
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.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to development, clinical trials and regulatory approval of our pipeline products; (ii) risks relating to manufacturing and commercialisation of our pipeline products; (iii) risks relating to our financial prospects; (iv) risks relating to our intellectual property rights; (v) risks relating to our operations; (vi) risks relating to doing business in jurisdictions where we operate; and (vii) risks relating to the [REDACTED].

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

RISK FACTORS

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

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. As of the Latest Practicable Date, our Core Products, the Dexmedetomidine Hydrochloride Microneedle Patch, and XJN010 are in Phase II clinical trial stage, while our other pipeline products are in relatively earlier stage. 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. However, 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, obtain regulatory approvals or successfully commercialise our pipeline products in accordance with the anticipated timeline due to risks described below and elsewhere in this document.

We cannot guarantee timely or any regulatory approval for our pipeline products. Our commercial success is dependent on numerous factors, including but not limited to:

- the completion of preclinical studies and clinical trials, including 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;
- 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;

RISK FACTORS

- 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 that we have infringed, misappropriated or violated any intellectual property of any such third party;
- 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.

The R&D of our pipeline products involves a lengthy and expensive process with no guaranteed outcome, and we may need to prioritise certain pipeline products. We may not achieve favourable results for our pipeline products in clinical trials, and results of earlier studies and trials may not be predictive of future trial results. The timeline of clinical trials remains inherently unpredictable as it might be affected by various factors beyond our control.

Clinical trial is inherently uncertain, a process marked by substantial costs and multi-year timelines, with the potential for failure at any stage. In the past, we strategically prioritised the development of our Core Products. Both of our Core Products are in the clinical stage, while our other pipeline products are in relatively earlier stage. Our decision was based on multiple factors including the anticipated competitive landscape and information about peer products leveraging the same underlying mechanism of action. In our future R&D efforts, we may experience numerous unexpected events during, or as a result of, clinical development that could delay or prevent our ability to receive regulatory approval or commercialise our pipeline products. Therefore, we cannot guarantee that we will not deprioritise any of the pipeline products described in the “Business” section of this Document.

RISK FACTORS

Failure can occur at any time during the R&D process. 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. Candidates advancing through preclinical studies and initial trials can still fail to demonstrate the desired safety and efficacy profile in later stages. 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. Consequently, we cannot assure you that our future clinical trials will be favorable. We cannot guarantee that the results from our future R&D efforts will 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, and we cannot assure you that any of our pipeline products will ultimately receive regulatory approval, and our ability to generate revenue may be materially impaired.

Regulatory approval from authorities such as the NMPA and the FDA 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.

Our pipeline products may fail to receive marketing approval from the NMPA, the FDA, or other comparable regulatory authorities for numerous reasons, which include, but are not limited to:

- disagreement with the design or execution of our clinical trials;
- inability to demonstrate that a pipeline product is safe, effective, and potent for its proposed indication;
- failure of our clinical trial results to meet the required level of statistical significance;
- failure of our clinical trial process to pass relevant GCP inspections;
- inability to demonstrate that the clinical benefits of a pipeline product outweigh its associated safety risks;

RISK FACTORS

- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from our clinical trials to support the submission of an IND or an NDA, or similar applications for approval;
- inability to obtain approval from the NMPA, the FDA or other comparable regulatory authorities for our clinical and commercial manufacturing supplies; and
- failure of our clinical trial processes to align with evolving scientific or technological standards required by regulatory authorities.

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. Even if approval is granted, regulatory authorities may approve a pipeline product for a narrower scope of indications 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.

If we are ultimately unable to obtain regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our pipeline products, we may face longer timelines and incur higher costs to obtain regulatory approvals, and we may ultimately be unable to complete the development or commercialisation of our pipeline products, which could substantially harm our business.

As confirmed by F&S, regulatory authorities such as the NMPA, the FDA and other comparable bodies have established expedited review and approval pathways for innovative or improved new pipeline products, and these pathways may be available to a pipeline product that addresses an unmet medical need for diseases that are life-threatening or seriously affect the quality of life, where there is no existing effective treatment, or where there is sufficient evidence to demonstrate clear clinical advantages over current existing treatment methods or meets other expedited registration requirements. However, there can be no assurance that any application under such an expedited regulatory designation will be accepted by the relevant regulatory authority for filing. Furthermore, even if an application is filed, there can be no assurance that such expedited development, review, or approval will be granted on a timely basis, or at all.

RISK FACTORS

Moreover, following initial correspondence or feedback from regulatory authorities, we may decide not to pursue or apply for an expedited pathway for any of our pipeline products, even if we had initially intended to do so. The failure to obtain any form of expedited development, review, or approval for our pipeline products would result in a prolonged period to commercialisation. This would, in turn, lead to increased development costs and could adversely affect our competitive market position.

It is also important to note that participation in an expedited registration pathway does not guarantee final marketing approval. An expedited program may not ultimately lead to expedited approval of our pipeline products, or indeed to approval at all. If such an outcome occurs, we may be unable to complete the development or commercialisation of the affected pipeline products.

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 do not guarantee success in identifying new pipeline products. While we have established proprietary R&D platforms, a dissolving microneedle drug formulation technology platform and a nasal inhalation drug formulation technology platform, and select optimal candidates to enrich our pipeline, the development and manufacture of certain pipeline products remain technically challenging. Furthermore, should we collaborate with third parties on discovery and development, we cannot assure that these collaborations will achieve their intended outcomes.

Research aimed at developing new indications for our existing candidates and identifying novel pipeline products and targets demands substantial technical, financial, and human resources. Although initial research may show promise in identifying potential indications or candidates, it may ultimately fail to yield viable results for clinical development for various reasons. These include, but are not limited to: (a) the failure of the research methodology to identify valid indications or candidates; and (b) the requirement of greater resources than anticipated to identify new therapeutic uses for our pipeline products or to develop suitable candidates, which can affect our ability to diversify and expand our drug portfolio. As a result, we cannot assure you that we will 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.

RISK FACTORS

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.

Subject enrollment for our clinical trials may be affected by a variety of factors, including but not limited to:

- the total size and nature of the relevant patient population;
- the design and eligibility criteria of the clinical trial in question;
- the perceived risks and benefits of our pipeline products under study;
- the severity of the disease being investigated;
- the resources we dedicate to facilitating timely subject enrollment;
- the patient referral practices of physicians;
- the availability of competing therapies also undergoing clinical trials;
- our ability to obtain and maintain informed consent from subjects;
- the efforts of our investigators or clinical trial sites to screen and recruit eligible patients;
- the geographical proximity and accessibility of our clinical trial sites for prospective patients; and
- the occurrence of natural disasters, health epidemics, acts of war, or other public events.

RISK FACTORS

Even if we manage to enroll a sufficient number of subjects, 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.

The preliminary, interim and top-line data obtained from our clinical trials which we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish preliminary, interim and top-line data from our clinical trials. Such interim data from trials we may complete are subject to the risk that one or more clinical outcomes may materially change as patient enrollment continues and additional patient data become available. Preliminary data also remain subject to verification procedures, which may result in the final data being materially different from the preliminary data we previously published. Consequently, preliminary, interim and top-line data should be viewed with caution until the final results are available. Differences between preliminary, interim data or, top-line data and the final data could have a significant impact on our business prospects and may cause the trading price of the H Shares to fluctuate materially following the [REDACTED].

Our preclinical programs may face delays or may never progress to clinical trials, which would adversely affect our ability to secure regulatory approvals or commercialise these pipeline products in a timely manner or at all, which ultimately would have a negative effect on our business.

