

RISK FACTORS

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. Particularly, we are a biotech company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the industry in which we operate involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations and prospects. In any such case, the market price of our 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 headed “Forward-looking Statements” in this document. You should seek professional advice from your relevant advisers regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR PIPELINE PRODUCTS

The efficacy and clinical benefit of our Core Products remain uncertain given their current stage of development and novel delivery mechanisms, and we may fail to obtain regulatory approval.

Our Core Products are in clinical development. As of the Latest Practicable Date, Phase I clinical trials for our Core Products have been completed. Phase I studies are primarily designed to evaluate safety, tolerability and pharmacokinetics, and are not generally designed to establish efficacy. Although conduct of Phase IIa and Phase II clinical studies for certain Core Products have also been completed as of the Latest Practicable Date, the relevant clinical study reports remain pending and the efficacy data from such trials were therefore not available yet. Accordingly, the clinical efficacy and benefit of our Core Products have not been established, and there is no assurance that the safety, tolerability, pharmacokinetic profile and other data observed to date will be predictive of outcomes in later-stage trials or in broader patient populations.

In addition, our Core Products employ novel delivery mechanisms and formulations that differ from conventional routes of administration used in clinical practice. Such delivery mechanisms may present unique scientific and clinical uncertainties. Further, favorable or comparable pharmacokinetic profile to other administration routes in certain studies demonstrated in our Core Products does not necessarily translate into clinically meaningful efficacy, safety or tolerability outcomes for the intended indications.

Our ability to succeed in the foreseeable future largely depends on successfully completing clinical trials, securing regulatory approvals and commercialising our pipeline products. Any negative results from clinical trials, delays or denial in obtaining regulatory approvals or failure in commercialisation of our pipeline products could significantly impact our ability to generate revenue and overall business outlook.

Our revenue and profitability are substantially dependent on our ability to complete the development of our pipeline products, which are still in clinical or pre-clinical development, obtain requisite regulatory approvals and successfully manufacture and commercialise our pipeline products. We have invested a considerable portion of our efforts and capital resources in the development of our pipeline products, and we expect to incur substantial and increasing expenditures for the development and commercialisation of our pipeline products in the future.

Our commercial success is dependent on numerous factors, including but not limited to:

- the completion of preclinical studies and clinical trials, including extensive preclinical testing and study obligations to obtain the necessary regulatory clearance from NMPA, FDA or other relevant health authorities, and successful patient enrollment;
- the generation of positive safety and efficacy data from our clinical trials;
- the procurement of sufficient supplies for our pipeline products, any necessary combination therapies, or comparator drugs for clinical trials;
- the establishment of scalable commercial manufacturing capabilities;

RISK FACTORS

- the ability of our CROs, clinical study sites, hospitals or other third parties to conduct their work in compliance with our protocols, applicable laws and good clinical practice requirements imposed by the NMPA, the FDA, or other regulatory authorities without compromising data integrity;
- securing, maintaining, and enforcing patent, trademark, trade secret, and other intellectual property protection and regulatory exclusivity;
- avoiding infringement and misappropriation or otherwise violation of the patents, trademarks, trade secrets or other intellectual property rights of third parties and successfully defending against any claims by third parties of such infringement and misappropriation ;
- receipt of regulatory approvals from applicable regulatory authorities;
- successfully launching our products into the market post-approval and achieving sufficient market demand, particularly for our Core Products;
- ensuring our pipeline products continue to demonstrate an acceptable safety profile after regulatory approval; and
- strong commercial manufacturing capabilities upon commercialisation of our pipeline products.

As of the Latest Practicable Date, our Core Products, DHMP, and XJN010 have completed their respective Phase IIa or Phase II clinical studies, although the relevant clinical study reports remain pending, while our other pipeline products are in relatively earlier stage. The process of development, obtain regulatory approvals for and commercialise products is long, complex and costly, with no assured outcome, and we may fail to complete our clinical trials or obtain regulatory approvals. If we experience a delay or failure in completion of our clinical trials or in obtaining regulatory approvals, it may result in us having to deprioritise the development of certain pipeline products or unable to successfully commercialise our pipeline products in accordance with the anticipated timeline. Clinical trials and regulatory approvals delay may also enable our competitors to introduce competing products to the market before we are able to successfully commercialise our products. Any of the above may materially and adversely affect our business and financial condition.

The R&D of our pipeline products involves a lengthy and expensive process with no guaranteed outcome. We may not achieve favourable results for our pipeline products in clinical trials, results of earlier studies and trials may not be predictive of future trial results.

Clinical trial is inherently uncertain, a process marked by substantial costs and multi-year timelines, with the potential for failure at any stage of drug development. Moreover, the results of our pipeline products from preclinical studies or early clinical trials may not reliably predict outcomes in later-stage trials, just as initial or interim results may not forecast a trial’s final conclusions. This variability in results can stem from numerous factors, including changes in trial procedures, differences in the size, type, and genetic makeup of patient populations, patient adherence to dosing regimens, and the rate of dropout among participants. Final data of our clinical trials may also materially differ from the interim data published from time to time as preliminary data may be revised during verification procedures and may also change when additional patient data become available as a result of increased patient enrollment. Consequently, results from our future clinical trials may not be favorable based on our currently available preclinical data and clinical data, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialisation of our pipeline products and may ultimately adversely affect our business and prospects.

Our pipeline products are subject to stringent regulations. We may not be able to receive regulatory approval for our pipeline products or may be subject to penalties if we fail to comply with regulatory requirements.

Regulatory approval from authorities typically entails a lengthy process, often extending many years from the commencement of preclinical studies through clinical trials. Furthermore, approval policies, regulations, and the type and volume of clinical data required for approval may evolve during the clinical development of a pipeline products and may also differ across jurisdictions. Consequently, additional time, effort, and expense may be necessary to ensure compliance with diverse international regulatory processes and to bring our approved pipeline products to global markets.

Regulatory authorities may request additional information, including supplementary preclinical or clinical data, to support our applications, which could result in delays to or denial of approval and adversely affect our commercialisation plans. We may also incur additional costs to refine the R&D of our products due to the longer development timeline and in order to fulfill the requirements of the regulatory authorities, and may materially affect our financial position. In the event an approval is granted, regulatory authorities may also approve a pipeline product for a narrower scope of indications

RISK FACTORS

than we have requested, or grant approval contingent upon the successful completion of costly post-marketing clinical studies. Any of the aforementioned outcomes could materially impair the commercial prospects and market potential of our pipeline products.

Furthermore, our products will also be subject to ongoing regulatory obligations and continued regulatory scrutiny pertaining to their manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, and the conduct of post-marketing clinical trials. These requirements also extend to the submission of information related to safety, efficacy and their post-marketing data. Any failure to comply with these requirements may result in sanctions or penalties imposed by regulatory authorities that could adversely affect our business, financial condition and results of operations.

We may not be successful in identifying or discovering new pipeline products through our internal research and development, or in pursuing additional therapeutic opportunities through indication expansion, to build and maintain our product pipeline.

We may not be successful in identifying new pipeline products.

Research aimed at developing new indications for our existing candidates and identifying novel pipeline products and targets demands substantial technical, financial, and human resources. Potential indications or candidates which have shown promise in initial research may ultimately fail to yield viable results for clinical development for various reasons. As a result, we may not be able to identify new pipeline products or develop additional therapeutic opportunities for existing ones, a failure that could materially and adversely affect our future growth and prospects. Our strategic focus on certain candidates or programs may result in a concentration of resources on initiatives that ultimately prove to be unsuccessful.

If we face delays or challenges in enrolling patients for our clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or adversely affected.

We may be unable to initiate or continue clinical trials for our pipeline products if we cannot locate and enroll a sufficient number of eligible subjects, or if enrollment is delayed due to a competitive clinical trial environment. An inability to recruit enough subjects who meet the applicable criteria outlined in the protocol could result in significant delays to our clinical trials. In addition, some of our competitors may be conducting clinical trials for pipeline products targeting the same indications as ours. Consequently, subjects who would otherwise qualify for our trials may enroll in those of our competitors, which could further delay our enrollment efforts.

Delays in enrollment could lead to increased costs or negatively impact the timing and outcomes of our planned clinical trials. Such delays could delay or prevent the completion of these trials, ultimately adversely affecting our ability to advance our pipeline products.

We may invest substantial resources in research and development of pipeline products, allocate our limited resources to pursue a particular pipeline product or indication and fail to capitalize on pipeline products or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

The global biopharmaceutical market is constantly evolving, and the development of drugs faces many risks and challenges. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance our research and development capabilities. We intend to continue to enhance our technical capabilities in drug discovery and development, which are capital-and-time intensive.

Furthermore, as we have limited financial and managerial resources, we manage development risks and allocate our resources in accordance with different development timelines of our pipeline products for selected indications. As a result, we may forgo or delay pursuit of opportunities with other pipeline products or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Accordingly, our resource allocation decisions may cause us to fail to capitalize on other viable commercial products or profitable market opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular pipeline product, we may lose the chances to timely commercialize such pipeline products and our prospects may be adversely affected.

RISK FACTORS

We work with various CROs to develop our pipeline products. If we fail to maintain or develop clinical collaborations and relationships with any of the CROs, or if any of the CROs fail to duly perform their contractual obligations or meet expected timelines, we may be unable to secure regulatory approvals for or to commercialize our pipeline products, which in turn may potentially result in significant adverse impacts on our business, financial condition and operation results.

Our R&D strategy and future commercialisation efforts depend significantly on third-party service providers. We engage CROs to monitor, support, and conduct our non-clinical studies and clinical trials for our pipeline products. Clinical trial sites, consultants, principal investigators, physicians and other medical experts involved in such studies and trials are confirmed and determined by us, but engaged and coordinated by the CROs, and we do not have direct contractual relationships with such parties, and we exert control only over certain aspects of their activities. Nevertheless, we remain responsible for ensuring that all studies are conducted in accordance with applicable protocols, regulatory requirements, and scientific standards. Our collaboration with CROs does not absolve us of our ultimate regulatory responsibilities.

