due to adjustments in taxable income. However, there is no assurance that we would successfully recover such taxes from the relevant authorities which could have a material adverse effect on our business, results of operations, and financial condition.

*We may be affected by exchange rate fluctuations.*

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in global political and economic conditions. Any significant appreciation or depreciation of Renminbi against US dollars may affect our revenues, earnings and financial position, and the value of, and any dividends payable on, our Shares. To the extent that we need to convert Hong Kong dollars we receive from this [REDACTED] into Renminbi for our operations, appreciation of the Renminbi against the Hong Kong dollars would have an adverse effect on the Renminbi amount we would receive. Conversely, if we decide to convert our Renminbi into Hong Kong dollars for making payments for dividends on our ordinary shares or for other business purposes, appreciation of the Hong Kong dollars against the Renminbi would have a negative effect on the Hong Kong dollar amount. With the development of the foreign exchange market, there might be further changes to the exchange rate system. Any significant fluctuation of relevant currencies could adversely affect our business, results of operations and financial condition, and the value of any dividends payable in Hong Kong dollars. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure or at all.

## RISK FACTORS

***We may require additional financing to fund our research and development activities, capital expenditures, potential acquisitions and other growth initiatives, and if we are unable to obtain such financing on acceptable terms or at all, our business, financial condition and growth prospects may be materially and adversely affected.***

We operate in a capital-intensive industry that requires substantial capital and other short-term expenditures, including commitments for equipment and facilities, as well as working capital for daily operations. To the extent that we grow our business, we expect to fund the related financial commitments and other capital and operating expenses from a combination of cash on hand, banking facilities, and the [REDACTED] from the [REDACTED]. We may require additional financing if we incur operating losses and/or incur additional capital expenditures for the development of our business. If our financing is insufficient to satisfy our working capital requirements, we may seek to issue additional equity or debt securities or obtain new or expanded credit facilities. Our ability to obtain external financing in the future is subject to a variety of uncertainties, including our future financial condition, results of operations, cash flows, share price performance, liquidity of international capital and lending markets and the PRC regulations over foreign investment and the industry we operate. In addition, incurring indebtedness would subject us to increased debt service obligations and could result in operating and financing covenants that would restrict our operations and growth. There can be no assurance that financing would be available in a timely manner or in amounts or on terms favorable to us or at all. Any failure to raise sufficient funds on terms favorable to us, or at all, could severely restrict our liquidity as well as have a material and adverse effect on our business, financial condition and results of operations. Moreover, any issuance of equity or equity-linked securities could result in significant dilution to our existing Shareholders.

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

From time to time, we may evaluate acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property, technologies or businesses, to advance our business plan. Any such transaction may involve risks, including increased operating expenses and cash requirements; assumption of additional debt or contingent liabilities; dilution to existing Shareholders from equity issuances; diversion of management attention from existing programs; loss of key personnel or disruption to key business relationships; and integration challenges relating to operations, corporate culture, intellectual property, products and personnel. Such transactions also expose us to risks relating to the counterparty (including its prospects, products, pipeline and regulatory status), the possibility that acquired assets fail to generate sufficient revenue to meet our objectives or offset associated costs, and changes in accounting principles that may materially affect our financial results.

In addition, acquisitions may require significant one-time expenses and result in the recognition of intangible assets and related amortization charges. We may also be unable to identify suitable opportunities, which could limit our ability to grow or access important technologies or products. Further, under the PRC Anti-Monopoly Law and the State Council's notification thresholds, certain concentrations through mergers, acquisitions or contractual arrangements that confer control or decisive influence may be subject to mandatory prior notification and clearance requirements in the PRC, and may not be implemented without obtaining the requisite clearance once the relevant thresholds are met.

## RISK FACTORS

***We may incur unexpected charges relating to our operations.***

Certain post-production processes, including transportation, storage, warehousing and usage, may adversely affect the quality of our products. We generally rely on transport operators for delivery of our products. Delivery disruptions for reasons beyond our control, including weather conditions, political turmoil, social unrest and strikes, could lead to delayed deliveries. The nature of pharmaceutical products may also mean that poor handling or storage by pharmacies, hospitals, patients or transport operators could result in damage to our products, including contamination or degeneration. For example, prolonged exposure to heat or sunlight may damage certain pharmaceutical products. Some of these processes are managed by third parties, over which we have limited control. In particular, once we have sold our products to distributors, we have limited control over how our distributors store and transport our products.