The advancement of many of our pipeline products is contingent upon successful completion of the preclinical development stage and the risk of failure in the preclinical development stage is high. Prior to commencing clinical trials, we are required to fulfill extensive preclinical testing and study obligations to obtain the necessary regulatory clearance, including but not limited to, clearance from the NMPA, the FDA, and other relevant health authorities. We face considerable uncertainty regarding the timely completion and ultimate conclusions of our preclinical studies. There is no guarantee that regulatory agencies such as the NMPA or the FDA will grant acceptance to our proposed clinical programs, or that the data generated from our preclinical studies will be sufficient to warrant further clinical development. As a direct result, we are unable to provide assurance that we will file IND applications or equivalent submissions for our contemplated preclinical pipeline products within the anticipated timeframes, if at all. Even upon filing, we cannot assure that such submissions will be approved by the NMPA, the FDA or other regulatory authorities, authorising the commencement of clinical trials.

RISK FACTORS

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. In contrast to generic drugs, drugs emphasize novel mechanisms of actions, and discovering new molecular is challenging due to complex technological obstacles and limitations in R&D capabilities. 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.

Regulatory authorities may impose new regulations on promotion or uses of drugs that may affect our reputation and our potential market upon commercialisation of our pipeline products.

The NMPA, the FDA and comparable regulatory authorities from time to time impose regulations on the marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. Government regulators like the NMPA, the FDA, and others may enforce laws against promoting a drug for uses that have not been officially approved which may render our future approved drugs less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm the reputation of our Company and of the relevant drugs, our commercial operations and our financial condition. Such occurrences may subject us to liability and cause delays in our clinical trials, which could ultimately result in our inability to obtain regulatory approval for our pipeline products. In addition, the off-label use of our competitors' products could intensify the competitive

RISK FACTORS

landscape for our pipeline products. This practice may lead to a reduction in our potential market share upon commercialisation, which could adversely affect our business, financial condition, and operating results.

We work with various third parties to develop our pipeline products. If any of these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to secure regulatory approvals for or to commercialise 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, clinical trial sites, consultants, and other third parties to monitor, support, and conduct our preclinical studies and clinical trials for our pipeline products. While we collaborate with these entities to execute our programs, 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, our CROs, and our clinical investigators 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, which could prevent us from securing alternative arrangements on commercially reasonable terms. 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. This may prevent us from obtaining regulatory approvals or successfully commercialising our pipeline products. The process of switching or adding CROs involves substantial costs and time delays, which could materially impede our ability to meet our desired clinical development timelines and have a material adverse effect on our business, financial condition, results of operations, and prospects.

RISK FACTORS

All material aspects of the research, development and commercialisation of pharmaceutical products are heavily regulated. Non-compliance with the applicable laws, regulations, industrial standards may adversely affect our Group’s business operations, financial condition and future prospects.

The jurisdictions in which we propose to conduct our biopharmaceutical business activities are subject to extensive and detailed regulation. The pharmaceutical industry within these jurisdictions is subject to stringent oversight through a comprehensive framework of governing the development, approval, manufacturing, promotion, sales, and distribution of pharmaceutical products. For more details, see the section titled “Regulatory Overview” in this Document.

Differences in regulatory regimes across various jurisdictions may increase our compliance burden. The processes required to obtain regulatory approvals and to maintain compliance with applicable laws and regulations demand substantial investment of time and financial resources. Any recently enacted or future legislation may increase the difficulty and cost for us to obtain the regulatory approvals necessary to commercialise our pipeline products, and may also affect the prices we may achieve. Adverse changes in government regulations or practices relating to the pharmaceutical industry, such as a relaxation of regulatory requirements; the introduction of simplified approval procedures, which could lower the barrier to entry for potential competitors; or an increase in regulatory requirements, which may heighten the difficulty for us to satisfy such requirements, could materially and adversely affect our business, financial condition, results of operations, and prospects.

The failure to comply with applicable requirements or industrial standards at any time during the drug development or approval process, or after approval, may expose us to administrative or judicial sanctions. Such sanctions may include, but are not limited to, a refusal by a regulatory authority to approve pending applications, the withdrawal of an approval, the revocation of a licence, the imposition of a clinical hold, voluntary or mandatory product recalls, the seizure of products, a total or partial suspension of production or distribution, the issuance of injunctions, imposition of fines, the refusal of government contracts, orders for restitution or disgorgement, or civil or criminal penalties. The occurrence of any of the foregoing could thereupon materially and adversely affect our business, financial condition, results of operations, and prospects.

RISK FACTORS

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

RISK FACTORS

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.

RISKS RELATING TO MANUFACTURING AND COMMERCIALISATION OF OUR PIPELINE PRODUCTS

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. While the Company has gained certain operational experience through its MAH Business, such experience 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 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. Therefore, we cannot give any assurance that we will be able to establish or maintain relationships with third-party partners to successfully commercialise any product. As a result, we may not be able to generate the anticipated product sales revenue.

RISK FACTORS

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, including but not limited to:

- equipment malfunction;
- failure to adhere to specific protocols and procedures;
- alterations to product specifications;
- inadequate or insufficient supply of raw materials;
- delays in the construction of new facilities, which may result from changes to manufacturing production sites or limitations on manufacturing capacity imposed by regulatory requirements;
- changes in the types of products manufactured;
- technological advancements in manufacturing techniques;
- physical limitations that could impede a continuous supply; and
- man-made or natural disasters and other environmental factors.

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

RISK FACTORS

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.

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, the Dexmedetomidine Hydrochloride Microneedle Patch, 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

RISK FACTORS

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.

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, which may diminish our market share, hinder the successful commercialisation of our pipeline products and adversely impact our financial condition and business prospects.

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 advanced 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,

RISK FACTORS

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.

Our future pricing strategy and potential price fluctuations, particularly downward adjustments in the price of our future products, may have a material adverse impact on our business and operating results.

Our future financial success is contingent upon our ability to appropriately price our products. This valuation, however, is not solely within our control and will be subject to the bargaining power of healthcare providers and the dictates of various regulatory bodies.

For instance, hospitals possess significant influence over pricing, with their ability to negotiate lower retail prices depending on the availability of competing products and the preferences of physicians and patients. Such negotiations will adversely impact our profit margins. Moreover, the potential for our products to be included in national or regional medical insurance reimbursement schemes may play an important role in facilitating market penetration; however, this typically comes at the cost of mandatory price reductions that can negate the volume-driven benefits of inclusion.

Furthermore, we operate in a dynamic and competitive market where technological innovation can rapidly erode the pricing power of established products. If more advanced therapies, particularly those offering delivery mechanisms (such as improved patient compliance or reduced side effects), could exert significant downward pricing pressure on our products after their commercialization. This risk is amplified if we are unable to contain our own cost base of manufacturing and materials. Consequently, any failure to innovate with new, high-margin products or to maintain cost control could have a material and adverse effect on our business, financial condition, and future results.

RISK FACTORS

Even if we are able to commercialise our pipeline products, the 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.

We cannot assure you that reimbursement will be available for our future approved drugs, nor can we guarantee the level of reimbursement that may be provided. In the PRC, the level of reimbursement for programme participants is 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. Although the number of innovative drugs included in the NRDL is expected to increase in the future, we cannot assure you that any of our future approved drugs will be included in the NRDL or other similar government-sponsored medical insurance programmes.

RISK FACTORS

Our approved products will be subject to ongoing regulatory obligations and continued regulatory scrutiny, which may incur significant additional costs and expenses, and we may be subject to penalties if we fail to comply with such regulatory requirements.

Upon approval, our products will 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 other post-marketing data.

Drug manufacturers are required to comply with rules promulgated by the NMPA to ensure that quality control and manufacturing procedures conform to current GMP regulations. Consequently, we will be subject to continuous review and inspections by regulatory authorities to assess our compliance with current GMP and our adherence to commitments made in, for example, any NDA or Biologics Licence Application (BLA), or in our responses to queries and observations from such authorities. We expect to expend significant time and resources in order to meet our various regulatory compliance obligations in relation to manufacturing, production and quality control.