We and our CROs are required to comply with GCP, regulations and guidelines, which are enforced by regulatory authorities such as the NMPA, and the FDA. Non-compliance with GCP standards by any party could render clinical data unreliable, potentially leading regulatory authorities to require us to conduct additional trials before approving our marketing applications. Additionally, our pivotal clinical trials must be conducted with products manufactured under GMP regulations. Any failure to comply with GMP could necessitate the repetition of clinical trials, thereby delaying the regulatory approval process.

Furthermore, our relationships with third-party CROs are subject to termination risk, in the event that these relationships are terminated, we may not be able to secure alternative arrangements on commercially reasonable terms which may affect the execution of our clinical trials and may delay the intended R&D and commercialization timeline of our pipeline products. These CROs are not our employees, and beyond the contractual remedies available to us, we cannot control their dedication of time and resources to our programs. The failure of a CRO to perform its contractual obligations, meet deadlines, adhere to clinical protocols, or provide reliable data could result in significant delays, extensions, or termination of our clinical trials. The above may cause us to incur additional substantial costs and may prevent us from obtaining regulatory approvals or successfully commercialising our pipeline products.

Our pipeline products may cause undesirable or unwanted side effects or have other properties that could delay or prevent regulatory approvals, or restrict the scope of the commercial profile of an approved label, or otherwise lead to significant negative consequences on our ability to launch, market and distribute our pipeline products or maintain market acceptance of such drugs if commercialised.

Undesirable or unwanted side effects stemming from our pipeline products could lead us or regulatory authorities to interrupt, delay, or halt clinical trials, potentially resulting in more restrictive product labels, delays or denial of regulatory approval by the NMPA, the FDA, or other comparable authorities, or significant alterations to our clinical protocol or overall development plan. Trial results might also reveal a high and unacceptable severity or prevalence of certain adverse events. Should this occur, our trials could be suspended or terminated, and the NMPA, the FDA, or other comparable authorities could order us to cease development or deny approval for our pipeline products across some or all targeted indications. Adverse events related to our pipeline products could impede patient recruitment or the ability of enrolled subjects to complete the trial, and might give rise to potential liability claims. Any of these outcomes could materially damage our reputation, business, financial condition, and prospects. Furthermore, if we or others identify undesirable or unwanted side effects in our other pipeline products after they have received regulatory approval, this could trigger potentially significant negative consequences, including, but not limited to, the following:

- we may suspend the marketing of the pipeline products;
- regulatory authorities may withdraw their approvals or revoke the licenses for the pipeline products;
- regulatory authorities may mandate additional warnings on the label;
- the FDA may require the implementation of a REMS, or the NMPA or a comparable authority may require a similar strategy that could, for example, restrict drug distribution and impose onerous implementation requirements on us;
- we may be required to conduct post-marketing studies of a specified nature;

RISK FACTORS

- we could face litigation proceedings and be held liable for harm caused to subjects or patients; and
- our reputation could be negatively affected.

Any of these events could prevent us from achieving or maintaining market acceptance for an approved pipeline products and could materially and adversely affect our business, operating results, and future prospects.

Clinical trials for CNS nasal drug delivery may be discontinued or terminated, which could adversely affect the clinical development of XJN010 and the overall business outlook.

XJN010 is an intranasal drug product for CNS indication and involves a novel delivery mechanism. Clinical trials for CNS nasal drug delivery have in some cases been discontinued or terminated, including due to insufficient efficacy. As such, their efficacy and clinical benefit remain uncertain.

If the clinical trials of XJN010 produce negative results, or are discontinued or terminated, the clinical development, regulatory approval and commercialisation of XJN010 may be delayed or may not proceed as planned. This could adversely impact our overall business outlook. For details of the challenges in relation to CNS nasal drug delivery, please refer to the section headed “Industry Overview — Nasal Spray Formulation Market” in this Document.

RISKS RELATING TO MANUFACTURING AND COMMERCIALISATION OF OUR PIPELINE PRODUCTS

The market size of our pipeline products might be smaller than we expected.

Our estimates of the potential market for our pipeline products are based upon a number of factors, including our estimates of the eligible patient population, pricing, available coverage and reimbursement. Our estimated market size may differ materially from the actual market addressable by our pipeline products. Our estimates of both the number of people with the diseases we target, as well as the subset of those patients who may be eligible for treatment with our pipeline products, are based on our beliefs and analysis. These estimates are derived from a variety of sources, including patient foundations and market research, and may prove to be incorrect. Furthermore, new studies may change the estimated incidence or prevalence of the diseases we are targeting, and the number of our target patients may turn out to be lower than we expect. Likewise, the potential addressable patient population for each of our pipeline products may be more limited than we anticipate, or this population may not be receptive to treatment with our pipeline products, and new patients may become increasingly difficult to identify or access. Should the market opportunities for our pipeline products prove to be smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

For example, one of our Core Products, DHMP, an dissolving microneedle patch has been developed for pre-operative sedation in both pediatric and adult patients. However, given the presence of well-established and varied competing methods for preoperative sedation, including, but not limited to, oral and intranasal administration, as confirmed by F&S, the market potential of the Core Product may be limited. Besides, our other Core Product, XJN010, a novel, clinical-stage nasal inhalation drug formulation developed for the on-demand treatment of “Off” episodes in patients with Parkinson’s disease who are already receiving a dopa decarboxylase inhibitor/levodopa regimen. Nevertheless, such indications can also be treated by a treatment method in the U.S. market via pulmonary inhalation as confirmed by F&S. Besides, XJN1102, a glucagon-like peptide-1 (GLP-1) microneedle patch, has been developed for the treatment of type II diabetes and for overweight or obese adult weight management. However, it targets the same indications for which established GLP-1 therapies, primarily administered via oral or subcutaneous injection, are already a standard treatment option as confirmed by F&S. Additionally, any preference among patients and physicians for lifestyle-based weight management solutions could reduce the addressable market for our product. As a result, even though the number of patients of our targeted indications may be large, the actual addressable patients of our pipeline products may be limited and smaller than we expected.

RISK FACTORS

We may face intense competition if competing drugs are more effective, have fewer side effects, are better marketed and cost less than our drugs or pipeline products, or receive regulatory approval or enter the market ahead of ours, or if our drugs or pipeline products are not approved. We may also face rapid technological advancements and changes which may possibly allow our competitors to develop therapies that are similar, more advanced, or more effective than ours.

The development and commercialisation of novel medicinal products is inherently highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biopharmaceutical companies on a global scale. As confirmed by F&S, a number of large pharmaceutical and biopharmaceutical companies are currently pursuing the development of drugs formulated using microneedle and nasal inhalation technologies. We, in turn, are developing our pipeline products using these same alternative drug delivery platforms. Some of these competitors may possess superior resources and expertise than we do.

Potential competitors also include academic institutions, government agencies, and other public and private research organisations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialisation. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be diminished or entirely eliminated if our competitors develop and commercialise drugs that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any pipeline products that we may develop or commercialise. Our competitors may also obtain approval from the NMPA, the FDA, or other comparable regulatory authorities for their products more rapidly than we obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our pipeline products obsolete or non-competitive before we can recover the expenses associated with developing and commercialising any of our pipeline products.

Merger and acquisition activity within the biopharmaceutical industry may result in even greater resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and well-established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and registering patients for clinical trials, and in acquiring technologies that are complementary to, or necessary for, our pipeline products.

The emergence and availability of competing products will affect our ability to appropriately price our products. For instance, hospitals will negotiate lower retail prices depending on the availability of competing products and preferences of physicians and patients, and the emergence of more advanced therapies, particularly those with improved patient compliance or reduced side effects, could exert downward pricing pressure on our products after their commercialisation, all of the above may have a material and adverse effect on our business, financial condition, and future results.

We have limited experience in launching and marketing pipeline products, and successful commercialisation of new products will require additional resources. There is no assurance that we will be able to successfully commercialise our pipeline products.

We rely on our current and future collaborators’ willingness and ability to devote resources to the development and commercialisation of our Core Products and other pipeline products and to otherwise support our business as contemplated in our collaboration agreements, and we may not have adequate control over patents and patent applications covering the pipeline products that may involve our current and future collaborators. As none of our pipeline products has reached the commercialisation stage, we have not yet demonstrated an ability to launch and commercialise our pipeline products. Our MAH Business operational experience is not directly comparable with the commercialisation of our pipeline products and may not fully translate to the successful commercialisation of our pipeline products. Given our lack of experience, we may require a longer timeframe or be less cost-efficient in the commercialisation process than a company with more experience launching and marketing medicinal products. This inexperience may expose our business operations to greater risk. We cannot give any assurance that we will succeed in the commercialisation process.

Furthermore, if we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our pipeline products, we will likely pursue collaborative arrangements regarding the sales and marketing of our pipeline products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Upon pursuing this path, our control over the marketing and sales activities of such third parties will be limited to the terms of our

RISK FACTORS

contractual agreements, which may result in lower product revenues than would have been generated through direct commercialisation by ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our pipeline products. This competitive environment extends to the recruitment, hiring, training, and retention of qualified marketing and sales personnel, a resource we would not control directly. Our ultimate revenue would, therefore, be contingent upon the commercial efforts of these third parties. As a result, we may not be able to generate the anticipated product sales revenue.

The manufacturing of pharmaceutical products is a highly exacting and complex process. Any disruption, deviation, or failure in manufacturing our products could materially and adversely affect our ability to consistently supply products, which in turn may materially and adversely affect our business.

We possess no prior experience in the commercial-scale manufacture of our products. Moreover, the manufacture of pharmaceutical products is intrinsically complex. Should we elect to undertake the commercial manufacture of our products in the future, a range of problems may arise during the manufacturing process for a variety of reasons.

Products of an unsatisfactory quality may have to be discarded, leading to product shortages or increased expenses. This could result, amongst other things, in heightened costs, lost revenue, damage to customer relationships, and significant time and expense spent investigating the cause. Depending on the nature of the problem, similar losses may be incurred with respect to other batches or products. Furthermore, if quality issues are not identified prior to a product’s release to the market, the costs associated with product recalls and product liability may also be incurred.

Manufacturing methods and formulations are frequently altered throughout the developmental lifecycle of a pipeline products from clinical trials, through to approval, and into commercialisation in an effort to optimise manufacturing processes and outcomes. Such alterations carry the risk that they may not achieve their intended objectives. Any such change could cause the pipeline products to perform differently, thereby affecting the results of planned clinical trials or other future trials conducted with the altered materials. This could delay the commercialisation of our pipeline products and necessitate bridging studies or the repetition of one or more clinical trials. In turn, this may result in increased clinical trial costs, delays in regulatory approvals, and jeopardise our ability to commence product sales and generate revenue.