We may incur future charges relating to inventory that expires or as a result of customer failures to pay invoiced amounts timely or in full. We may have significant bad debt expenses or write-offs in the future. We could also experience additional charges for bad debt if other distributors do not pay outstanding receivables in full. Those or similar future events would have an adverse impact upon our operating results.

***If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.***

We will become a H share [REDACTED] [REDACTED] upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our managerial, operational and financial resources and systems in the foreseeable future. To address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. The violation of or deviation from these internal controls and procedures by any of our employees could adversely affect our reputation, financial position and current and future business relationships. If one or more of our employees or former employees were to engage in misconduct or were to be accused of such misconduct, our businesses and our reputation could be adversely affected. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

## RISK FACTORS

### RISKS RELATING TO LAWS AND REGULATIONS

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

We mainly operate in the pharmaceutical industry in China. The industries we operate in are subject to comprehensive government regulation and supervision, including but not limited to comprehensive governance around the approval, registration, manufacturing, packaging, licensing, marketing, sales and distribution of drugs. Ensuring that we remain compliant with the various rules and regulations can be time- and cost-consuming, particularly for a company like us that operates in various jurisdictions with different policies. For example, the process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislations may increase the difficulty and cost for us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain.

Changes in regulatory requirements or industry practices, whether through relaxed requirements or streamlined procedures that lower entry barriers for competitors, or more stringent requirements that increase compliance burdens, could materially and adversely affect our business, financial condition, results of operations and prospects. We are also subject to scheduled and unscheduled inspections to assess compliance. Any non-compliance at any stage of development, approval or after commercialization may result in administrative or judicial sanctions, including rejection of pending applications, withdrawal of approvals, license revocation, clinical holds, product recalls or seizures, suspension of production or distribution, injunctions, fines, and civil or criminal penalties, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

## RISK FACTORS

Any changes in the standards used by governmental authorities in considering whether to renew or reassess our licenses, permits, approvals and certificates, as well as any enactment of new regulations that may restrict the conduct of our business, may also 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 new regulations come into effect, so as to require us or parties upon whom we rely to obtain any additional permits, licenses, approvals or certificates that were previously not required to operate our business, there can be no assurances that we or parties upon whom we rely will successfully obtain such permits, licenses, approvals or certificates.

***The regulatory approval processes of the NMPA, FDA, EMA and other comparable regulatory authorities for our market products are lengthy and the approval result is inherently unpredictable.***

The time required to obtain approval by the NMPA, FDA, EMA and other comparable regulatory authorities is unpredictable but typically takes 10–15 years following the commencement of preclinical studies and clinical trials (or, as applicable, product registration, regulatory filings and other requisite evaluations for medical devices and APIs) and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our market products could fail to receive regulatory approval for many reasons, including but not limited to: (i) failure to begin or complete clinical trials due to disagreements with regulatory authorities; (ii) failure to demonstrate that our market products is safe, pure and potent for its proposed indications; (iii) failure of clinical trial results to meet the level of statistical significance required for approval; (iv) data integrity issues related to our clinical trials; (v) disagreement with our interpretation of data from preclinical studies or clinical trials; (vi) our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and (vii) clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial. In addition, for our medical devices and APIs, we may be required to satisfy applicable registration, technical review, testing and/or inspection requirements and failure to do so could delay, suspend or prevent the relevant approvals. In regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

## RISK FACTORS

***Even after we obtain regulatory approval for the marketing and distribution of our market products, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drug candidates.***

If any of our products are approved in the future, we will be required to comply with extensive post-approval requirements relating to manufacturing, labeling, packaging, storage, advertising and promotion, record-keeping, post-marketing studies, and the submission of safety, efficacy and other post-market information in China, the United States, Europe and other jurisdictions. We must also continue to comply with cGMP requirements and, for any post-approval clinical trials, GCP requirements.

Regulatory approvals may be subject to limitations on indicated uses, conditions of approval, and potentially costly post-marketing testing, surveillance or risk evaluation and mitigation measures. In addition, previously unknown issues, such as safety concerns, third-party manufacturing or process problems, or non-compliance, may be identified after approval. Any such developments could result in restrictions on marketing or manufacturing, product withdrawal or recalls, fines, warning letters or clinical holds, refusal to approve pending applications or supplements, suspension or revocation of approvals, seizure or detention, import/export restrictions, or civil, administrative or criminal penalties. Because regulatory requirements and policies continue to evolve, if we fail to maintain compliance or adapt to changes, we could lose approvals and our ability to achieve or sustain profitability could be materially and adversely affected.