Furthermore, the regulatory approvals we obtain for our pipeline products may be subject to conditions that could affect their commercial potential, or may require us to conduct costly post-marketing clinical trials or implement other measures to monitor their safety and efficacy. The NMPA may also compel us to establish a Risk Evaluation and Mitigation Strategy (REMS) program. Such conditions and requirements could lead to a substantial increase in our compliance costs. Any failure to comply with these conditions and requirements may result in sanctions or penalties imposed by regulatory authorities that could adversely affect our business, financial condition and results of operations.

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.

RISK FACTORS

Although the importation of unapproved foreign prescription drugs is illegal under the laws of the PRC, the United States, and many other jurisdictions, such illegal imports may persist or even increase, particularly as the ability of patients and other customers to obtain these lower-priced goods grows. 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.

Guidelines, recommendations and studies published by various organisations could adversely affect our pipeline products.

Government agencies, professional societies, practice management groups, private health and science foundations, and patient-focused organisations may publish guidelines, recommendations, or studies that could influence the demand for our pipeline products. Any such publication that reflects adversely, either directly or by comparison to competing therapies, on our pipeline products could diminish demand and adversely affect our future sales revenues. Furthermore, the

RISK FACTORS

sales potential of our future approved drugs will, in part, depend on our ability to educate patients and the medical community (including healthcare providers) regarding our products. Our ability to communicate effectively may be impeded by the publication of negative guidelines, recommendations, or studies concerning our pipeline products.

If we cannot maintain or develop clinical collaborations and relationships with principal investigators, key opinion leaders, physicians and experts, our operation results and prospects could be adversely affected.

Our relationships with Principal Investigators (PIs), physicians and other medical experts, if any, are integral to our R&D and commercialisation activities. We have established extensive channels of communication with such experts to gain first-hand insight into unmet clinical needs and prevailing practice trends, which is critical to our ability to develop new, market-responsive therapeutics. However, we cannot assure you that we will be able to maintain or strengthen these clinical collaborations, or that our endeavours to do so will result in the successful development and marketing of new products. These collaborators may leave their current roles, change their professional focus, cease to cooperate with us, or choose to engage with our competitors instead. Even if our collaborations continue, their market insights, which we rely upon in our R&D process, may prove to be inaccurate, potentially leading us to develop products with limited market potential.

Furthermore, we cannot assure you that our academic promotion and marketing strategies will be effective. Industry participants, may refuse to collaborate with us or attend our conferences, and our marketing strategy may fail to generate returns commensurate with the investment made. If we are unable to develop new drugs or achieve the expected returns from these relationships, our operation results and prospects could be adversely affected.

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, 2023 and 2024 and the six months ended June 30, 2025, we recorded net

RISK FACTORS

losses of approximately RMB63.7 million, RMB147.1 million and RMB20.8 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 obtain regulatory approval, or if approved, fail to achieve market acceptance, we may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. 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 [REDACTED].

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 RMB136.1 million, RMB283.2 million and RMB304.0 million as of December 31, 2023, 2024 and June 30, 2025. We also had net current liabilities of approximately RMB154.2 million, RMB308.6 million and RMB332.3 million as of December 31, 2023, 2024 and June 30, 2025, respectively, primarily due to the financial liabilities on series shares of approximately RMB134.9 million, RMB335.3 million and RMB336.6 million representing certain special rights granted to certain Pre-[REDACTED] Investors as at the same dates, 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 RMB21.2 million, RMB15.3 million and RMB18.7 million for the years ended December 31, 2023 and 2024 and the six months ended June 30, 2025, respectively. For further details, please see the section titled

RISK FACTORS

“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 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, 2023 and 2024 and June 30, 2025, our interest-bearing bank and other borrowings amounted to approximately RMB19.3 million, RMB12.9 and RMB23.6 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.

However, changes in our ability to obtain financing or generate sufficient revenue could impact our liquidity, cash flow, and overall financial performance. Despite the expected [REDACTED] from this [REDACTED], 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. Our future funding requirements will depend on various factors, including but not limited to:

- the pace of our headcount expansion and the related personnel costs;
- the progress, timing, scope, and costs of our clinical trials, including our ability to identify and enroll suitable patients in a timely manner for current and future trials;

RISK FACTORS

- the timing, cost, and outcome of regulatory review and approval processes for our pipeline products;
- the progress, timing, scope, and expenses associated with the discovery and early-stage development of additional pipeline products;
- the expenses associated with filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the preparations necessary for the anticipated commercialization of our pipeline products, and, if regulatory approvals are obtained, the funding required to support product launches; and
- the manufacturing needs and related capabilities necessary for clinical development and the eventual commercialization of any approved pipeline products.

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.

RISK FACTORS

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 2023 and 2024, and 30 June 2025, our financial assets measured at fair value through profit or loss amounted to approximately RMB10.4 million, nil and RMB2.7 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 cannot assure you that we will 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 RMB2.4 million, RMB1.8 and RMB1.9 million during the two years ended December 31, 2023, 2024 and the six months ended June 30, 2025, 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 cannot assure you that we will 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 cannot assure you that the government incentives and support we currently enjoy will be maintained at existing levels 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.

RISK FACTORS

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

Our prepayments, other receivables 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. However, there is no assurance that our suppliers, service providers, and other third parties will fulfill their contractual obligations on time, and we are exposed to credit risks associated with these prepayments, other receivables and other assets.

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, we cannot assure you that our assumptions and estimates will not 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. For further details, 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.

RISK FACTORS

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. Failing to comply with these requirements may result in a weakening or complete loss of our patent protection.

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. We engage legal advisers and other professionals to assist us in meeting these obligations in relation to our intellectual property.

While inadvertent lapses may be remedied by paying a late fee or through other means permitted under the applicable regulations, there may also be circumstances in which non-compliance 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. Instances of non-compliance that could cause abandonment or lapse include failure to respond to official communications within prescribed time limits, non-payment of required fees, or failure to properly execute and submit formal documentation. 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 (including patents, trademarks, trade secrets and other forms of intellectual property protections) 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. Examples of these limitations include:

- others may be able to design and manufacture drug products that are identical or substantially similar to our own, but which do not fall within the scope of the claims of the patents we own or may exclusively license;

RISK FACTORS

- others may independently develop alternative or similar technologies, or otherwise replicate our technologies, without infringing our intellectual property rights;
- third parties may be able to conduct research and development activities in territories where we do not have patent protection and then use the knowledge gained from these activities to develop and launch competitive products into our principal commercial markets; and
- we may not develop new technologies that are eligible for patent protection.

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. As a result, our ability to successfully commercialise any product or technology may be potentially reduced and our competitive position may be undermined.

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. Even if we successfully obtain patent protection for a product candidate, our ability to market it without competition cannot be guaranteed. Manufacturers of similar or identical products may 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. To address the risk of patent expiry following lengthy regulatory approval, the Patent Law of the PRC (as amended) provides for a mechanism to extend the patent term for certain invention patents relating to new drugs. This compensation may be utilized to offset the time taken during the evaluation and approval process for a new drug to be marketed in China. However, we cannot rely on such measures to fully protect our commercial position. Our patents and pending applications may not provide us with sufficient rights to exclude competitors from commercialising products that are similar to or identical to ours. This is because, in the absence of supplementary protections such as patent term extensions and data exclusivity, the statutory term of a patent may be inadequate. Even where we believe we are eligible for such extensions, there can be no assurance that the relevant

RISK FACTORS

authorities will grant them, or that any extension will be as extensive as we may request. 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. We cannot guarantee that our pipeline products, or their intended uses, do not infringe existing third-party patents or other intellectual property rights, nor can we guarantee that they will not do so in the future. 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. Even if we believe that third-party intellectual property claims lack merit, there can be no assurance that a court would rule in our favour 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.

RISK FACTORS

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. Even if secured, 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. Even if we were to prevail or reach an early settlement, such proceedings could still impose substantial and unforeseen adverse effects on our business and financial condition.

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 proprietary 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.

RISK FACTORS

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.