We may also encounter challenges in achieving adequate or clinical-grade products that meet the standards or specifications of the NMPA, the FDA or other comparable regulatory agencies, in maintaining consistent and acceptable production costs, and in securing an adequate supply of qualified personnel, raw materials, or key contractors. In such circumstances, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs on terms, and with levels of quality and cost, acceptable to us, or at all. Such an event could delay our clinical trials and/or the commercial availability of our products.

Our pipeline products may become subject to national or other third-party insurance coverage, reimbursement practices, healthcare reform initiatives or unfavourable pricing regulations, which could make it difficult for us to sell our pipeline products profitably.

The successful commercialisation of our future approved drugs will, in part, depend on the availability of adequate insurance coverage and reimbursement from government and private payers, as patients frequently rely on such reimbursement to cover a significant portion, or all, of the costs associated with their treatment. Government authorities and private medical insurers determine coverage and reimbursement levels based on their assessment of various factors, including:

- the safety, efficacy and medical necessity of the drug and/or treatment;
- its suitability for specific diseases and/or patient groups;
- whether the drug and/or treatment is considered experimental or investigational; and
- its cost-effectiveness in the context of their respective budgets or profit margins.

Reimbursement may not be available for our future approved drugs and the level of reimbursement may vary. In the PRC, the level of reimbursement for programme participants is

RISK FACTORS

contingent upon the inclusion of our drugs in the National Reimbursement Drug List (the “NRDL”) or other government-sponsored medical insurance schemes, as well as the specific tier under which a drug is classified. The inclusion or removal of drugs from the NRDL and their tier classification are subject to regular review by the National Healthcare Security Administration, the Ministry of Human Resources and Social Security, and their respective provincial or local counterparts. Our future approved drugs may not be included in the NRDL or other similar government-sponsored medical insurance programmes.

The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved pipeline products and could have a negative impact on our reputation, sales and business.

The illegal importation of competing products that are not currently approved or marketed in our target territories, or sourced from jurisdictions with government price controls or other market dynamics resulting in lower prices, could adversely affect demand for our future approved drugs. In turn, this may adversely impact our sales and profitability in the PRC, the United States, and other jurisdictions where we plan to commercialise our products.

Furthermore, the phenomenon of cross-border imports from lower-priced markets (known as “parallel imports”) into higher-priced markets could harm sales of our future approved products and exert downward commercial pressure on pricing within one or more markets. Additionally, competent government authorities may expand the ability of consumers to import lower-priced versions of our future approved products or competing products from outside the PRC, the United States, or other countries where we plan to commercialise. Any future legislation or regulation that increases such access to lower-priced medicines from outside these key jurisdictions could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licences or approvals, or may be fraudulently mislabelled as to their content or manufacturer. These products are commonly referred to as “counterfeit pharmaceutical products”. The systems for controlling and enforcing against such counterfeits, particularly in developing markets, may prove inadequate to deter or eliminate the manufacture and sale of products imitating our own. As a result, we are exposed to these risks by virtue of our substantial operations within a developing economy. Since counterfeit pharmaceutical products often closely resemble the authentic versions in appearance but are typically sold at lower prices, counterfeits of our products could rapidly erode demand for our future approved drugs.

Moreover, counterfeit drugs may differ in their chemical composition, potentially rendering them less effective, entirely ineffective, or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even lead to litigation, including product liability claims. Furthermore, counterfeit pharmaceutical products are not expected to meet our or our collaborators’ rigorous manufacturing, testing and inventory standards. A patient who receives a counterfeit pharmaceutical product may face significant health risks. Our reputation, sales and business could suffer harm as a result of counterfeit pharmaceutical products sold under the branding of our Company or our collaborators.

RISKS RELATING TO OUR FINANCIAL PROSPECTS

We have incurred net losses during the Track Record Period. We anticipate that we will continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in the biopharmaceutical industry is inherently uncertain and unpredictable in terms of commercial success. It requires substantial upfront capital investment and carries significant risk that product candidates may fail to obtain regulatory approval or achieve commercial viability. We have incurred net losses during the Track Record Period. For the years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, we recorded net losses of approximately RMB147.1 million, RMB110.9 million and RMB197.2 million, respectively. The majority of our operating losses have been attributable to expenses incurred in connection with our R&D programs and administrative costs associated with our operations.

We expect to continue to incur material expenses and losses in the foreseeable future, and we expect these losses to increase materially as we continue to expand our development of, and seek regulatory approvals for, our pipeline products, and continue to build up our commercialization and sales workforce in anticipation of the future rollout of our pipeline products. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, and our ability to generate revenues. Should any of our pipeline products fail to succeed in clinical trials or fail to

RISK FACTORS

obtain regulatory approval, or if approved, fail to achieve market acceptance, we may not become profitable. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. Such a decline in the value of our Company may also cause you to incur a substantial loss of your investment.

We had net liabilities, net current liabilities and net operating cash outflows during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

We had net liabilities of approximately RMB283.2 million, RMB343.6 million and RMB532.8 million as of December 31, 2024 and 2025 and May 31, 2026, respectively. We also had net current liabilities of approximately RMB308.6 million, RMB380.8 million and RMB573.3 million as of December 31, 2024 and 2025 and May 31, 2026, respectively. A net liabilities position and net current liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all. For further details, please refer to the above paragraph headed “— We may require significant additional financing to support our operations and future expansion, which could dilute the interests of our shareholders or limit our operational flexibility. If we are unable to secure such funding, we may not be able to complete the development or commercialization of our pipeline products.”

We had net cash flows used in operating activities of approximately RMB15.3 million, RMB66.5 million and RMB30.8 million for the years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, respectively. For further details, please see the section titled “Financial Information — Liquidity and Capital Resources — Cash Flows of our Group — Net Cash Flows Used in Operating Activities” in this Document. Failure to generate adequate operating cash flow or to obtain sufficient external funding could materially and adversely affect our liquidity, financial condition, and ability to grow our business as planned. If we encounter long-term and continuous net operating cash outflow in the future, we may not have sufficient working capital to cover our operating costs, and our business, financial condition and results of operations may be materially and adversely affected.

We have incurred impairment losses with respect to our trade receivables and contract assets during the Track Record Period. Significant impairment losses with respect to our trade receivables and contract assets may materially and adversely affect our business, financial condition, and results of operations.

We had gross trade receivables and contract assets of approximately RMB17.1 million, RMB28.2 million and RMB25.9 million as of December 31, 2024 and 2025 and May 31, 2026, respectively. We have incurred impairment losses on trade receivables and contract assets on contract assets from the CRO Services for the two years ended December 31, 2024 and 2025 and five months ended May 31, 2026 of approximately RMB0.4 million, RMB0.4 million, and RMB0.8 million, respectively. In the event that our customers’ cash flow, working capital, financial condition or results of operations deteriorates, our customers may not be able to timely pay trade receivables due to us or at all. Delay in a customer’s payment obligations or substantial default may materially and adversely affect our business, financial condition and results of operations.

We may require significant additional financing to support our operations and future expansion, which could dilute the interests of our Shareholders or limit our operational flexibility. If we are unable to secure such funding, we may not be able to complete the development or commercialization of our pipeline products.

During the Track Record Period, we financed our operations, including research and development activities for our preclinical studies and clinical trials, primarily through a combination of interest-bearing bank and other borrowings and equity financing. As of December 31, 2024, 2025 and the five months ended May 31, 2026, our interest-bearing bank and other borrowings amounted to approximately RMB12.9, RMB9.8 million and RMB24.7 million, respectively.

We believe that our existing cash and cash equivalents, available debt financing, together with the estimated net [REDACTED] from the [REDACTED], will be sufficient to meet at least 125% of our anticipated funding needs for at least the next 12 months from the date of this Document. Going forward, we expect to finance our operations primarily through the capital contributions from the Shareholders, debt financing (including loans from the banks), and the net [REDACTED] from this [REDACTED]. Following the successful commercialisation of one or more of our pipeline products, we also expect to rely, in part, on revenue generated from product sales to support our operations.

RISK FACTORS

However, changes in our ability to obtain financing or generate sufficient revenue could impact our liquidity, cash flow, and overall financial performance. We may still require significant additional capital to meet our ongoing operational needs, particularly to fund research and development activities, advance the commercialisation of our pipeline products, and expand our manufacturing capabilities.

As our business continues to grow, we may seek additional financing through equity issuances, debt arrangements, licensing, collaboration agreements, or other funding sources. However, such financing may not be available on commercially reasonable or favorable terms, or may not be available at all. If we raise additional capital by issuing equity or convertible debt securities, your ownership interest may be diluted, and such securities may include terms, such as liquidation preferences or other rights, that could adversely affect your interests as a holder of our H Shares.

Taking on additional debt could increase our fixed payment obligations and subject us to restrictive covenants, including limitations on incurring further indebtedness or issuing additional equity, constraints on acquiring or licensing intellectual property, and other operational restrictions that may impair our ability to conduct our business effectively. Our ability to obtain financing will also depend on prevailing financial, economic, and market conditions, as well as our relationships with banks and financial institutions — factors that are largely beyond our control. If sufficient funds are not available when needed, we may be forced to delay, scale back, or discontinue certain preclinical studies, clinical trials, research and development programs, or the commercialization of our pipeline products, any of which could adversely affect our business and growth prospects. Furthermore, if we pursue collaboration or licensing arrangements to raise capital, we may be required to agree to unfavorable terms. These may include granting third parties rights to our technologies or pipeline products under less favorable conditions than we might otherwise obtain, or at an earlier stage than we would prefer, potentially foregoing future opportunities to secure more advantageous arrangements.

We are subject to fluctuations in the fair value of our financial assets measured at fair value through profit or loss (“FVPL”) and to uncertainties in their valuation.