***Real or perceived incidents of severe side effects caused by our products could subject us to regulatory actions and contractual liabilities.***

Allegations of serious adverse effects, even if unsubstantiated, may trigger heightened scrutiny and enforcement by regulators such as the NMPA or the FDA, and may be influenced by determinations or guidance from international institutions, particularly where products with the same or similar ingredients, raw materials or delivery technologies are implicated. As a result, we could face product recalls or withdrawals, revocation of product or facility approvals, more frequent and stringent inspections, removal from medical insurance catalogues or relevant provincial lists, restrictions on participation in centralized procurement/tender processes, lawsuits or regulatory investigations resulting in fines, penalties or other liabilities, and potential breaches of contracts with major customers. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

## RISK FACTORS

***We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, the United States, Philippines and other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our products and drug candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法), the PRC Criminal Law (中華人民共和國刑法), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, the Health Insurance Portability and Accountability Act of 1996, and the U.S. Physician Payments Sunshine Act.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Government authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business. Furthermore, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***We are subject to stringent 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 and other personal or sensitive information.***

We receive, collect, generate, store, process, transmit and maintain de-identified codes of subjects enrolled in our clinical trials and the corresponding clinical trial data. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. As of the Latest Practicable Date, we are primarily subject to PRC laws and U.S. federal and state laws governing data protection and privacy.

## RISK FACTORS

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 condition, results of operations and prospects.

Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business.***

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

In terms of the construction of our manufacturing facilities, they can be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety examine and approve such facilities. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan.

## RISK FACTORS

***We may be required to make additional contributions of social insurance fund and/or housing provident fund and late payments and fines under PRC laws and regulations.***

Companies operating in China are required to participate in various employee benefit plans, including social insurance fund and housing provident fund, and contribute amounts equal to certain percentages of salaries, including bonuses and allowances, of their employees up to a maximum amount specified by the local government at locations where they operate their business. During the Track Record Period, we did not make adequate contributions to the social insurance and housing provident fund with respect to certain of our employees, as required by the relevant PRC laws and regulations. Considering that (i) we have obtained confirmations from the relevant competent government authorities, confirming that no administrative penalty was imposed on us in relation to our social insurance and housing provident fund contributions during the Track Record Period, (ii) during the Track Record Period and up to the Latest Practicable Date, we had not received any administrative penalty in relation to social insurance and housing provident fund contributions, and we had not received any notice from relevant competent government authorities regarding any claim for inadequate contributions of our current and former employees, nor any notifications from the relevant competent government authorities requiring us to pay the shortfalls, (iii) we were not aware of any material employee complaints or claims with respect to inadequate social insurance and/or housing provident fund contributions and (iv) we undertake that, in the event that competent government authorities require us to make contributions within a stipulated time period or make supplementary contributions and late fees, we will duly comply in a timely manner. Our PRC Legal Advisor is of the view that assuming there is no material change in the applicable policies, regulations and local enforcement or supervisory practices, and absent any large-scale employee complaints, reports or related litigation or arbitration, the likelihood of us being required by the competent authorities to make a one-off consolidated settlement of any historical shortfalls in social insurance and housing provident fund contributions is remote. As a result, we did not make any provisions in connection with the foregoing incident during the Track Record Period.

As advised by our PRC Legal Advisor, if the competent PRC government authority determines that the social insurance contributions we made for our employees violate the requirements under the relevant PRC laws and regulations, we may be required to pay all outstanding social insurance contributions within a stipulated period, with late fees at a daily rate of 0.05% of the outstanding amount, accruing from the date when the social insurance contributions were due. In the unlikely event that we are required to settle the shortfall of social insurance contribution, if this payment is not made within the stipulated period, the competent authority may further impose a fine of one to three times of the overdue amount on us. We cannot assure that the relevant local government authorities will not require us to pay the outstanding amount within a specific time limit or impose late or additional fees or fines on us in the future, nor can we assure you that there are no, or will not be any, employee complaints regarding payment of the outstanding amount of the social insurance and housing provident fund contributions against us, or that we will not receive any claims in respect of the outstanding amount of the social insurance and housing provident fund contributions under national laws and regulations. In addition, we may incur additional expenses to comply with such laws and regulations promulgated by the PRC government or relevant local authorities.