We consider our proprietary protection to be fundamental to our business operations. We have sought to protect our commercially significant pipeline products and technologies through a combination of filing patent applications in key jurisdictions, including China and the United States, and by relying on trade secrets and pharmaceutical regulatory data protection. 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. The landscape for intellectual property rights in the biotechnology and pharmaceutical sectors is highly uncertain, characterised by complex legal and factual issues, and has been the subject of significant litigation. This uncertainty extends to the issuance, scope, validity, enforceability, and commercial value of our own patent portfolio. Patents may be invalidated and applications refused for a variety of reasons, including the existence of known or unknown prior art, deficiencies in the drafting of the application, or a lack of novelty or inventiveness in the underlying invention. We cannot guarantee that we were the first to invent the technologies underpinning our pipeline products, and our applications could therefore be rejected.

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

RISK FACTORS

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 proprietary technology.

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 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, we cannot be certain that every individual or organisation with access to our trade secrets or proprietary technology has entered into a suitable confidentiality agreement. Pursuing legal action to enforce claims of unauthorised disclosure or misappropriation of trade secrets is often costly, time consuming and unpredictable. If a competitor or another third party were to lawfully acquire or independently develop the same technology or information, we may have no right to prevent them from using it, which could weaken our competitive position.

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. Although we seek to ensure that our personnel do not use the confidential information or know-how of third parties in their work for us, we may nevertheless face allegations that we or our employees have misused or disclosed intellectual property, including trade secrets or proprietary information, belonging to a former employer. While we are not currently aware of any such claims or disputes involving our senior management or other personnel, litigation could arise in the future. If we were to lose any such case, 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. Additionally, such disputes could lead to the loss of key personnel or deter prospective employees and contractors from joining us. The loss of key individuals or their expertise could significantly impede our ability to develop and commercialise our products and technologies, adversely affecting our business, operations, financial position and prospects. Even if we were successful in defending against such claims, litigation would still involve substantial costs and distract our management and staff from core business activities.

We also generally require our consultants and contractors who may contribute to the creation or development of intellectual property to sign agreements assigning such rights to us. However, we may not always succeed in securing such agreements from every contributor. Moreover, even

RISK FACTORS

when signed, the assignment of rights may not automatically take effect or may be breached, potentially leading to disputes over ownership. Some individuals may also have pre-existing obligations to third parties, such as universities or research institutions, which could render our agreements ineffective in securing ownership of certain inventions. If we fail to defend or enforce our ownership rights, we could lose valuable intellectual property.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercialising similar drugs or technology, without payment to us, or could limit the duration of the patent protection covering our pipeline products and technology. Such challenges may restrict our capacity to develop, manufacture or commercialise our pipeline products without infringing the patent rights of others. If the strength or scope of protection provided by our patents is questioned, potential partners may be discouraged from entering into collaborations with us to develop or commercialise our current or future products. Any of these circumstances could materially and adversely affect our competitive position, business, financial condition, results of operations and long-term prospects.

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. As a result, we may be required to obtain and maintain licences from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes, in order to continue the development, manufacture and commercialisation of one or more of our product candidates. However, such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

RISK FACTORS

Unfavorable outcomes in intellectual property litigation could limit our R&D activities and/or our ability to commercialise our pipeline products.

If third parties are successful in asserting their intellectual property rights against us, we could be enjoined from utilising certain aspects of our technology, or be prevented from developing and commercialising our pipeline products. Such prohibitions may be imposed by a court or as a result of a settlement agreement between us and the claimant. Furthermore, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of third parties, we may be liable to pay substantial damages to the claimant. Litigation, including intellectual property litigation, is inherently uncertain. Accordingly, we cannot provide any assurance that we would prevail in any such proceeding, even if the merits of the case against us were weak or unfounded.

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.

In China, intellectual property laws continue to evolve as part of ongoing efforts to strengthen protection. For example, under the fourth amended patent law, a patentee of an invention relating to a new drug may apply for an extension of the patent term to compensate for the time taken for regulatory review and approval in China. The extension may not exceed five years, and the total effective patent term following the approval of the new drug for commercial sale must not exceed fourteen years. According to the PRC Patent Law Implementing Rules (《中華人民共和國專利法實施細則》), the compensation period is calculated by subtracting five years from the total number of days between the filing date of the patent application and the date on which the new drug receives approval for marketing in China.

RISK FACTORS

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. We cannot assure you that any trademark applications we submit in the future will be approved. During the registration process, our applications may be rejected, and although we would have an opportunity to respond, 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. As our products become more established, we will rely increasingly on our trademarks to distinguish us from competitors. If we are unable to prevent others from adopting, registering or using marks or trade dress that infringe, dilute or otherwise conflict with our trademark rights, or from engaging in conduct that constitutes unfair competition, defamation or other infringements of our rights, our business could be materially affected. 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. There is also the possibility that other trademark owners could bring claims of infringement against us, alleging that our registered or unregistered marks, or variations thereof, infringe their rights. 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. Our efforts to enforce and protect our proprietary rights in trademarks, trade secrets, domain names, copyrights and other intellectual property may not always be successful and could involve significant expense and diversion of management resources. Any of these circumstances could materially and adversely affect our competitive position, business operations, financial condition and future prospects.

RISK FACTORS

RISKS RELATING TO OUR OPERATIONS

The industry we target is developing rapidly. If we are not able to develop and release new products that are competitive in the market, or develop successful enhancements or indication expansion of our platform or any future products in a timely manner our products may become obsolete and our business, operating results and financial condition could be materially adversely affected.

With the rise of precision medicine and patient-centered care, innovative high-end drug formulations are transforming drug development. We believe that technologies like microneedles, nasal sprays, and controlled-release systems could overcome limitations of traditional drugs by enabling targeted delivery, efficient absorption, and better compliance. The new drugs with advanced formulations market is expected to have robust and sustainable market growth with sustained policy supports. Also as confirmed by the F&S, the global weight management market is undergoing explosive expansion and is transitioning from traditional lifestyle interventions and basic drug therapies to a new phase characterized by diversified mechanisms, personalized treatment, and innovative delivery methods. Similarly, the global Parkinson’s disease “Off” episodes market is undergoing rapid expansion, necessitating increasingly urgent solutions that provide faster onset, simpler administration, and enhanced safety as confirmed by the F&S. Our future financial performance will be contingent upon growth in these markets and our ability to adapt to emerging customer demands. It is inherently difficult to predict the future growth rate and size of our target markets. Our success therefore hinges on our ability to accurately forecast industry trends and continuously identify, develop, and market more advanced products in a timely manner that address unmet clinical needs. Product designs may change in response to market conditions, alongside the demands and preferences of hospitals and medical professionals. We cannot give assurance that we will successfully identify new technological opportunities, enhance or adapt to new technologies and methodologies, develop new products, or improve or expand the indication coverage of our existing products in a timely manner. Even if we develop new or improve existing technologies, our ability to commercialise them may be constrained by the need for regulatory clearance or approval, restrictions on approved indications, entrenched clinical practice patterns, uncertainty surrounding third-party reimbursement, or other obstacles.

Technological innovations often entail significant uncertainty. Successful innovation cannot follow a linear or predictable path; rather, it must account for the inherent unpredictability of the process and the incomplete knowledge industry participants possess of the domain. We may not succeed in developing, marketing, and delivering enhancements or improvements to our commercialised products in the future, or any new products responding to evolving market demands and customer requirements, in a timely and cost-effective manner, or achieve market acceptance. The timeline for the release of new products and enhancements to existing products is difficult to predict due to the complexity inherent in product development, and we may not

RISK FACTORS

introduce new products and updates as rapidly as our users require or expect. Any new products that we develop or acquire may not be introduced in a timely or cost-effective manner, may contain errors or defects, or may not achieve the broad market acceptance necessary to generate significant revenue or any revenue at all. Furthermore, technological innovations often require substantial time and investment before their commercial viability can be determined. Accordingly, our R&D efforts may not yield new or improved technologies or products that achieve commercial success. Additionally, we may lack the financial resources necessary to fund future projects. Even if we successfully develop new products or improve or expand the indication coverage of existing products, we may not generate revenue exceeding the costs of development and procurement, or achieve the desired financial return. These products and related technologies may be rendered obsolete or less competitive due to changing customer preferences, the introduction by competitors of products featuring newer technologies or functionalities, or other factors.