As of 31 December 2024 and 2025 and May 31, 2026, our financial assets measured at fair value through profit or loss amounted to approximately nil, RMB1.4 million and RMB8.2 million, respectively. These financial assets primarily consist of wealth management products and structured deposits issued by various banks in the PRC, which offer floating returns payable together with the principal upon maturity. We may not be able to realise fair value gains on these financial assets, and we may incur fair value losses in the future. The fair value of such assets is subject to fluctuations influenced by factors beyond our control, including changes in macroeconomic and market conditions.

We benefit from government grants, the expiration or modification of these grants could adversely affect our financial condition and results of operations.

During the Track Record Period, we recognised government grants of approximately RMB1.8 million, RMB3.0 million and RMB0.6 million during the two years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, respectively. Certain government financial incentives, grants, or funding are awarded on a project-by-project basis and/or are subject to the fulfillment of specific conditions. These conditions may include compliance with applicable financial incentive agreements, completion of designated projects, and adherence to various requirements, such as maintaining operations or physical facilities.

We may not be able to continue to meet all eligibility requirements relating to government financial incentives, grants and funding. If we fail to satisfy any of these requirements due to changes in our business activities, ownership structure or other circumstances, we may lose our entitlement to, or be required to return, all or part of the relevant government incentives, funding, or grants we currently enjoy.

We may not be able to maintain the existing level of government incentives and support in the future. Any reduction, delay, or termination of such programs due to government budget changes, policy updates or other factors could adversely affect our business, financial condition, and results of operations.

We may experience impairment losses related to our prepayments, other receivables and other assets.

We had gross prepayments, other receivables and other assets of approximately RMB6.6 million, RMB14.7 million and RMB17.5 million as of December 31, 2024 and 2025 and May 31, 2026, respectively. We have incurred impairment losses on prepayments, other receivables and other assets of approximately RMB5,000 for the year ended December 31, 2024, reversal of impairment losses on prepayments, other receivables and other assets of approximately RMB3,000 for the year ended December 31, 2025 and impairment losses on prepayments, other receivables and other assets of approximately RMB2,000 for the five months ended May 31, 2026. Our prepayments, other receivables

RISK FACTORS

and other assets primarily consist of prepayments for property, plant and equipment, deposits, prepayment, value-added tax and other taxes recoverable, other receivables and impairment allowance. We are exposed to credit risks associated with these prepayments, other receivables and other assets if our suppliers, service providers, and other third parties fail to timely fulfill their contractual obligations.

The assessment of potential impairment losses involves a significant degree of management judgment and estimation in determining key assumptions. In addition, unforeseen adverse developments could lead to decreases in the value of our prepayments and other receivables. Accordingly, our assumptions and estimates may result in material adjustments to the carrying amounts of these assets in the future, which could give rise to impairment losses. Any material impairment losses on prepayments, other receivables and other assets could adversely affect our business, financial condition, and results of operations.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a negative effect on our financial performance.

We have established an employee incentive platform for the benefit of our employees, Directors and senior management as remuneration for their services provided to us and to incentivize and reward the eligible persons who have contributed to the success of our Company. During the years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, we incurred share-based payment expenses of nil, approximately RMB13.6 million and RMB7.9 million, respectively. For further details of the employee incentive platform, please refer to the section titled “History, Development and Corporate Structure — Employee Incentive Platform.”

To further incentivize our employees, we may incur additional share-based payment expenses in the future. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a negative effect on our financial performance. Issuance of additional H Shares with respect to such share-based payments may dilute the shareholding of our Shareholders and could result in a decline in the value of our H Shares.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Our ability to obtain and maintain our patent protection depends on compliance with procedural obligations, timely document submission, fee payments, and other requirements set by patent authorities.

Periodic maintenance, renewal and annuity fees, as well as various other government charges relating to patents and patent applications, must be paid to the China National Intellectual Property Administration (“CNIPA”), the United States Patent and Trademark Office (“USPTO”) and other patent authorities in different jurisdictions at several stages throughout the life of a patent. These authorities also require compliance with a range of procedural, documentary and administrative requirements during the patent application process.

There may be circumstances in which non-compliance is not capable of being remedied by payment of fees or other permitted means under the applicable regulations, and may result in the abandonment, loss of priority or expiry of a patent or patent application. This could lead to the partial or complete loss of patent rights in the relevant jurisdiction. If any of these events occurs, competitors or other third parties may be able to enter the market, which could materially and adversely affect our competitive position, business operations, financial condition and future prospects.

Intellectual property rights may not fully safeguard us from all potential threats to our competitive advantages. If these protections are insufficient or are circumvented, our market position and competitiveness may be materially harmed.

There is inherent uncertainty regarding the degree of protection afforded by our intellectual property rights. Intellectual property rights have their limitations, and may therefore be insufficient to adequately protect our business or enable us to maintain a competitive advantage.

The life of patent protection is limited. Once expired, or if our patent rights are circumvented, third parties may develop and commercialise similar or alternative products and technologies in a non-infringing manner, or products and technologies similar or identical to ours and compete directly against us.

The period of protection afforded by patents is inherently limited. This risk is particularly significant for our product candidates due to the substantial time required for development, clinical testing, and regulatory review, which may cause our patents to expire before or shortly after product launch. We may face challenges in enforcing our rights, and our business, financial condition, and prospects could be materially harmed as a result. Manufacturers of similar or identical products may

RISK FACTORS

initiate proceedings before a patent office or in court to challenge the scope, validity, or enforceability of our patents. We may be unsuccessful in defending these intellectual property rights, which would prevent us from marketing the product exclusively and materially adversely affect its potential sales.

In China, for instance, the standard term of patents is finite, subject to the timely payment of maintenance fees. Invention patents, design patents, and utility model patents have respective maximum terms of 20 years, 15 years, and 10 years from their filing date. The relevant authorities may not grant patent term extensions to our patents or the extension granted may not be as extensive as we may request. In the absence of supplementary protections such as patent term extensions and data exclusivity, the statutory term of a patent may be inadequate to protect our commercial position as we may not be able to enjoy the full patent standard term caused by lengthy regulatory approval of the patent. The expected expiry dates of our pending patent applications are set out in the section “Business — Intellectual Property”. Upon their expiration, we will be unable to assert these patent rights against potential competitors, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may from time to time face intellectual property infringement or misappropriation claims or other legal challenges in courts or before the CNIPA, the USPTO, or comparable foreign authority, which could result in costly litigation, significant expenses or substantial damages, limit our R&D activities, and ultimately delay or prevent us from marketing and selling our products. Our patent rights relating to our pipeline products could be found invalid or unenforceable if being challenged.

Our commercial success depends on our ability to develop, manufacture, market and sell our pipeline products without infringing, misappropriating or otherwise violating the intellectual property rights of others. The pharmaceutical industry is known for frequent disputes and litigation concerning patents and other intellectual property rights. Our pipeline products, or their intended uses, may infringe existing third-party patents or other intellectual property rights. It is also possible that we have not identified, or may fail to identify in the future, certain patents or patent applications owned by third parties that relate to our pipeline products. In addition, published patent applications may later be amended, within certain limits, in ways that could encompass our products or their uses.

Third parties may allege that we are infringing their patents, misappropriating their trade secrets, or otherwise violating their intellectual property rights in connection with our research activities, the use or manufacture of our products, or other aspects of our operations. Such parties may initiate legal proceedings against us or against third parties that we have agreed to indemnify. These claims may relate to existing intellectual property or to rights that arise in the future. If infringement, misappropriation or other intellectual property claims are brought against us, the claimants may seek injunctions or other equitable remedies that could prevent us from continuing to develop or commercialise one or more of our pipeline products. Defending against such claims, irrespective of their validity, could involve considerable litigation costs and divert significant management and employee resources from our core business activities. The outcome of such proceedings is uncertain and a court may rule against us on matters such as validity, enforceability, priority or non-infringement. A competent court could determine that the third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialise any products or technologies covered by such patents.

To avoid or settle potential disputes relating to third-party patents or other intellectual property rights, we may decide, or be required, to obtain a licence from the relevant patent holder. This could involve paying significant licence fees or royalties, which may be substantial. Such licences may not always be available on terms acceptable to us, or indeed available at all. For instance, these licences might be non-exclusive, allowing competitors to use the same intellectual property and thereby eroding our competitive position. Ultimately, as a result of actual or threatened intellectual property claims, we could be prevented from commercialising approved products or compelled to cease certain or all aspects of our operations, either through court orders or other enforcement measures. We could also be held liable for significant monetary damages, including treble damages and legal costs, if found to have willfully infringed a third party’s patent. Defending against claims of patent infringement, misappropriation of trade secrets or other alleged violations of intellectual property rights could be both costly and time-consuming, regardless of the eventual outcome, and may impose substantial and unforeseen adverse effects on our business and financial condition.

RISK FACTORS

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our pipeline products or development pipelines throughout the world, which depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends in large part on our ability to protect our technologies and pipeline products from competition by obtaining, maintaining, defending and enforcing our intellectual property rights. We seek to safeguard the pipeline products and technologies that we consider commercially important by filing patent applications in China and the United States. Extending the filing, prosecution, maintenance and defence of patents for our pipeline products to all other countries worldwide could be prohibitively costly. The scope and strength of any intellectual property rights obtained in other jurisdictions may differ from those secured in our target markets. Moreover, the laws of certain jurisdictions provide weaker protection for intellectual property rights than others. Competitors may take advantage of our technologies in jurisdictions where we have not secured patent protection to develop their own products. They may also export products that would otherwise infringe our patents into jurisdictions where our patents are valid and enforceable. We may be unable to prevent third parties from using our inventions in other jurisdictions outside our target markets, or from selling or importing products made using our technologies into our target markets or other regions. Such products could compete with our own pipeline products, and our patents or other intellectual property rights may prove insufficient to prevent or restrict this competition.

A portion of our intellectual property portfolio currently consists of pending patent applications that have not yet matured into granted patents, and if our pending patent applications are eventually rejected or face significant delays, our ability to protect key innovations and maintain competitive differentiation could be compromised, and our business will be adversely affected.

Our business, financial condition, results of operations, and prospects could be materially and adversely affected if we fail to obtain or maintain adequate intellectual property protection for our key assets.

The processes of patent filing, prosecution, maintenance, enforcement, and licensing are inherently expensive, time-consuming, and complex. Accordingly, we may be unable to secure or administer all necessary patents and applications in a timely and cost-effective manner across all desired territories. For instance, in China, the CNIPA may, following substantive examination, require us to amend our applications to narrow their scope, and failure to respond within the prescribed timeframe may result in the application being deemed as withdrawn. As a result, we might be unable to prevent competitors from developing and commercialising competing products in relevant therapeutic areas and jurisdictions.