## **RISK FACTORS**

***We are subject to certain risks relating to third-party payment arrangements.***

During the Track Record Period, we accepted payments made by third parties to settle the amounts that several customers owed to us in connection with their purchases of our products. See “Business — Third-party Payment Arrangements” for details. We are subject to the risks relating to such third-party payments, including potential claims from third-party payors seeking reimbursement of funds as they may not have been contractually obligated to us, and possible claims from liquidators representing these third-party payers. In the event of any claims or legal actions, whether civil or criminal, initiated against us by third-party payers or their liquidators regarding third-party payments or for violation or noncompliance of laws and regulations, we would need to allocate significant financial and managerial resources to defend ourselves, and we may be forced to comply with the court ruling and return the payment for the products that we sold and services that we provided, and our business, prospects, financial condition, results of operations, and cash flows may be adversely affected.

***Under the EIT Law, we may not be classified as a “high and new-technology enterprise” of the PRC. Such classification could result in unfavorable tax consequences.***

During the Track Record Period, our Company and some of our subsidiaries were entitled to preferential income tax rates pursuant to the relevant tax regulations. For example, during the Track Record Period, certain entities within our Group enjoyed preferential EIT tax rate of 15% as they were High and New Technology Enterprise (HNTE). For details, see Note 12 to the Accountants’ Report in Appendix I to this document. Preferential tax treatments and other incentives granted to us by PRC governmental authorities are subject to review and renewal and may be adjusted or revoked in the future. We cannot guarantee that the preferential tax treatments and other incentives to which our PRC subsidiaries are currently entitled would be kept valid or successfully renewed. There can be no assurance that the local tax authorities will not, in the future, change their position and discontinue any of our current tax treatments. The discontinuation of any of our current tax treatments could materially increase our tax obligations and adversely impact our net income.

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

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

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

## RISK FACTORS

According to the Enterprise Income Tax Law of the PRC, which was revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC, which was revised and implemented on April 23, 2019, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

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

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

To the extent our R&D of our drug candidates are subject to the relevant 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 condition 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. Cross-border data transfer from other jurisdictions may also be limited if we fail to comply with relevant requirements, such as obtaining authorization from subjects regarding the use, transfer and retrieval of their personal information or data and adopting measures to ensure the safety of personal information or data in the transfer. Also, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions, and thus any failure to comply with data privacy protection may lead to a restriction of transferring our data across different jurisdictions.

***The evolution of the legal system of the jurisdiction where we operate could affect our business, financial condition and results of operations and our [REDACTED] could be affected as a result.***

We are based in China and our business in China are governed by PRC laws and regulations. The PRC legal system is a civil law system based on written statutes. As the legal system in China continues to develop, laws and regulations may continue to evolve and be subject to interpretation. As these laws and regulations are continually evolving in response to changing economic and other conditions, we cannot foresee how these laws, rules and regulations will be interpreted and enforced, which may affect the legal protections and remedies that are available to us and our [REDACTED].

## RISK FACTORS

***If we, our management or directors become party to litigation, legal disputes, claims or administrative proceedings, our management or directors' attention may be diverted and our operations, reputation, revenue and profitability could be adversely affected.***

We, our management or directors may from time to time become party to litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. Involvement in litigation, legal disputes, claims or administrative proceedings may distract our management's or directors' attention and consume our time and other resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate due to the various factors involved, such as the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us.

In addition, negative publicity arising from litigation, legal disputes, claims or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us, we could be required to pay significant monetary damages, assume other liabilities, and suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

***If we, our employees, distributors or other business partners engage, or are perceived to engage, in misconduct or breaches, including corrupt or bribery practices, leakage of confidential information, unfair competition, or insider trading, or if we, our employees, distributors, or other business partners are involved in negative publicity or allegations, our operations and reputation could be adversely affected, and we could be exposed to regulatory investigations, costs and liabilities.***

We are subject to risks in relation to actions taken by us, our employees, distributors or other business partners that may constitute violations of applicable anti-corruption and other related laws. We are subject to the anti-bribery and corruption laws of China. The anti-bribery laws in China 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 subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption laws to our operations has increased. Further, there have been instances of corrupt practices in the pharmaceutical industry in recent years, including, among other things, provision of kickbacks, bribes or other illegal gains or benefits to pharmacies, hospitals and medical practitioners from manufacturers, distributors and pharmacies in connection with the prescription of pharmaceutical products. Any allegations of such behavior against us, our employees, distributors, other business partners or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects.