We may encounter difficulties with industry standards, design, or marketing that could delay or prevent the development, introduction, or implementation of new products, expanded indication coverage, additional features, or capabilities. If patients and healthcare providers do not widely adopt our products, we may be unable to realise a return on our investment. If we fail to accurately anticipate patient and physician demands, or are unable to develop, license, or acquire new features and capabilities in a timely and cost-effective manner, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance, or litigation claims from patients or healthcare providers against us. Each of these outcomes could have a material and adverse effect on our reputation, business, results of operations, and financial condition.

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 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

RISK FACTORS

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 cannot assure you that we will 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. Our expansion plans are based on forward-looking assessments of market opportunities, and we cannot provide any assurance that such assessments will prove to be accurate.

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 cannot assure you that we will be able to establish or maintain such arrangements, or, even if successful, establish effective sales forces and distribution networks. A proportion of our revenue will be contingent upon the efforts of these third parties, the success of which we cannot guarantee. 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, there can be no assurance that we will 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.

RISK FACTORS

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. Although we have not historically faced unique difficulties in attracting and retaining qualified employees, we anticipate that intense competition for such talent within the pharmaceutical and life sciences sectors will persist. The pool of suitably qualified candidates is inherently limited. The departure of one or more members of our senior management or other key scientific personnel, regardless of whether they join a competitor or form a competing entity, could subject us to significant operational disruption. We may be unable to replace them on a timely basis, or at all, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Furthermore, as we build and expand our commercialisation capabilities in anticipation of future product launches, we will be required to hire additional personnel. There can be no assurance that we will 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 of our production facilities in Zhuhai and Liangyungang in the PRC and other potential manufacturing facilities as planned, 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 commercial production facilities in Zhuhai and Liangyungang. 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, 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

RISK FACTORS

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; even if this were possible, the transition could 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 cannot guarantee that we will consistently adhere to, and adequately document compliance with, GMP and other regulatory requirements. Furthermore, new regulations or changes in the interpretation or enforcement of existing laws could require us to seek further approvals, permits, or licences, and we cannot assure you that we would be successful in obtaining them.

If our Zhuhai and Liangyungang facilities fail to receive regulatory approval, are damaged or destroyed, or are otherwise disrupted, rebuilding our manufacturing capacity would require substantial lead time. Any new facility constructed to replace an existing one would need to meet necessary regulatory standards and be tailored to our specific production requirements and processes. Additionally, we would require fresh regulatory approvals before any products or drugs manufactured at a new facility could be used in clinical trials or sold to the market.

We may not be able to maintain effective quality control over our products.

The quality of our products, including pipeline products manufactured by us for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. We operate a quality control system which extends across key stages of the research and development, manufacturing and commercialisation processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China and the United States. For details, please see the section titled “Business — OUR BUSINESS MODEL” in this Document. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use,

RISK FACTORS

result in gaps in the audit of our processes, jeopardise any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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. Even in the event of a successful defence, the process would require significant outlays of financial and management resources. Regardless of their ultimate merits or outcome, liability claims may lead to:

- diminished demand for our pipeline products;
- material harm to our reputation and brand;
- withdrawal of clinical trial participants, potentially preventing the continuation of clinical trials;
- the initiation of investigations by regulatory authorities;
- substantial costs associated with defending related litigation;
- a diversion of management attention and corporate resources;
- significant monetary awards to trial participants or patients;
- product recalls, withdrawals, or restrictions on labelling, marketing, or promotion;

RISK FACTORS

- a loss of revenue and erosion of profitability;
- exhaustion of available insurance coverage and our capital resources;
- an inability to commercialise any approved pipeline products; and
- a decline in the market price of our H Shares.

To mitigate liabilities arising from clinical studies, we maintain clinical trial insurance to cover adverse events. However, our total liabilities may exceed the limits of our insurance coverage, or our policies may not provide protection in all circumstances where a claim could be asserted. We may also be unable to secure insurance on commercially reasonable terms, or to obtain coverage that is adequate to satisfy any potential liability. 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 [REDACTED] 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 [REDACTED] 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 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.

RISK FACTORS

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. A disruption in production, or an inability of our suppliers to produce adequate quantities, could impair our operational capabilities and our research and development programmes.

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. We cannot, however, assure you that our current suppliers will 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. Our suppliers may be unable to cater to our growing requirements or may reduce or cease their supply to us at any time. We are also exposed to the risk of increased input costs, which may adversely impact our profitability. In the event of significant price increases for such materials, we cannot assure you that we will 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.

Finally, we cannot assure you that these third parties will be able to maintain and renew all of the licences, permits, and approvals necessary for their operations or will comply with all applicable laws and regulations. Their failure to do so could lead to interruptions in their own business, which in turn may result in a shortage of materials and equipment supplied to us, causing delays in clinical trials, regulatory filings, or product recalls. The non-compliance of these third parties may also expose us to potential product liability claims, lead to a failure by us to comply

RISK FACTORS

with continuing regulatory requirements, and incur significant costs to rectify such incidents. The occurrence of any of these events could have a material adverse effect on our business, financial condition, and results of 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, 2023 and 2024 and the six months ended June 30, 2025, our R&D expenditures were approximately RMB18.4 million, RMB16.4 million and RMB11.6 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 cannot assure you that we will 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. Future legislative or regulatory changes promulgated by the Chinese authorities may impose additional burdens on employers, which could materially

RISK FACTORS

adversely affect 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.

Failure to comply with existing laws, regulations and industry standards such as quality standards set out by applicable laws, regulations or industry standards, or any adverse actions by the drug approval authorities against us could negatively impact us.

A number of governmental agencies or industry regulatory authorities in the PRC, the United States and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical R&D activities, which may apply to us. Our failure to comply with such regulations may result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations.

Furthermore, the preoperative sedative drug market, the Parkinson’s disease “Off” episodes treatment market, the diabetes treatment market or other industries in China and other jurisdictions into which we intend to expand are characterised by stringent regulation and constant evolution, with laws, regulations, and policies subject to amendment as confirmed by F&S. Should we fail to remain current with or comply with applicable laws, regulations, industry standards, and policies, we may be subject to fines or other penalties. Additionally, our ongoing development projects could be terminated, and any data submitted to regulatory authorities may be disqualified. Any of these outcomes could have a material adverse effect on our reputation, business, financial condition, results of operations, and prospects. Moreover, any enforcement action taken against us for breaches of relevant regulations or industry standards, even if successfully defended, may result in significant legal expenses and divert management attention from core business operations.

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.

RISK FACTORS

For example, changes in regulatory requirements and guidance may necessitate amendments to clinical trial protocols submitted to the authorities. Such modifications could impact the costs, timelines, or successful completion of our clinical trials. Furthermore, amendments to existing regulations concerning the registration and approval of pharmaceutical products are possible. These could include a relaxation of requirements or the introduction of simplified approval procedures, which might lower the barriers to entry for potential competitors. Conversely, increased regulatory stringency could heighten the challenge of satisfying the applicable criteria. Any new administrative or legislative regulatory measure could also lead to more stringent coverage criteria and exert downward pressure on the pricing of any approved products.

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. Consequently, if we act as an MAH for our future drug products, we will be required to obtain a pharmaceutical manufacturing permit from the NMPA, even if we utilise CMOs for manufacturing activities. As the MAH, we will bear full legal responsibility for the entire product lifecycle, encompassing non-clinical studies, clinical trials, manufacturing, marketing, distribution, and pharmacovigilance (adverse drug reaction monitoring). 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.