Confidentiality agreements with employees and third parties may not necessarily prevent unauthorised disclosure of trade secrets and other proprietary information. We may also face claims alleging that our employees, consultants, independent contractors and advisers have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

We rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive advantage and to protect our pipeline products. We seek to safeguard this information in part through confidentiality and non-disclosure agreements with individuals and organisations that have access to it. These parties include our employees, corporate partners, external scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers, agents and other third parties. However, we may not always be able to prevent the unauthorised use or disclosure of our trade secrets and confidential information by such parties. Monitoring potential misuse or disclosure is challenging, and it is uncertain whether the measures we have implemented will be sufficient to protect our technologies.

Any party that has signed a confidentiality agreement with us could breach or disregard the terms of that agreement and disclose our proprietary information. In such cases, we may be unable to obtain

RISK FACTORS

adequate remedies, and as a result, we could lose valuable trade secrets. Third parties could then use this information to compete with us, which would harm our competitive position. Furthermore, our trade secrets or technologies may be incidentally accessed by certain individual or organisation which we may not have entered into confidentiality agreement with. Pursuing legal action to enforce claims of unauthorised disclosure or misappropriation of trade secrets is often costly, time consuming and unpredictable.

Many of our employees, including members of senior management, previously worked for other pharmaceutical or biopharmaceutical companies, some of which are our competitors or potential competitors. These individuals may have entered into confidentiality, proprietary rights or non-competition agreements with their former employers. We may face allegations or legal proceedings against us that we or our employees have misused or disclosed intellectual property, including trade secrets or proprietary information, belonging to a former employer. The outcome of such proceedings may be unfavourable against us and we could be required to pay damages, relinquish valuable intellectual property rights or obtain licences on terms that may be commercially unfavourable or unavailable. Any of these outcomes could harm our business or hinder the successful commercialisation of our pipeline products.

We may face intellectual property disputes with our business partners or other third parties.

We may be subject to claims that former employees, business partners or other third parties have an interest in our owned patents or other intellectual property. If we are unsuccessful in any interference proceedings or other priority or validity disputes to which we or they are subject, we may lose valuable intellectual property rights, such as loss of one or more patents or exclusive ownership, or our patent claims’ being narrowed, invalidated, or held unenforceable. We may also incur substantial costs in such interference proceedings or other similar priority or inventorship disputes, regardless of the outcome.

Changes in patent law in the jurisdictions where we conduct business could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products and future products.

As with other companies in the pharmaceutical and biopharmaceutical industries, our success depends heavily on our ability to obtain, maintain, protect and defend our intellectual property, particularly our patents. Securing and enforcing patents in these sectors involves both technological and legal complexity and is often costly, time consuming and uncertain. Changes to patent legislation or its interpretation in China or other jurisdictions may increase the difficulty and cost of obtaining or enforcing patents, limit our ability to safeguard our inventions and intellectual property, or reduce the overall value and scope of our patent rights.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We currently own a number of registered trademarks, any of which could become the subject of an objection from a government authority or a third party, potentially preventing their continued validity. Trademark applications we submit in the future may not be approved. During the registration process, our applications may be rejected, and we might not succeed in overcoming such rejections. In proceedings before the CNIPA and similar authorities in other jurisdictions, third parties may oppose our pending applications or seek to cancel existing registrations. If opposition or cancellation actions are filed against our trademarks, we may be unable to defend them successfully. Failure to secure trademark protection for our key brands could require us to change brand names, which could have a material adverse effect on our business. Our trademarks and trade names may also be challenged, infringed, circumvented or deemed generic, or found to infringe the rights of others. We may not always be able to protect our rights to these marks, which are essential for establishing brand recognition among potential partners and customers in our target markets. At times, competitors or other parties may use trade names or trademarks similar to ours, which could hinder our efforts to build a distinct brand identity and create confusion in the marketplace. Over time, if we fail to establish or maintain recognition based on our trademarks and trade names, we may find it difficult to compete effectively, which could adversely affect our business.

RISKS RELATING TO OUR OPERATIONS

We may encounter difficulties in managing our growth and expanding our operations successfully.

As confirmed by our Directors, business growth strategy has been focused on organic development since our inception. As we progress our pipeline products through the clinical trial

RISK FACTORS

pipeline and prepare for the potential commercial launch of multiple products in the future, we will be required to materially expand our internal development and manufacturing capabilities. Furthermore, we intend to establish strategic partnerships to facilitate the sales and marketing of our future approved drug products.

This anticipated growth will impose significant additional demands on our management and operational infrastructure. Key areas of focus will include: (i) identifying, recruiting, and effectively integrating additional qualified personnel to support our development plan; (ii) managing our internal development functions, including the clinical and regulatory review processes for our pipeline products, while simultaneously ensuring compliance with our contractual obligations to various third-party collaborators; and (iii) strengthening our operational, financial, and internal controls, as well as our reporting systems and procedures. The establishment and management of strategic relationships, will also place considerable strain on our management resources.

We may not be able to effectively execute our growth strategy. Our future prospects are, in part, subject to external factors beyond our control, including changes in the general economic and political conditions in China, the overall biopharmaceutical industry landscape, and relevant government regulations. It is inherently difficult to extrapolate future performance from our historical experience, and you should not rely solely on past operating results to assess future prospects or the likelihood of our growth plan being realised.

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

We have not yet demonstrated an ability to launch and commercialize any of our pipeline products. Our ability to successfully commercialize our pipeline products may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug products. Furthermore, we will face stiff competition with other biopharmaceutical companies to attract, recruit, train, and retain commercial personnel.

We may plan to form partnerships with established third-party commercial teams to facilitate rapid market entry. However, we may not be able to establish or maintain such arrangements, or establish effective sales forces and distribution networks. We would exercise limited or no control over their marketing and sales efforts, and our product sales revenues might be lower than if we were to commercialise the products ourselves. We will also face competition in seeking reputable third parties to assist with the commercialization of our pipeline products. Furthermore, we may not be able to build in-house sales and marketing capabilities or establish or maintain successful relationships with collaborators, and as a result, we may be unable to generate any product sales revenue.

Failure to retain the services of our senior management and key scientific personnel could severely disrupt our business and growth.

The success of our business is highly dependent on the continued expertise, leadership and strategic insights of our senior management and key scientific personnel. Furthermore, the successful recruitment, retention and motivation of qualified scientific, clinical, manufacturing and commercial personnel will be critical to our future development and commercial objectives. The loss of the services of any of our senior management or key scientific personnel could impair our ability to maintain current development timelines, advance our pipeline products through clinical trials, or achieve our planned commercialisation goals. The pool of suitably qualified candidates is inherently limited and we may face difficulties and competition in attracting or retaining qualified employees within the pharmaceutical and life sciences sectors.

Furthermore, as we build and expand our commercialisation capabilities in anticipation of future product launches, we will be required to hire additional personnel. We may not be able to attract and retain such qualified employees on acceptable terms, if at all. Any failure to secure necessary personnel could hinder our commercialisation strategy and have a materially adverse effect on our business.

We may not be able to develop our manufacturing capacity at our Microneedle Formulation Industrial Base in Lianyungang and Nasal Inhalation Formulation Industrial Base in Zhuhai, or obtain approval from regulators for our manufacturing facilities, or avoid damage or interruption to our manufacturing facilities.

We intend to develop our own manufacturing capacity by building a Microneedle Formulation Industrial Base in Lianyungang and a Nasal Inhalation Formulation Industrial Base in Zhuhai. These sites must meet the stringent quality standards imposed by regulatory authorities worldwide. The development of our capabilities could be adversely impacted if the enhancement or construction of these facilities is materially delayed by events such as the COVID-19 pandemic or similar public health crises. Furthermore, should regulatory or other difficulties, including potential breaches of contract,

RISK FACTORS

necessitate the suspension or abandonment of the Zhuhai and Liangyungang facility projects, we will be unable to develop our manufacturing capacity as planned, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Once operational, our facilities and equipment could be significantly damaged or destroyed by events such as fire, flood, power failure, or other similar occurrences. We may not be able to replace such a facility quickly or inexpensively. In the event of a temporary or prolonged loss of a facility, we might be unable to transfer manufacturing operations to a third party; any transfer of manufacturing operations may also likely be expensive and time-consuming, especially given the extensive regulatory requirements the replacement process could entail.

Moreover, our manufacturing facilities will be required to obtain and maintain various regulatory approvals, a process that involves undergoing periodic inspections by the NMPA and other comparable bodies to ensure continued compliance with GMP regulations. Consequently, we must continue to expend significant time, monetary resources, and effort to ensure compliance across all areas of our manufacturing, production, and quality control operations. We may not be able to consistently adhere to, and adequately document compliance with, GMP and other regulatory requirements.

We are exposed to product and professional liability and other liability claims or lawsuits, which may cause us to incur substantial liabilities.

As a consequence of our clinical testing and any future commercialisation of our pipeline products both within and outside China, we face inherent risks of product and professional liability. For instance, we may become subject to legal claims if our pipeline products are alleged to have caused or to be perceived to have caused personal injury, or are otherwise deemed unsuitable for use, at any stage from clinical development and manufacturing through to marketing and sale. Such product liability claims could include allegations of manufacturing defects, design defects, failure to warn of inherent dangers, negligence, strict liability, or breach of statutory or implied warranties. Claims might also be brought against us under applicable consumer protection legislation.

We may be unable to successfully defend against such claims, which could result in significant liabilities or compel us to restrict the commercialisation of our pipeline products. The process of defending against such claims would require significant outlays of financial and management resources. Regardless of their ultimate merits or outcome, liability claims may lead to:

- material harm to our reputation and brand leading to diminished demand for our products;
- withdrawal of clinical trial participants, potentially preventing the continuation of clinical trials;
- the initiation of investigations by regulatory authorities;
- financial loss including loss of revenue and substantial costs associated with defending related litigation;
- a diversion of management attention and corporate resources;
- product recalls, withdrawals, or restrictions on labelling, marketing, or promotion;
- exhaustion of available insurance coverage and our capital resources; and
- a decline in the market price of our H Shares.