## RISK FACTORS

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

***Our legal right to certain properties may be challenged.***

Pursuant to the applicable PRC laws and regulations, property lease contracts must be registered with the local branches of the Ministry of Housing and Urban Development. As of the Latest Practicable Date, 37 lease agreements of our leased properties which are leased from third parties and used for production or office had not been registered and filed with relevant land and real estate management departments in China. Under the relevant PRC laws and regulations, the parties to a lease agreement have the obligation to register and file the executed lease agreement. As advised by our PRC Legal Advisor, the validity of the lease agreements are not affected by the failure to register or file the lease agreements with the relevant government authorities. According to the relevant PRC regulations, we may be ordered by the relevant government authorities to register the relevant lease agreements within a prescribed period, failing which we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each unregistered lease. As of the Latest Practicable Date, we have not received any order from the relevant government authorities requiring us to register these lease agreements. We undertake to cooperate fully to facilitate the registration of lease agreements once we are notified of any requirements by the relevant government authorities.

In addition, as of the Latest Practicable Date, we had not obtained the real property ownership certificates for 12 properties occupied by us, with an aggregate gross floor area of approximately 182,436.2 sq.m. These properties are primarily used for production, research and development, office operations, employee dormitories, ancillary commercial services and other supporting facilities. According to the written confirmation issued by the competent authorities, the registration of the relevant real property interests is currently in progress, and such properties have been duly planned and constructed in compliance with applicable requirements, do not constitute illegal or unauthorized constructions, do not affect safe use or our normal operations, and are not expected to be subject to demolition in the future. In view of the foregoing, we believe that the title defects in respect of these properties will not have a material adverse impact on our production and business operations.

***Failure to adequately protect our intellectual property throughout the world, including the intellectual property relating to our innovative and generic products, active pharmaceutical ingredients and other technologies, or if the scope of our intellectual property fails to sufficiently protect our proprietary rights, other pharmaceutical companies or generic drug manufacturers could compete against us directly or indirectly, which may have a material adverse impact on our business and results of operations.***

Our success depends in large part on our ability to obtain, maintain, defend and enforce intellectual property rights (including patents) covering our innovative and generic products, APIs and other technologies. We seek protection through patents filed in China, the United States and other jurisdictions, as well as through trade secrets, regulatory protection and confidentiality measures. For further details, please refer to “— Business — Intellectual Property.”

## RISK FACTORS

However, patent prosecution and enforcement are costly, time-consuming and uncertain, and we may be unable to file, prosecute, maintain, defend, enforce or license patents in all jurisdictions on a timely and cost-effective basis. Patentability standards vary by jurisdiction; patent applications may not be granted; and issued patents may be narrowed, challenged, invalidated or found unenforceable due to, among other reasons, prior art, deficiencies in applications or lack of novelty. Many jurisdictions also permit compulsory licensing or limit enforceability against government agencies or contractors, which could diminish the value of our patents and impair our competitive position.

In addition, we may fail to timely identify patentable aspects of our R&D output, and confidentiality arrangements with employees and third parties may be breached, jeopardizing our ability to secure protection. Publication lags and the "first-to-file" system in jurisdictions such as China and the United States also create uncertainty as to whether we were the first to invent or file for relevant technologies.

Even where patents are granted, they may not provide meaningful protection or competitive advantage. Patent rights are time-limited and may expire before or shortly after commercialization; once patents expire, we may face increased competition, including from generics or biosimilars. Competitors may also challenge our patents, and we may be unsuccessful in defending or enforcing our rights. Any of the foregoing could materially and adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

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

## RISK FACTORS

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

***Issued patents covering one or more of our drug candidates, marketed products or other technologies could be found invalid or unenforceable if challenged in court.***

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office ("USPTO"), China National Intellectual Property Administration ("CNIPA"), or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable.

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

## RISK FACTORS

***Changes in patent and other intellectual property laws could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs and products.***

Our success depends on obtaining, maintaining, enforcing and defending intellectual property rights, particularly patents. In the pharmaceutical industry, patent procurement and enforcement are complex, costly, time-consuming and inherently uncertain. Legislative, regulatory or interpretive changes could increase the uncertainty and cost of patent prosecution, narrow the scope or enforceability of our patent rights, reduce the value of our intellectual property, and weaken our ability to protect our inventions.