RISK FACTORS

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 cannot assure you that we will be able to obtain any such additional authorisations on a timely basis, or at all. Our inability to secure the necessary authorisations could restrict our business operations, increase our operational costs, and in turn, materially and adversely affect our business, financial condition, results of operations, and prospects.

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. For instance, we may face claims if our pipeline products cause or are alleged to cause injury, or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Such product liability claims may include allegations of manufacturing defects, design defects, failure to warn of inherent dangers, negligence, strict liability, or breach of warranty.

Our involvement in legal proceedings and litigation can divert management's and directors' attention and consume significant time and resources. Furthermore, a matter that is initially not considered material may escalate due to various factors, including the specific facts and circumstances of the case, the prospects of litigation, the monetary amount at stake, and the parties involved. This escalation, in turn, could render the case material to us. 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. Moreover, if a judgment or award is made against us, we could be required to pay significant monetary compensation, assume other liabilities, and be compelled to suspend or terminate related business ventures or projects. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

RISK FACTORS

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 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.

Our employees, collaborators, service providers, independent contractors, PIs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are potentially exposed to the risk of fraud, bribery, or other misconduct by our employees or any of our third parties, which could result in financial loss and regulatory sanctions. Such events could also severely damage our reputation. During the Track Record Period and up to the Latest Practicable Date, we are not aware of any material instances of fraud, bribery, or other misconduct by our directors, officers, employees, or contractors that have had a materially adverse effect on our business. However, we cannot give an assurance that we will not experience such incidents in the future. Although we believe our internal controls and procedures to be sound, they cannot provide an absolute guarantee that we will prevent, detect, or deter all such misconduct. Any such act, whether historical and undetected or future in nature, could have a material adverse effect on our business, financial condition, and results of operations.

RISK FACTORS

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through in-licenses and acquisitions.

Our development programmes may require the utilisation of proprietary rights owned by third parties. Consequently, our future growth and commercial prospects may be dependent, in part, on our ability to secure and maintain licences or other rights essential to these proprietary rights. We may be unable to successfully in-license specific compositions, methods of use, or other intellectual property assets that we identify as necessary.

The market for the licensing and acquisition of third-party intellectual property is highly competitive, with numerous more established companies pursuing similar strategies. These competitors may hold a significant competitive advantage over us due to their greater size, financial resources, and more advanced clinical development and commercialisation capabilities. Furthermore, third parties who view our activities as competitive may be unwilling to grant us licences or assign the relevant rights. We may also be unable to acquire such rights on commercially acceptable terms, or at all. If we cannot successfully obtain, or if we fail to maintain, the requisite third-party intellectual property rights, we may be forced to abandon the development of the relevant programmes or pipeline products. Such an event could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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, including, but not limited to, the following:

- substantial expenditure of time and financial resources on negotiations or due diligence that may not result in the successful completion of any such transaction;
- adverse effects on our financial results, including the potential for material impairment charges against goodwill and significant amortisation expenses for intangible assets;
- increased operating expenses, cash requirements, and capital deployment;
- assumption of additional indebtedness or contingent and unforeseen liabilities;
- issuance of equity securities, which could be dilutive to our existing shareholders;

RISK FACTORS

- difficulties in assimilating the operations, intellectual property, products, and personnel of an acquired entity, resulting in a failure to achieve anticipated synergies or from operational disruption;
- diversion of management's attention and resources from our core business and existing development programmes;
- risks and uncertainties arising from the other party to a transaction, including the commercial prospects of their business, the status of their product candidates, and the outcome of their regulatory approval processes;
- difficulties in retaining key employees of an acquired business and uncertainties in our ability to maintain key customer and supplier relationships;
- inability to generate revenues from acquired technologies or products sufficient to meet our investment objectives or to offset the associated acquisition and ongoing costs; and
- post-acquisition discovery of material deficiencies in the acquired business, including but not limited to, internal controls, data integrity, regulatory compliance, product quality, and product liabilities, which may expose us to significant financial penalties, legal claims, or other liabilities.

We may be unable to identify or successfully conclude attractive acquisitions. Furthermore, our management team has limited experience in executing acquisitions, and even if we identify a suitable target, we may fail to acquire it despite expending significant resources in the pursuit. 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. If we undertake acquisitions, we may be required to issue equity securities, assume debt, incur significant one-time transaction costs, and acquire intangible assets that could give rise to substantial future amortisation charges.

RISK FACTORS

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.

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. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. 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. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

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, including but not limited to COVID-19, avian influenza, SARS, influenza A (H1N1), and Ebola, 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 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.

RISK FACTORS

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.

Our risk management and internal control systems, along with the risk management tools and processes available to us, may not fully and adequately protect us against various risks inherent in our business operations.

In preparation for the [REDACTED], we engaged an internal control consultant to perform an internal control review; the scope of this review is limited to certain areas, including financial closing and reporting. While we have implemented a number of measures and procedures to manage our risk exposure, there is a risk that we may not effectively monitor such risks due to constraints in our information systems or other factors.

Furthermore, we cannot provide assurance that all employees will consistently comply with our internal control policies and procedures. Although we regularly update our risk management and internal control frameworks, new risks may emerge that we fail to anticipate arising from, among other things, rapid changes in market conditions, new or evolving regulatory measures, and our entry into new markets. If we are unable to materially strengthen our risk management and internal control systems, or if these systems fail to operate effectively and as intended, our business, financial condition, and results of operations could be materially adversely affected.

Our internal information technology system, or those used by our partners or other contractors or consultants, may fail or suffer failures, security breaches, cyberattacks or other disruptions. Any such incident may compromise sensitive data, hinder operational continuity and negatively affect our business and reputation.

We have established risk management and internal control frameworks, which comprise an organisational structure, policies, and procedures to manage our key risk exposures, such as security breaches, cyberattacks or other disruption. However, there is a risk that we may not successfully implement these systems. We are committed to enhancing our systems from time to time; nevertheless, we cannot guarantee that our systems will be deemed adequate or effective at all times, despite our efforts. Similarly, we cannot guarantee that the internal information technology systems adopted by third parties, such as our partners, other contractors or consultants will be secure as we do not have a direct control over their systems. A failure to identify and mitigate potential risks or to address material weaknesses in our internal controls, or those used by our partners or other contractors or consultants could have a material adverse effect on our business, financial condition, and results of operations.

RISK FACTORS

As our risk management and internal control frameworks rely on the diligence of our employees, we cannot assure you that all employees will consistently adhere to these policies and procedures. Their implementation may also be subject to human error. Furthermore, our anticipated growth and expansion could place pressure on our ability to enforce stringent controls as our business scales. If we are unable to timely, and as necessary, adopt, implement, and update our risk management and internal control policies and procedures, our business, financial condition, and results of operations could be materially adversely affected.

Failure to comply with existing or future laws and regulations related to privacy or data security or cybersecurity may expose us to governmental enforcement actions, which could include civil or criminal penalties, private litigation, reputational damage, other liabilities and/ or adverse publicity, and could negatively affect our operating results and business.

We routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorised disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they may be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients' privacy, they may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials also involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with the applicable laws and regulations or our data privacy

RISK FACTORS

measures. We also cooperate with third parties including PIs, hospitals, CROs, CMOs and other third-party contractors for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure.

Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorised release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with applicable anti-corruption or anti-bribery laws may expose us to investigations, sanctions, fines and/or reputational harm, which may materially and adversely affect us. Despite our compliance efforts, we may be unable to detect, deter and prevent all instances of fraud, misconduct or unethical behaviour committed by our employees or other third parties.