In the event that a successful product liability claim, or a series of such claims, is brought against us for uninsured liabilities or for amounts that exceed the insured limits, our assets may prove insufficient to cover such liabilities, our business operations could be seriously impaired, and we may face material adverse consequences.

Our Controlling Shareholder Group has and will continue to have substantial influence over the outcome of shareholder actions in our Company. The interests of our Controlling Shareholder Group may not necessarily be aligned with the interests of our other Shareholders.

Immediately before the [REDACTED], our Controlling Shareholder Group will be entitled to exercise approximately [51.01%] voting rights in our Company (assuming the [REDACTED] is not exercised). As a result, our Controlling Shareholder Group is, in the aggregate, entitled to exercise approximately [38.26%] of the voting rights in our Company upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised). This affords them significant influence over our business, including decisions pertaining to mergers, consolidations, liquidations, the sale of all or substantially all of our assets, the election of directors, and other significant corporate actions.

Our Controlling Shareholder Group may exercise their influence in a manner that is not in the best interests of our Company or our other Shareholders. The concentration of ownership may discourage, delay or prevent a change of control of our Company. This outcome could have the effect of depriving out other Shareholders of the opportunity to receive a premium for their shares that might be available in the event of a sale of our Company and may also depress the market price of our H Shares. Such

RISK FACTORS

concentrated control will also limit your ability to influence corporate matters and may discourage potential third parties from pursuing any merger or takeover offer that other Shareholders might consider to be attractive.

We depend on a stable and adequate supply of quality materials, including raw materials and consumables from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

During the Track Record Period, we have procured raw materials, consumables and our contract manufacturing services. For further details, please see “Business — Raw Materials” in this Document. We have supply agreements in place with manufacturers and suppliers that we believe possess sufficient capacity to meet our current and anticipated demands. We also believe that adequate alternative sources for these supplies exist. However, there is a risk that if the supply of materials is interrupted, we may be unable to secure alternative supplies on a timely or commercially reasonable basis, or at all. Any such failure would materially harm our business.

Furthermore, the volume of materials required for our pipeline products is expected to increase significantly upon the commencement of commercial production following the granting of marketing approvals. Our current suppliers may not have the capacity to meet this increased demand. Any delay in the receipt of materials in the required quantities and to the required quality could delay the completion of our clinical trials, the regulatory approval of our pipeline products, or our ability to satisfy market demand for our commercialised products, as applicable. In the event of significant price increases for such materials, we may not be able to offset this by increasing the prices of our future drug products sufficiently. Consequently, any significant price increase in our essential materials could have an adverse effect on our profitability.

Additionally, our suppliers may fail to maintain the requisite quality of the services, materials, and equipment we require. Suboptimal or deficient supplies of services, materials, and equipment could hinder the development of our pipeline products, subject us to product liability claims, or otherwise have a material adverse effect on our operations.

If our products and supplies are not stored and shipped properly, the products and supplies could be damaged, which could negatively affect us.

Our supplies may become rendered unusable or unsafe for their intended purpose when exposed to adverse environmental conditions, or due to improper storage or shipping. A failure by us or any third-party logistics provider to provide and maintain adequate storage and shipping conditions for our research and development supplies, ingredients, or pipeline products could render such products unsuitable for use in our operations. This, in turn, could lead to costly replacement orders and delays in our operating activities, potentially resulting in a material adverse effect on our business, financial condition, and results of operations.

Our investment in R&D for the development, enhancement or adaptation of new technologies and methodologies may not be successful.

The global biopharmaceutical sector is characterised by rapid and continuous evolution. To maintain and enhance our competitive position, we must keep pace with emerging technologies and methodologies. For the two years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, our R&D expenditures were approximately RMB16.4 million, RMB38.2 million and RMB19.0 million, respectively.

We intend to continue to invest in strengthening our technical and methodological capabilities in the development and manufacture of our pipeline products, however, such endeavours require substantial capital and time. We may not be able to successfully develop, adopt or adapt to new technologies and methodologies, identify new technological opportunities, or develop and bring to market new or enhanced products, or secure sufficient intellectual property protection for such products in a timely or cost-effective manner. Any failure to achieve these objectives could render our existing platforms and pipeline products obsolete, which would likely impair the competitiveness of our technology platforms and pipeline products and could have a material adverse effect on our business and future prospects.

Increased labour costs could slow our growth and affect our profitability.

All of our workforce is based in China. As confirmed by F&S, over recent years, average labour costs in China have risen steadily, reflecting government-mandated wage increases and evolving legislative requirements. During the years ended December 31, 2024 and 2025 and the five months ended May 31, 2026, we incurred staff costs of approximately RMB39.2 million, RMB58.4 million and RMB25.3 million, respectively. Future legislative or regulatory changes promulgated by the Chinese authorities may impose additional burdens on employers, which could materially and adversely affect

RISK FACTORS

our operations. We anticipate that this upward trend in labour costs will continue in line with China’s economic growth. However, this trend, coupled with competition for qualified talent, may require us to offer higher wages and benefits, leading to increased labour expenditure.

Changes in government regulations or practices relating to the biopharmaceutical industry may increase the complexity and cost of existing obligations and introduce additional compliance risks, which may have a material adverse impact on us.

The policies of the relevant regulatory authorities are subject to change, and new government regulations may be enacted that could prevent, delay or limit the regulatory approval of our product candidates, impose restrictions on post-approval activities, and adversely affect prospects for our commercial success and profitability. We are unable to predict the likelihood, nature, or extent of future governmental policies or regulations which may arise from legislative or administrative action in the jurisdictions in which we operate.

Failure to obtain or renew certain approvals, licences, permits and certificates required for our business operations may lead to operational disruptions, legal penalties, or restrictions on our ability to conduct business, thereby materially and adversely affecting our business, financial conditions and operation results.

We are required to obtain, maintain and renew the approvals, licences, permits and certificates we have obtained from various regulatory and governmental authorities. Certain of these authorisations are subject to periodic renewal and reassessment by the relevant authorities, and the applicable standards for such processes may be subject to change over time. Any failure to obtain or successfully renew any material authorisation necessary for our operations could result in enforcement actions by the relevant authorities. These actions may include orders to take remedial steps, the suspension of our operations, or the imposition of significant fines and penalties. Any such event could materially and adversely affect our business, financial condition, results of operations, and prospects.

In China, a drug MAH may manufacture products either through its own facilities or through a CMO. In the latter case, the CMO must hold a valid pharmaceutical manufacturing permit and ensure each production facility complies with the requisite GMP standards stipulated by the NMPA and its branches. Moreover, pursuant to the Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》), which have been in effect since 1 July 2020, the MAH that entrusts a CMO must also apply for its own pharmaceutical manufacturing permit. For distribution activities, we or our commercial partners will require a pharmaceutical distribution permit from the NMPA and its branches, and must operate in compliance with the requirements of good supply practice.

Furthermore, we are subject to the risk that changes in the interpretation or enforcement of existing regulations, or the introduction of new legislation, could render some of our existing authorisations insufficient or require us to obtain new or additional approvals, licences, permits or certificates. We may not be able to obtain any such additional authorisations on a timely basis, or at all.

We, our management and directors may be involved in litigations, legal disputes, claims, arbitration or administrative proceedings in the ordinary course of business which could be costly and time-consuming to resolve.

From time to time, we, our management or directors may become party to litigations, legal disputes, claims, arbitration or administrative proceedings arising in the ordinary course of our business. These may relate to, among others, product liability, environmental issues, breaches of contract, employment or labour disputes, and intellectual property rights.

Our involvement in legal proceedings and litigation can divert management’s and directors’ attention and consume significant time and resources. If we are unsuccessful in defending against such claims, we may become liable for substantial damages or be required to curtail the commercialisation of our pipeline products. Additionally, negative publicity associated with any such proceedings may damage our reputation and adversely affect the perception of our brands and products. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

If we are found to have violated laws protecting the confidentiality of patients and other covered information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business.

We may be subject to patient privacy regulations imposed by governments in the jurisdictions where we conduct business or clinical trials. Various laws in these jurisdictions protect the confidentiality of individually identifiable patient health information and restrict the use and disclosure of such protected information. Failure in our information security efforts could expose us to

RISK FACTORS

enforcement actions, investigations, regulatory penalties, and significant legal liability under local and international laws. As these data protection regimes continue to evolve, growing public scrutiny, increasing enforcement action, sanctions, and higher compliance costs could be resulted.

The Personal Information Protection Law (PIPL, effective November 2021) (《中華人民共和國個人信息保護法》) governs the processing of personal information, defining its scope, legal basis, and consent requirements.

Determining whether protected information complies with applicable laws or contractual obligations may require complex analysis and is subject to evolving interpretations. Mishandling, unauthorised access, breaches, or loss of information could trigger legal claims, reputational harm, and liability under information protection laws, potentially causing a material adverse effect on our business, financial condition, or results of operations.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

To support our growth strategy, we may from time to time evaluate potential acquisitions and strategic partnerships. Such opportunities may be pursued to enhance our product development, technological advancement, or distribution network. However, completing or pursuing acquisitions or strategic partnerships may involve significant risks.

We may be unable to identify or successfully conclude attractive acquisitions. The integration of an acquired company, its intellectual property, or its technology into our own operations is a complex, resource-intensive, and expensive process. Successful integration may require, among other things, the consolidation of business and corporate cultures, the integration and retention of key personnel, the alignment of our technologies and services from both an engineering and a commercial perspective, the management of pre-existing supplier, distribution, and customer relationships, the coordination of research and development activities, and the rationalisation of duplicated facilities and functions. The success of such an integration is subject to significant risks and uncertainties, which may be exacerbated by geographic distance, the complexity of the assets being integrated, and disparities in corporate culture.

Fluctuations in exchange rates may expose us to exchange rate volatility.