In China, amendments to the PRC Patent Law (amended in October 2020 and implemented in June 2021) introduced patent term compensation for eligible invention patents relating to new drugs. Third-party patents may be extended under this mechanism, potentially increasing infringement risks and constraining our ability to commercialize our drug candidates (if approved). Patent term compensation may not exceed five years, and the total effective patent term after marketing approval may not exceed 14 years. Extended delays in our commercialization could also allow technological advances or new product launches to erode our competitiveness, and future changes to PRC IP laws could further adversely affect us.

***If we are unable to protect the confidentiality of our trade secrets and confidential information, including know-how relating to our products, drug candidates, active pharmaceutical ingredients, production processes and traditional Chinese medicines, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisers have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.***

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drugs and drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, consultants, advisors and other third parties that have access to them.

We may also face claims that our employees, consultants or advisers have misappropriated trade secrets or other proprietary rights of their current or former employers, or disputes regarding ownership of intellectual property we believe is ours. Even if such claims are unsubstantiated, defending or prosecuting them could be costly, time-consuming and disruptive; adverse outcomes could result in damages, loss of valuable rights, narrowed exclusivity or freedom to operate, or constraints on our ability to develop, manufacture or commercialize our products and candidates. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

## RISK FACTORS

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

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the CNIPA, USPTO or comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

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

Our commercial success depends on our ability to develop, manufacture, market and sell our products without infringing or misappropriating the intellectual property of others. The pharmaceutical industry is subject to extensive patent and other IP litigation, and we cannot assure you that our products or their use do not, and will not, infringe third-party rights. We may also fail to identify relevant third-party patents or applications, and published applications may later be amended in a manner that could cover our products.

## **RISK FACTORS**

If third parties assert infringement or trade secret misappropriation claims, they may seek injunctive or other equitable relief that could delay, restrict or prevent the development or commercialization of one or more of our products. Defending such claims, regardless of merit, could require substantial expense and divert management and personnel resources, and there can be no assurance that courts will rule in our favor on validity, enforceability, priority or non-infringement.

To avoid or resolve claims, we may need to obtain licenses on terms that may be costly, non-exclusive, unavailable or otherwise unacceptable, which could reduce our profitability or constrain our operations. We could also be required to pay significant damages, including enhanced damages and attorneys' fees in certain circumstances. Even if we ultimately prevail or settle, any such dispute could materially and adversely affect our business, financial condition, results of operations and prospects.

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

Intellectual property rights are subject to inherent limitations and may not protect us from all competitive threats. For example, third parties may be able to develop or manufacture products similar to our drug candidates, or apply similar technologies, without infringing our patents or other rights, particularly where the scope of protection is limited by applicable laws or legal proceedings. We may not have been the first to file for certain inventions, our pending applications may not mature into issued patents, and we may be unable to develop additional patentable technologies. In addition, we may elect to keep certain know-how as trade secrets, but third parties could later obtain patent protection over similar subject matter. Our patents may also be challenged and found invalid or unenforceable, and competitors may conduct R&D in jurisdictions where we lack protection and use the resulting knowledge to compete in our key markets. Any of these developments could materially and adversely affect our business, financial condition, results of operations and prospects.

### **RISKS RELATING TO THE [REDACTED]**

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

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

## RISK FACTORS

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

***We will be concurrently subject to [REDACTED] and regulatory requirements of Chinese mainland and Hong Kong.***

As we are listed on the Shenzhen Stock Exchange and will be [REDACTED] on the Main Board of the Stock Exchange of Hong Kong, we will be required to comply with the applicable listing rules and other regulatory regimes in both jurisdictions, unless an exemption is available or a waiver has been obtained. The need to comply with two sets of continuing obligations (including disclosure, notifiable/connected transactions and corporate governance requirements) may increase the complexity of our compliance management and require additional internal resources and external professional support.

There can be no assurance that we will not incur higher ongoing compliance costs, or that differences in timing or content requirements between the two regimes will not create operational challenges. Any failure to comply with the applicable requirements in either jurisdiction could result in regulatory actions and could adversely affect our reputation, business, financial condition and results of operations.