We are subject to anti-corruption and anti-bribery laws in China and other applicable jurisdictions that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policy and procedures designed to ensure that we, our employees and business partners comply with anti-corruption laws and anti-bribery laws, there is no assurance that such policy and procedures will prevent our business partners, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-corruption laws or anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and exclusion from participation in government supported healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

RISK FACTORS

We and our third-party collaboration partners may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in relevant jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians, and other relevant professionals perform a primary role in the recommendation and prescription of our products, following their regulatory approval. Should we obtain approval from the NMPA, the FDA, or other comparable regulatory authorities for our pipeline products and commence commercialisation in China, the U.S., and our other target markets, our operations will be subject to various anti-fraud and anti-bribery laws in these jurisdictions, including, but not limited to, the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), the PRC Criminal Law (《中華人民共和國刑法》), the U.S. Federal Anti-Kickback Statute, the U.S. False Claims Act, and the Physician Payments Sunshine Act. These regulations may, for instance, impact our sales, marketing, and educational programmes.

Furthermore, we may also be subject to analogous healthcare laws in other jurisdictions. The scope of these laws varies and they may apply to healthcare services reimbursed by a range of payers, comprising both governmental and private insurers. Ambiguity exists as to the precise steps required to achieve compliance with these regulations, and a failure to do so could expose us to penalties.

Breach of these anti-fraud and anti-bribery laws may result in criminal or civil sanctions, including monetary penalties, fines, and potential exclusion from or suspension participation in national healthcare programmes, in addition to debarment from government procurement contracts. Ensuring that our business arrangements with third parties comply with applicable healthcare laws necessitates significant cost. Government authorities may determine that our business practices are not in compliance with existing or future statutes, regulations, or interpretations of the law. In the event of any such action being brought against us, and should we be unsuccessful in our defence, it could result in the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, the possibility of exclusion from governmental healthcare programmes, contractual liabilities, reputational damage, reduced profits and future earnings, and a curtailment of our operations. Any one of these outcomes could materially and adversely affect our business, financial condition, and results of operations. Finally, if any of the physicians, other providers, or entities with whom we propose to enter into arrangements are found to be non-compliant with applicable laws, they may be subject to similar sanctions, including exclusion from government-funded healthcare programmes, an eventuality that could also adversely affect our business.

RISK FACTORS

We, our contractors and business partners are subject to environmental protection, health and safety laws and regulations, and we may incur potential costs for compliance and liabilities, including consequences of accidental contamination, biological hazards or personal injuries.

Our operations are subject to numerous laws and regulations pertaining to environmental, health, and safety matters, including those governing the treatment and discharge of pollutants and the use of toxic and hazardous chemicals in our business activities. In addition, our construction projects will need to obtain the requisite regulatory approvals from relevant environmental and health and safety authorities in the relevant jurisdictions before they may be commissioned. We cannot guarantee that we will secure all such approvals in a timely manner, or at all. Delays or failures in obtaining these approvals could impede our ability to develop, manufacture, and commercialise our pipeline products as planned. Because the requirements of such legislation are subject to change and more stringent laws or regulations may be enacted, we may be unable to comply with such laws and regulations or accurately predict the potential substantial costs of compliance. A failure to comply with applicable environmental, health and safety laws and regulations may expose us to remediation orders, substantial monetary penalties, potential damages, or injunctive orders, including the suspension of our operations. Accordingly, any failure to control the use or discharge of hazardous substances could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We do not currently carry insurance for environmental liabilities that may be asserted against us. Furthermore, we may be required to incur substantial costs to comply with current and future environmental, health, and safety regulations. These regulations could adversely affect our research, development, production, and commercialisation activities. Failure to comply may also result in significant fines, penalties, or other sanctions. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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, although we maintain insurance coverage for adverse events occurring during our clinical trials, we cannot assure you that this coverage will prove to 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.

RISK FACTORS

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. Any liability or damage caused by, or arising from, our facilities or our personnel, which is not covered by our insurance policies, may result in our incurring substantial costs and a diversion of management attention and resources.

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, even if unfounded, 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. Consequently, any negative publicity about us could adversely affect our ability to maintain existing collaboration arrangements or secure new partners, and we may be unable to rectify the resulting damage to the satisfaction of our investors and customers.

RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

Volatile conditions and turbulence in the global economic, political and financial environment may materially and adversely affect our business operations, financial condition, operating results and future prospects.

The current global macroeconomic environment is subject to numerous challenges. In particular, there is significant uncertainty surrounding the future geopolitical and trade relationship between the United States and its major trading partners, including China, concerning issues such as trade policies, treaties, regulations and tariffs.

RISK FACTORS

Furthermore, there is considerable uncertainty regarding the long-term impact of expansionary monetary and fiscal policies implemented by the central banks and financial authorities of major world economies, including the United States and China. Geopolitical instability, including unrest and terrorist threats may also contribute to market volatility. Additionally, geopolitical tensions involving China and other nations, including the United States and surrounding Asian nations, may have significant economic repercussions. For instance, on 21 February 2025, the President of the United States issued a memorandum entitled the “America First Investment Policy” (the “**America First Memo**”). This memorandum outlines the ongoing review of potential new or expanded restrictions on U.S. outbound investment into the PRC in sectors such as semiconductors, artificial intelligence, quantum computing, biotechnology, hypersonics, aerospace, advanced manufacturing, and directed energy, as well as other areas implicated by the PRC’s national military-civil fusion strategy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments, and other limited partner investors. Such political frictions and policy shifts could adversely affect global economic conditions, the stability of international financial markets, and international trade policy, and in turn affect the Chinese economies. Accordingly, our business, results of operations and financial condition may be adversely affected.

The trade relations between PRC and the United States or other jurisdictions may affect our business operations, and any changes in the United States and international trade policies, particularly those involving the PRC, may adversely impact key aspects of our clinical development, drug manufacturing processes and other aspects of our business and operating results.

Recent years have seen significant shifts in the trade policies of the United States, including the imposition of tariffs on certain products originating from the PRC. For instance, in 2018 March, the U.S. administration imposed tariffs on steel and aluminium imports, followed by further tariffs on selected PRC-origin goods in June 2018. 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.

Although none of our pipeline products have yet reached the commercialisation stage, 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,

RISK FACTORS

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.

Furthermore, existing trade disputes 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. We cannot provide assurance that our existing or potential service providers, or collaboration partners, will not 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 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.

In recent years, U.S.-China relations have added uncertainty to the global economy. Since 2018, the U.S. government has imposed several tariffs on Chinese goods, and in response, China has implemented tariffs on U.S. products. These trade tensions have led to increasing economic restrictions and sanctions, creating more uncertainty in global markets. Since 2019, the U.S. has also imposed stricter rules on Chinese tech companies exporting sensitive goods. In 2021, over 40 Chinese tech firms were blacklisted by the U.S. for activities seen as threats to national security or foreign policy. The future effects of U.S.-China relations on the chronic disease treatment industry are still unclear. If these relations negatively impact the global economy, our customers’ purchasing power may decline, which would hurt our business and financial performance.

RISK FACTORS

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. For instance, on 17 March 2018, the General Office of the State Council issued the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which set out a broad definition of scientific data and rules governing its management. Under these measures, where the provision of scientific data involving “state secrets” is required in the course of international exchanges or cooperation, Chinese enterprises must specify the type, scope and intended use of such data, and obtain approval from the competent authority in line with confidentiality management procedures. In addition, where the publication of an article in a foreign academic journal requires submission of relevant scientific data generated with government funding, the author must first submit such data to their institution for unified management before publication. We cannot assure that we will consistently be able to secure the necessary approvals to transmit scientific data abroad, such as the results of our preclinical or clinical studies conducted in the PRC, or to our foreign partners in the PRC. Failure to obtain such approvals in a timely manner, or at all, may hinder the research and development of our pipeline products and could materially and adversely affect our business, financial position, operating results and prospects. Furthermore, if the authorities determine that the transmission of our scientific data breaches the requirements of the Scientific Data Measures, we may be subject to corrective actions and other administrative penalties imposed by the relevant government bodies.

Moreover, the interpretation and enforcement of laws and regulations governing the pharmaceutical sector also evolve periodically, we cannot guarantee that our operations will not be negatively affected in the future.

RISK FACTORS

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. We cannot assure you that a valid judgment rendered in accordance with the New Arrangement will be recognised and enforced by a PRC court.