Fluctuations in exchange rates may have a material adverse effect on our results of operations and financial performance. The value of the Renminbi against the US dollar and other currencies is subject to a range of factors, including changes in regulation and developments in the PRC’s and international political and economic landscapes. As the majority of our cash and cash equivalents are held in Renminbi, any appreciation of the Renminbi against the U.S. dollar could result in a reduction in the value of our foreign currency-denominated assets. During the Track Record Period, we recorded no gain or loss in foreign exchange rate changes for the year ended December 31, 2024, a gain in foreign exchange rate changes of approximately RMB0.06 million and RMB0.2 million for the year ended December 31, 2025 and five months ended May 31, 2026, respectively.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in a decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. Furthermore, we are also currently required to complete applicable filings with the State Administration of Foreign Exchange of the PRC (SAFE) before converting significant sums of foreign currencies into Renminbi.

Our business and operations may be adversely affected by natural disasters, health pandemics or epidemics, acts of war, terrorism or other unforeseen catastrophic events or force majeure events that are beyond our control, which may have a material adverse effect on our business, financial condition, operation results and prospects.

Our business and operations could be disrupted by a variety of events beyond our control, including natural disasters, such as floods, earthquakes, sandstorms, and other extreme weather events. A serious natural disaster could result in loss of life, personal injury, the destruction of physical assets, and a material disruption of our business and operations. Furthermore, our business is exposed to the risk posed by epidemics and pandemics. Outbreaks of infectious diseases, could cause severe disruption to our day-to-day operations. Such events may even necessitate a temporary closure of our offices, laboratories, or other critical facilities. The increasing frequency of global epidemic outbreaks in recent years heightens this risk. Similarly, acts of war or terrorism could lead to injury or loss of life among

RISK FACTORS

our employees, disrupt our supply chain and business network, and destroy our key markets. Other risks include fires, prolonged shortages of essential utilities or fuel, failures or malfunctions of our information technology systems, unexpected equipment downtime, or geopolitical events such as war or terrorism.

The occurrence of any such event, or other external factors not within our control, could adversely affect the general business environment, create significant uncertainty in the regions in which we operate, and cause our business to suffer in ways that cannot be presently predicted, thereby materially and adversely affecting our business, financial condition, and results of operations.

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

We maintain a portfolio of insurance policies, both as mandated by applicable laws and regulations and in accordance with our operational needs and prevailing industry practice. For details, please see “Business — Insurance” in this Document. However, the coverage of insurance policies maintained by us may not be adequate in all circumstances, or that this coverage will continue to be available to us on commercially reasonable terms, or at all. The defence and settlement of a claim brought against us that is uninsured or only partially covered could materially harm our business, financial condition and results of operations.

Furthermore, our existing insurance coverage may be insufficient to cover certain potential claims, including those relating to product liability, damage to our fixed assets, or employee injuries.

Our reputation is key to our business success. Negative news or publicity about us, our Controlling Shareholder Group, Directors, our management, officers, employees and/or business partners may adversely affect our recognition and reputation, which in turn may materially and adversely affect our business, financial condition, operation results and growth prospects.

We, our Shareholders, Directors, officers, employees and business partners may from time to time be subject to negative media coverage and publicity. Any negative publicity concerning us, our affiliates, our Shareholders, Directors, officers, employees or business partners could adversely affect our reputation and business prospects. Such negative coverage could damage the public perception of our brand. Furthermore, should our Shareholders, Directors, officers, employees or business partners be found to be non-compliant with any laws or regulations, or become involved in litigation, disputes or other legal proceedings, or be subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer adverse publicity and reputational harm. As a result, we may be required to expend significant management time and incur substantial costs in responding to allegations and managing negative publicity. Moreover, referrals and industry reputation are crucial for establishing new partnerships.

RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

Changes in geopolitical relationships, healthcare and drug approvals policies and regulations, and international trade policies such as tariffs and export control, particularly those involving the PRC, may adversely impact our business and operating results.

During the Track Record Period, we carried out the R&D and manufacturing of our pipeline products in the PRC. As substantial part of our R&D capacity and manufacturing facilities are currently located in the PRC and that our products are intended to be commercialised and distributed in both the PRC and other jurisdictions, including the U.S., accordingly, changes in geopolitical relationships, healthcare and drug approvals policies and regulations, and international trade policies such as tariffs and export control may affect the demand for our products or our ability to export products to such foreign jurisdictions at all, and may adversely affect our business, financial conditions and results of operations.

Recent years have seen significant shifts in the trade policies of the United States and intensified trade frictions between the U.S. and the PRC, including the imposition of tariffs on certain products originating from the PRC. For instance, the U.S. government has announced a significant tariff increase on imports from the PRC in February 2025, and between February 2025 and April 2025, the U.S. government has cumulatively imposed additional 145% tariffs on PRC imports, the U.S. government subsequently reduced the rate of tariff on PRC imports and announced that the U.S. will maintain its suspension of heightened reciprocal tariffs on PRC imports until November 10, 2026. The future direction of U.S. trade policy remains uncertain, and it is unclear what actions the U.S. government may take with respect to existing international trade agreements, or whether, and to what extent, new tariffs or other regulatory measures will be adopted. The potential impact of any such future actions on our business and the wider industry is also unknown.

RISK FACTORS

The implementation of unfavourable government policies, such as capital controls or the imposition of tariffs, could adversely affect our future business. Such policies could impact the demand for and competitive position of our future drug products, hinder our ability to hire key scientific and R&D personnel, impede the import or export of raw materials critical to drug development, or prevent our future products from being commercialised in certain countries. If new tariffs, legislation, or regulations are implemented, or if existing trade agreements are renegotiated — particularly in response to retaliatory U.S. trade actions — our business, financial condition, and results of operations could be materially and adversely affected.

Governments or regulators of markets in which our Company may be commercialised and distributed, such as the U.S., may impose healthcare and drug approvals policies and regulations targeted at foreign biotechnology companies, including the PRC. For example, the U.S. BIOSECURE Act which was enacted on 18 December 2025, prohibits the procurement and grants involving biotechnology products or services by any of the “biotechnology companies of concern” (BCCs) and that executive agencies of the U.S. federal government are prohibited from extending loans or granting funds to procure biotechnology equipment or services produced or provided by any of the BCCs, and during the Track Record Period and up to the Latest Practicable Date, we are not included in the lists of BCCs, and during the Track Record Period and up to June 30, 2026, we have not engaged in business dealings with any of the BCCs. However, in the event that we are listed as one of the BCCs or that we are engaged in business dealings with any of the BCCs, or the U.S. or any other jurisdictions tightens or introduces regulatory policies against PRC biotechnology companies, our ability to commercialise and distribute products in these markets could be materially and adversely affected.

Furthermore, existing trade disputes and geopolitical tensions may escalate in the future, which could render certain goods, such as advanced R&D equipment and materials, significantly more expensive to procure from overseas suppliers or even subject to export bans. Our existing or potential service providers, or collaboration partners, may alter their perception of or preference for us as a result of adverse changes in the relationship between the PRC and relevant foreign countries or regions. Consequently, the geopolitical relationship between the PRC and other countries and the changes in healthcare and drug approvals policies and regulations, and international trade policies, may materially and adversely impact our business, financial condition, results of operations, cash flows, and prospects.

Changes in economic and social developments, laws, rules, regulations and licensing requirements in jurisdictions where we operate could have a material effect on us.

Most of our assets and operations are conducted in the PRC. As such, our business, financial conditions, results of operations and prospects depend heavily on the overall economic and social conditions in the PRC.

China’s economy has grown significantly over the past few decades, and we expect that growth to continue. Various measures have been implemented to boost economic development. While some of these measures may benefit the Chinese economy as a whole, they may influence how we conduct our business operations, and therefore have impacts on our business, financial conditions, results of operations and prospects. It may be difficult for us to predict all the risks that we could face as a result of the current economic and social developments and failure to respond to such development and risks could materially affect our business operations and financial performance.

Future new laws or regulations promulgated or interpretations of the laws and regulations in the future may materially affect our business, financial condition, operation results and prospects. Failure to timely respond to changes and development with respect to PRC laws, rules and regulations of the jurisdictions where we operate could expose us to compliance risks, operational disruptions or reputational harm.

Regulatory authorities may alter their policies, and new government regulations could be introduced that may hinder, restrict, or delay the approval of our product candidates, impose limitations on post-approval activities, and affect our capacity to market our products profitably. We are unable to predict the likelihood, scope, or nature of future legislation or administrative measures in jurisdictions where we operate that may give rise to such policies or regulations.

Given our extensive operations in the PRC, our business, financial position, operating results and future prospects are subject to the impact of changes in PRC legislation. Laws, rules and regulations concerning economic matters are introduced from time to time, including those relating to foreign investment, corporate structure and governance, commerce, taxation, finance, foreign exchange and trade.

RISK FACTORS

Moreover, the interpretation and enforcement of laws and regulations governing the pharmaceutical sector also evolve periodically, we may be deemed to be in breach of or non-compliant with existing laws and regulations under revised interpretation, accordingly, which may result in enforcement or disciplinary actions and may materially and adversely affect our operations.

There may be difficulties or uncertainties in effecting service of legal process on us or our management who reside in the PRC or enforcing judgements obtained from foreign courts against us or our management.

We are incorporated under PRC law and the majority of our assets are located within the PRC. In addition, most of our Directors and senior management reside in the PRC, and substantially all of their assets are also located there. Consequently, investors may find it difficult to serve legal process on us or on our Directors and senior management in China.

In July 2006, the Supreme People’s Court of the PRC and the Government of the Hong Kong Special Administrative Region 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》) (the “**Arrangement**”). Under this Arrangement, where a designated PRC or Hong Kong court has issued a final and enforceable judgment requiring monetary payment in a civil or commercial case under a written choice of court agreement, either party may apply to the relevant PRC or Hong Kong court for recognition and enforcement of that judgment. A written choice of court agreement refers to an agreement entered into after the Arrangement took effect, expressly designating either a Hong Kong or PRC court as having exclusive jurisdiction over the dispute. Accordingly, if no such agreement exists, a judgment rendered by a Hong Kong court may not be enforceable in the PRC. This could make it difficult or impossible for investors to enforce judgments against our assets or Directors in China.

On 18 January 2019, the Supreme People’s Court of the PRC and Hong Kong entered into a new arrangement concerning the recognition and enforcement of civil and commercial judgments (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”). The New Arrangement came into effect on 29 January 2024 in both China and Hong Kong, replacing the prior Arrangement. Under the New Arrangement, jurisdiction may be exercised by the court where the judgment was sought, in accordance with the rules set out in the New Arrangement, without the need for a prior agreement between the parties. However, the practical outcome and enforceability of any action brought under the New Arrangement remain uncertain, a valid judgment rendered in accordance with the New Arrangement may not be recognised and enforced by a PRC court.