***Our A Shares were listed in China in July 2004, and the characteristics of the A share and H share markets may differ.***

Our A Shares were listed on the Shenzhen Stock Exchange Market in July 2004. Following the [REDACTED], our A Shares will continue to be traded on the Shenzhen Stock Exchange Market and our H Shares will be traded on the Stock Exchange. Under current PRC laws and regulations, our H Shares and A Shares are neither interchangeable nor fungible, and there is no [REDACTED] or settlement between the H Share and A Share markets. With different [REDACTED] characteristics, the H Share and A Share markets have divergent [REDACTED] volumes, liquidity and [REDACTED] bases, as well as different levels of retail and institutional [REDACTED] participation. As a result, the [REDACTED] performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the price of our H Shares, and vice versa. The fluctuations in the price of our A Shares may also affect our [REDACTED] in Hong Kong. Due to the different characteristics of the H Share and A Share markets, the historical prices of our A Shares may not be indicative of the performance of our H Shares. You should therefore not place undue reliance on the trading history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

## RISK FACTORS

***There has been no prior [REDACTED] for our H Shares, and an active [REDACTED] market for our H Shares may not develop or be sustained.***

Prior to the [REDACTED], there was no [REDACTED] for our H Shares. We cannot assure you that a [REDACTED] for our H Shares with adequate liquidity and [REDACTED] volume will develop or be sustained following the completion of the [REDACTED]. The [REDACTED] of our H Shares will be the result of negotiations between the [REDACTED] (for themselves and on behalf of the [REDACTED]) and us, and may not be indicative of the [REDACTED] at which our H Shares will [REDACTED] after the [REDACTED]. If an active [REDACTED] for our H Shares does not develop or is not sustained, the [REDACTED] and liquidity of our H Shares may be materially and adversely affected.

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

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

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

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

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

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

## RISK FACTORS

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

We have declared dividends in the past. However, there is no assurance that dividends of any amount will be declared or distributed by us in any future year. Under applicable PRC laws and regulations, the payment of dividends is subject to certain limitations, and our profit determined under the PRC Accounting Standards for Business Enterprises may differ from profit determined under IFRSs. Any declaration, payment and amount of future dividends will be at the discretion of our Board, taking into account, among other factors, our results of operations, financial condition, cash flows, capital expenditure requirements, market conditions, strategic plans and business prospects, and regulatory restrictions on dividend payment, and will be subject to approval by our Shareholders as well as our constitutional documents and applicable PRC laws and regulations. No dividend shall be declared or paid except out of profits and reserves lawfully available for distribution. Accordingly, our historical dividends should not be taken as indicative of our dividend policy in the future.

***You should not place any reliance on any information released by us in connection with the listing of our A Shares on the Shenzhen Stock Exchange.***

As our A Shares are listed on the Shenzhen Stock Exchange, we are subject to periodic reporting and other information disclosure requirements in Chinese mainland and, from time to time, publicly release information on the Shenzhen Stock Exchange or other media designated by the CSRC. Such information is prepared in accordance with regulatory requirements, industry standards and market practices in Chinese mainland, which differ from those applicable to the [REDACTED]. The presentation of financial and operational information for the Track Record Period disclosed on the Shenzhen Stock Exchange or other CSRC-designated media may not be directly comparable to the financial and operational information contained in this document. Accordingly, prospective [REDACTED] in our H Shares should rely only on the financial, operating and other information contained in this document. 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 and any formal announcements we make in [REDACTED] with respect to the [REDACTED].

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

This document, particularly the “Industry Overview” section, contains information and statistics, including, but not limited to, information and statistics relating to the PRC, the PRC economy and the healthcare industry in the PRC that have been derived from various official government publications, third-party reports or publicly available sources. We believe that the sources of such information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. Neither we or the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources, and no representation is given as to its accuracy. We cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy, as the case may be, as that in other jurisdictions.

## RISK FACTORS

***Forward-looking statements contained in this document are subject to risks and uncertainties.***

This document contains forward-looking statements with respect to our business strategies, operating efficiencies, competitive positions, growth opportunities for existing operations, plans and objectives of management, certain [REDACTED] information and other matters. The words "aim", "anticipate", "believe", "could", "predict", "potential", "continue", "expect", "intend", "may", "might", "plan", "seek", "will", "would", "should" and the negative of these terms and other similar expressions identify a number of these forward-looking statements. These forward-looking statements, including, amongst others, those relating to our future business prospects, capital expenditure, cash flows, working capital, liquidity and capital resources are necessarily estimates reflecting the best judgment of our Directors and management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. As a consequence, these forward-looking statements should be considered in light of various important factors, including those set out in this section. Accordingly, such statements are not a guarantee of future performance and [REDACTED] should not place undue reliance.

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

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

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED]. By applying to purchase our 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.