RISK FACTORS

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 investment.

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, there can be no assurance that new regulations will not be introduced in the future that could impose further restrictions on the remittance of Renminbi into or out of China.

Holders of our H Shares may be subject to PRC income tax obligations.

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

Under the EIT Law and its implementation rules and Notice on the Issues concerning Withholding the Enterprise Income Tax on the Dividends Paid by Chinese Resident Enterprises to H-share Holders Which Are Overseas Non-resident Enterprises (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897) (國稅函[2008]897號), dated November 6, 2008, issued by the STA, subject to any applicable tax treaty or similar arrangement between China and your jurisdiction of residence that provides for a different income tax arrangement, PRC withholding tax at the rate of 10% is normally applicable to dividends from PRC sources payable to investors that are resident enterprises outside of the PRC, which do not have an establishment or a place of business in the PRC, or which have such establishment or place of business if the relevant income is not effectively connected with the

RISK FACTORS

establishment or place of business. Any gain realized on the transfer of shares by such investors is subject to 10% (or a lower rate) PRC income tax if such gain is regarded as income derived from sources within the PRC unless a treaty or similar arrangement otherwise provides.

Under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and its implementation rules, income and gains from sources within the PRC paid to foreign individual investors who are not residents in the PRC are generally subject to a PRC withholding tax at a rate of 20%, unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. Pursuant to the Circular on Questions Concerning the Collection of Individual Income Tax Following the Repeal of Guo Shui Fa [1993] No. 045 (《關於國稅發[1993]045號文件廢止後有關個人所得稅徵管問題的通知》) (GuoShui Han [2011] No. 348) (國稅函[2011]348號) dated June 28, 2011, issued by the STA, dividends paid to non-PRC resident individual holders of H Shares are generally subject to individual income tax of the PRC at the withholding tax rate of 10%, depending on whether there is any applicable tax treaty between the PRC and the jurisdiction in which the non-PRC resident individual holder of H Shares resides as well as the tax arrangement between the PRC and Hong Kong. Non-PRC resident individual holders who reside in jurisdictions that have not entered into tax treaties with the PRC are subject to a 20% withholding tax on dividends received from us. However, pursuant to the Circular Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui [1998] NO. 61) (財稅[1998]61號) issued by the MOF and the STA on March 30, 1998, gains of individuals derived from the transfer of listed shares of enterprises may be exempt from individual income tax. In addition, on December 31, 2009, the MOF, the STA and the CSRC jointly issued the Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》) (Cai Shui [2009] No. 167) (財稅[2009]167號) which states that individuals' income from the transfer of listed shares on certain domestic exchanges shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restrictions as defined in the Supplementary Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of the Listed Shares Subject to Sales Limitations (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) (Cai Shui [2010] No. 70) (財稅[2010]70號). As of the Latest Practicable Date, the aforesaid provision has not expressly provided that individual income tax shall be collected from non-PRC resident individuals on the sale of shares of PRC resident enterprises listed on overseas stock exchanges.

RISK FACTORS

The interpretation and enforcement of applicable tax laws and regulations in the PRC by the PRC tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders, will be determined according to the laws and regulations then in effect. Non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realised from the disposition of our H Shares.

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, 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 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 Urgent Notice on Enforcing the Requirement of the General Meeting of the State Council and Stabilizing the Levy of Social Insurance Payment (《關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) promulgated on September 21, 2018 by the Ministry of Human Resources and Social Security, human resources and social security authorities are prohibited from organizing and conducting centralized collection of enterprises’ historical social insurance underpayments. 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.

In 2023, 2024 and the six months ended June 30, 2025, the aggregate shortfalls in our contributions to social insurance were approximately RMB4.5 million, RMB3.6 million, RMB1.9 million, respectively. 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

RISK FACTORS

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 cannot guarantee that local authorities will not require us 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.

Any failure to comply with the PRC regulations regarding our employee equity incentive plans may subject us to fines and other legal or administrative sanctions.

Our Directors, executive officers and other employees who are PRC residents may participate in our future employee equity incentive schemes. Following our [REDACTED], we will become an overseas listed company. Accordingly, we, together with our Directors, executive officers and other employees who are PRC citizens, or non-PRC citizens who have resided in China continuously for at least one year and who are granted restricted share units, restricted shares or share options, will be subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知). Under this notice, employees, directors, supervisors and other members of management who participate in an equity incentive plan of an overseas-listed company, and who are PRC citizens or otherwise non-PRC citizens resident in China for a continuous period of at least one year (subject to limited exceptions), are required to register with SAFE through a qualified domestic agent and complete the requisite procedures. We will be required to comply with these regulations at the time of adopting any additional equity incentive plans for our Directors and employees under PRC law.

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 20,890.57 sq.m. Upon the expiry of these leases, we will need to negotiate renewals, which may involve higher rental costs. We cannot guarantee that we will be able to renew the leases on favourable or otherwise acceptable terms, or at all. Should we fail to renew

RISK FACTORS

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 failure 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, may subject us to a fine ranging from RMB1,000 to RMB10,000 per lease as advised by our PRC legal Advisor. Although non-registration of the lease agreement does not in itself invalidate the lease, 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, we cannot assure you that such lessor is 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.

RISKS RELATED TO THE [REDACTED]

We may be required to be subject to filings with the CSRC for the [REDACTED] and [REDACTED] of our Shares on the Stock Exchange.

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures**”) and five supporting guidelines (collectively, the “**Trial Measures and Supporting Guidelines**”). which came into effect on March 31, 2023. The Trial Measures and Supporting Guidelines will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime. Pursuant to the Trial Measures and Supporting Guidelines, where an issuer submits an application for [REDACTED] to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Trial Measures and Supporting Guidelines also require subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and

RISK FACTORS

listings. Based on the foregoing, we are required to comply with the filing procedure of the CSRC. We cannot assure you that we will be able to complete filings procedures in connection with [REDACTED] and [REDACTED] on timely basis. Any failure to complete filings procedures may have a material adverse effect on the [REDACTED] and [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 itself 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.

RISK FACTORS

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.

Future sales or perceived sales or conversions of substantial amounts of our H Shares in the public market may materially and adversely affect the prevailing market price of our H Shares and may impair our ability to raise additional capital in the future.

The market price of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us.

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 pro forma 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.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On 30 April 2018, the Stock Exchange adopted rules under Chapter 18A of Listing Rules. Under these rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals

RISK FACTORS

or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot assure you that our H Shares will remain [REDACTED] on the Stock Exchange.

Although it is currently intended that the H Shares will 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.

Because 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. The calculation of our distributable profits under the PRC GAAP differs in many aspects from the calculation under IFRS. Moreover, our operating subsidiaries in China may not have distributable profit as determined under the PRC GAAP. 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. There is no

RISK FACTORS

guarantee that our H Shares will 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.

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may use the net [REDACTED] from the [REDACTED] in ways that you may not agree with or fail to generate favorable returns for our Shareholders. We plan to use the net [REDACTED] to continue advancing our pipeline products toward commercialisation and strengthen our R&D capabilities. For details of our [REDACTED], see “Future Plans and [REDACTED].” However, our management retains broad discretion over the actual application of these proceeds. By investing in this [REDACTED], you entrust these funds to the discretion of our management, whose judgement you must rely on, for the specific uses of the net [REDACTED] from this [REDACTED].

Certain statistics contained in this Document are derived from a third-party report and publicly available official sources.

This Document, particularly the section titled “Industry Overview”, contains information and statistics relating to the new drugs with advanced formulations market, microneedle formulation market and nasal spray formulation market in China and internationally. Such information and statistics have been derived from various official governments and other publications and from a third-party report commissioned by us. We believe that the sources of such information are appropriate and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. However, we cannot guarantee the quality or reliability of such information. The information and statistics from official governments 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.

RISK FACTORS

You should read the entire document and only rely on the information included in this document to make your [REDACTED] decision, and we strongly caution you not to rely 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.