Required procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

The convertibility of Renminbi into foreign currencies and, in certain circumstances, the remittance of funds into and out of China are governed by PRC foreign exchange regulations. As a significant majority of our future revenue is expected to be denominated in Renminbi, we will need to convert such revenue into foreign currencies in order to pay dividends, if any, to holders of our H Shares. A shortage in the availability of foreign currency may limit our ability to remit adequate amounts to pay dividends or meet other payment obligations denominated in foreign currencies.

Under China’s existing foreign exchange control regime, our foreign exchange transactions under the current account do not require prior approval from SAFE. However, we must provide the relevant supporting documentation for such transactions and carry them out through designated foreign exchange banks within China that are licensed to conduct such business. Approval from the relevant government authorities is required where Renminbi is to be converted into foreign currency and remitted outside China for capital account purposes, such as the repayment of foreign currency-denominated loans. If we are unable to obtain sufficient foreign currency under the current regime to meet our needs, we may be unable to distribute dividends in foreign currencies to our Shareholders. Moreover, new regulations may be introduced in the future that could impose further restrictions on the remittance of Renminbi into or out of China.

We may be subject to additional social insurance fund, housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.

Under PRC laws and regulations, employers are required to contribute to social insurance and the housing provident fund on behalf of their employees. During the Track Record Period and up to the Latest Practicable Date, we had made contributions to social insurance and the housing provident fund for our employees. However, we did not make full contributions to social insurance and housing provident fund for certain employees. Pursuant to the applicable regulations, if the relevant social insurance authorities determine that our contributions are insufficient, they may order us to settle the

RISK FACTORS

outstanding balance within a prescribed period, together with a late payment surcharge of 0.05% per day of the unpaid amount. Failure to comply within the specified timeframe could result in fines ranging from one to three times the total outstanding balance. In addition, if we fail to pay the housing provident fund within the prescribed time limit, we could be subject to compulsory enforcement from the courts if the payment is not made within the time limit prescribed by the competent authorities. Pursuant to the Notice on Implementing Several Measures to Further Support and Serve the Development of the Private Economy (《關於實施進一步支援和服務民營經濟發展若干措施的通知》) issued by the State Administration of Taxation on November 16, 2018, tax collection authorities shall not, on their own initiative, organize any centralized collection of payment arrears from previous years owed by payers, including private enterprises.

The potential maximum penalty with respect to fines that we may be exposed to due to shortfall of social insurance contributions during the Track Record Period would be approximately RMB22.1 million. In addition, in the case that if the relevant authority makes an application to relevant courts for enforcement, the amount of maximum potential enforcement due to shortfall of housing provident fund contributions during the Track Record Period would be approximately RMB0.4 million. As of the Latest Practicable Date, based on (i) the credit reports of our Group companies, and (ii) the public search results showing that we have not been subject to any penalties from the relevant authorities on the relevant websites of competent government authorities, (iii) the Ministry of Human Resources and Social Security and the State Administration of Taxation have strictly prohibited the centralized collection of historical shortfalls for social insurance, and (iv) the feedback our PRC Legal Advisor obtained from telephone consultation and on-site interview regarding housing provident fund policies and implementation indicating that they will not actively carry out a large-scale recovery of housing provident fund contributions from the enterprise. We had not received any administrative penalties, claims or notices from government authorities regarding inadequate contributions. We have confirmed to comply promptly with any requirement from the competent authorities to make outstanding contributions and late payments in the future, if any. Our PRC Legal Advisor are therefore of the view that under the premise that there are no significant changes to current PRC policies and regulations or to the enforcement and supervision requirements of local governments and that there are no material employee complaints, litigation or arbitration proceedings, the likelihood that we would be subject to material administrative penalties or centralized collection due to our failure to provide full social insurance and housing provident fund contributions is remote. Nevertheless, we may be required by local authorities to settle the outstanding amounts within a specified period or impose late payment charges or fines, which could adversely affect our results of operations and financial condition.

We are subject to risks associated with our leased properties.

As of the Latest Practicable Date, we leased 9 properties in China with a total gross floor area of approximately 21,251.48 sq.m. Upon the expiry of these leases, we will need to negotiate renewals, which may involve higher rental costs. We may not be able to renew the leases on favourable or otherwise acceptable terms, or at all. Should we fail to renew any lease, or if any lease is terminated, or if we are otherwise unable to continue using a leased property, we may be required to secure alternative premises and incur relocation expenses. Our operations and business activities could also be disrupted, or even suspended, if we are unable to complete such relocation, including the reconstruction of necessary facilities, in a timely manner. Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, one of our lease agreements had not been filed with competent governmental authority. The potential maximum penalty that we may be subject to for failing to file and obtain property leasing filing certificate for such lease within the prescribed time period required by the relevant PRC government authorities, as required under PRC laws, is RMB10,000 as advised by our PRC legal Advisor. We may not be able to defend this lease against bona fide third parties, which may affect our ability to operate our business covered under this lease.

The ownership certificate or other similar proof of one leased property has not been provided to us by the relevant lessor. Therefore, such lessor may not be entitled to lease the relevant real property to us. If the lessor is not entitled to lease the real property to us and the owner of such real property decline to ratify the lease agreement between us and the respective lessor, we may not be able to enforce our rights to lease such property under the respective lease agreement against the owner. If our lease agreement is claimed as null and void by third parties who are the real owners of such leased real property, we could be required to vacate the property, in the event of which we could only initiate the claim against the lessors under relevant lease agreement for indemnities for its breach of the relevant leasing agreement.

RISK FACTORS

RISKS RELATED TO THE [REDACTED]

There has been no prior public market for our H Shares.

No public market currently exists for our H Share. The initial [REDACTED] for our H Shares to the public will be the result of negotiations between our Company and the [REDACTED] (for themselves and on behalf of the [REDACTED]), which may not be indicative of the price at which our H Shares will be traded following the completion of the [REDACTED]. We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to deal in, the H Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the H Shares will rise following the [REDACTED].

The price of our H Shares when trading begins could be lower than the [REDACTED].

The [REDACTED] for our H Shares is ranging from HK\$[REDACTED] to HK\$[REDACTED], unless announced otherwise. However, trading of our H Shares on the Stock Exchange will not begin until they are delivered. As a result, investors will be unable to sell or otherwise deal in our H Shares before the commencement of trading. This exposes holders of our H Shares to the risk that the trading price may be lower than the [REDACTED] due to unfavourable market conditions or other unfavourable developments that may arise between the sale and the commencement of trading.

Furthermore, any future sales, or even the perception of potential sales, of a significant number of our H Shares in the public market after the [REDACTED] could have a material adverse impact on the price of our H Shares and our ability to raise additional capital in the future, potentially leading to dilution of your shareholding.

The trading volume and market price of our H Shares may be volatile, which may result in substantial losses for investors subscribing for or purchasing our H Shares pursuant to the [REDACTED].

The trading volume and the market price of our H Shares may experience significant volatility due to various factors beyond our control, including general market conditions for securities in Hong Kong and globally. Specifically, the business performance and market prices of other companies engaged in similar industries may influence the price and trading volume of our H Shares.

In addition to market and industry factors, our H Shares may be highly volatile for specific business reasons, such as the outcomes of clinical trials for our pipeline products, the results of our regulatory approval applications, regulatory developments impacting the biopharmaceutical industry, healthcare, health insurance, and related matters, as well as fluctuations in our revenue, earnings, cash flows, investments, and expenditures. Other influencing factors include our relationships with suppliers, the movements or activities of key personnel, and actions taken by competitors.

Furthermore, shares of other companies listed on the Stock Exchange with material operations and assets in China have historically experienced price volatility. Consequently, it is possible that our H Shares may undergo price changes not directly tied to our performance.

You will incur immediate and significant dilution and may face further dilution if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset book value. Moreover, in order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

Our H Shares may not remain [REDACTED] on the Stock Exchange.

There is no guarantee of the continued [REDACTED] of the H Shares. Among other factors, our Company may not continue to satisfy the [REDACTED] requirements of the Stock Exchange. Holders of our H Shares would not be able to sell their H Shares through trading on the Stock Exchange if the H Shares were no longer [REDACTED] on the Stock Exchange.

RISK FACTORS

Since we do not expect to pay dividends in the foreseeable future after the [REDACTED], there is no assurance whether and when we will pay dividends. You must rely on price appreciation of our H Shares for a return on your [REDACTED].

Under PRC law and regulations, we may only pay dividends out of distributable profits. Distributable profits are our after-tax profits, less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, we may not have sufficient or any distributable profit to enable us to make dividend distributions to our Shareholders, including in periods for which our financial statements indicate we are profitable. Any distributable profit not distributed in a given year is retained and available for distribution in subsequent years. Accordingly, we may not receive sufficient distributions from our subsidiaries for us to pay dividends. Failure by our operating subsidiaries to pay us dividends could adversely impact our ability to make dividend distributions to our Shareholders and our cash flow, including periods in which we are profitable.

In addition, we currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the R&D of our pipeline products and the continued growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] in our H Shares as a source for any future dividend income. Accordingly, the return on [REDACTED] in our H Shares, if any, will likely depend entirely upon any future price appreciation of the H Shares. Our H Shares may not appreciate in value or even maintain the price at which the holders of our H Shares are purchased. The holders of our Shares may not realise a return on their [REDACTED] in our H Shares and may even lose their entire [REDACTED] in the H Shares.

Information and statistics from official government sources contained in this Document have not been independently verified.

This Document contains information and statistics from official government sources that have not been independently verified by the Company, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], any of our or their respective directors, officers or representatives or any other person involved in the [REDACTED] and no representation is given as to their accuracy. In any event, you should consider carefully the importance placed on such information or statistics.

You should read the entire document and only rely on the information included in this document to make your [REDACTED] decision, and should exercise caution when relying on any information contained in press articles or other media coverage relating to us, our H Shares 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 do not have sufficient control over the press and media coverage, and analysts might issue negative views or recommendations on us, which could have an adverse effect on the market price of H Shares. We have not authorised 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, [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.