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, as well as our financial statements and the related notes, and the "Financial Information" section, before deciding to* [**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 conditions, operating results and growth prospects. In any such an event, the* [**REDACTED**] *of our Shares could decline, and you may lose all or part of your* [**REDACTED**]. *Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

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.

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

RISKS RELATING TO THE CLINICAL DEVELOPMENT AND REGULATORY APPROVAL OF OUR PRODUCT AND PRODUCT CANDIDATES

If we are unable to successfully complete clinical development, obtain regulatory approval and/or commercialize our product portfolio, including our Core Product, or if we experience delays in any of the foregoing, our business, financial conditions, results of operations and prospects will be materially and adversely affected.

We believe our future revenue and profitability will substantially depend on our ability to complete the development of our product candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our product portfolio. We have invested and expect to continue to invest a significant portion of our efforts and capital resources in the development of our existing product candidates. However, the development of product candidates can be time-consuming and costly, and the outcome may be uncertain. The success of our product candidates will depend on several factors, including (i) our successful enrollment of patients in and completion of clinical trials, as well as completion of preclinical studies; (ii) our ability to effectively and simultaneously design, manage and supervise a number and range of clinical trials in multiple jurisdictions; (iii) our ability to reach agreements on acceptable terms with prospective third-party service providers, whose performance complies with our protocols and applicable laws and regulations that protect the integrity of the resulting data; (iv) favorable safety and efficacy data from our clinical trials and other studies; (v) our receipt of regulatory approvals; (vi) establishing sufficient commercial manufacturing capabilities; (vii) successfully launching our product candidates, establishing and maintaining distribution network if and when approved; (viii) capturing sufficient market share in competition with other products and product candidates; (ix) allocating resources to pursue product candidates that prove to be more profitable or for which there is a greater likelihood of success; (x) continued acceptable safety profile following regulatory approvals; (xi) the sizes of the actual markets for our commercialized product and product candidates are as we anticipated; (xii) our product and product candidates achieving the degree of market acceptance by physicians, patients and others in the medical community; and (xiii) obtaining favorable reimbursement from third-party payers for drugs, if and when approved.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain approval for and/or to successfully commercialize our product candidates, which would materially and adversely harm our business and we may not be able to generate sufficient revenue and cash flow to continue our operations.

Some of our product candidates represent a significant improvement to the current approach to renal therapeutics while some other drug candidates represent a novel approach to renal therapeutics needs. Given their novelty and differentiated features, our product candidates may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. The successful development of certain product candidates does not guarantee the successful development of other product candidates. This may have a material and adverse effect on future profits generated from our product candidates, which in turn may materially and adversely affect our competitive position, business, financial conditions and results of operations.

Clinical development of drug products involves a lengthy, difficult and expensive process with uncertain outcomes, and results of earlier clinical studies and trials may not be predictive of future trial results.

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. We may encounter unexpected difficulties while executing our clinical development plans for our product candidates. Failure can occur at any time or stage during the clinical development process, which would result in a material and adverse effect on our business, financial conditions and results of operations.

Furthermore, the results of preclinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to verification procedures that may result in the final data being materially different from the preliminary data we previously published. In addition, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profiles despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have experienced significant setbacks in advanced clinical trials due to unsatisfactory efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in sizes and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability among clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and the commencement of commercialization of our product candidates.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, our ability to generate revenue will be materially impaired.

To obtain regulatory approvals for any product candidate, we must demonstrate in pre-clinical studies and well-controlled clinical trials, and, with respect to approval in China and the U.S., to the satisfaction of the NMPA and the FDA that the product candidate is safe and effective for use for that target indication and that manufacturing facilities, processes and controls are adequate. In addition to pre-clinical and clinical data, the NDA must include significant information regarding the chemistry, manufacturing and controls for the product candidate. Obtaining approval of the NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Relevant regulatory authorities may accept or reject the submission for filing.

We have limited experience in filing for regulatory approvals for our product candidates, and we have not yet demonstrated the ability to receive regulatory approval for our product candidates. As a result, our ability to successfully obtain regulatory approval for our product candidates may involve more inherent risk, take longer, and cost more than it would if we have more experience in obtaining regulatory approvals.

Regulatory requirements and approval processes can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Seeking foreign regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time-consuming. Other foreign regulatory approval processes may include all or more of the risks associated with obtaining the NMPA and/or FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all.

As reported publicly, the U.S. FDA underwent a workforce reduction affecting approximately 3,500 employees effective April 1, 2025. While the full impact of this development remains uncertain, it has been suggested that the FDA's ability to issue new guidance, respond to regulatory queries, or process applications in a timely manner may be affected in the short term. However, according to public statements made by the U.S. Department of Health and Human Services, the layoffs are not expected to affect personnel directly responsible for reviewing or inspecting medical products and food.

As of the Latest Practicable Date, the progress of our R&D activities in the U.S. had not been materially impacted by the workforce reduction in the FDA or other U.S. government agencies. Our principal R&D activities in the United States include: the ongoing multi-regional Phase III clinical trial of AP301; the planned multi-regional Phase IIb clinical trial of AP306; and the planned Phase II clinical trials of AP303. Given the FDA workforce reduction is a relatively new development, we cannot predict whether or to what extent the FDA workforce reduction may affect the review timeline or outcome of our IND application or other future regulatory interactions.

We rely on our current and potential business partners' willingness and ability to develop and commercialize our product and product candidates as contemplated in our collaboration agreements.

We rely on our current and potential business partners in various aspects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts.

Our current and potential business partners have certain discretion regarding whether and on what timeline to pursue the planned activities and the quantity and nature of resources devoted to the development, commercialization, marketing and distribution of our product or product candidates. There can be no assurance that our current or potential business partners may perform their obligations under our agreements to our satisfaction. Consequently, our clinical trials may be extended, delayed or terminated, we may not be able to obtain regulatory approvals for, or successfully commercialize, our product candidates. For example, CROs and clinical investigators may fail to duly perform their contractual obligations or meet expected timelines; the scale, quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons. They may fail to maintain necessary licenses or comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory authorities may require us to repeat or perform additional clinical trials before approving our marketing applications.

Switching or adding additional business partners involves additional cost and delays, which can significantly influence our ability to meet our desired clinical development and commercialization timelines. Our business partners may terminate the collaboration agreements prior to the expiry of contemplated terms or seek to change the terms of the collaboration agreements with adverse impact to us. The occurrence of any of the above events could significantly impact the development and commercialization of our product candidates and our business, financial conditions and results of operations could be materially and adversely affected.

If we cannot maintain or develop clinical collaborations and relationships with our principal investigators, key opinion leaders, physicians, experts and leading hospitals, our business, financial conditions and results of operations could be adversely affected.

Our relationships with principal investigators ("**PIs**"), key opinion leaders ("**KOLs**"), physicians, experts and leading hospitals play important roles in our research and development and future marketing activities. We have established extensive interaction channels with PIs, KOLs, physicians, experts and leading hospitals to gain first-hand knowledge of clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs.

However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with such PIs, KOLs, physicians, experts and leading hospitals, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These business partners may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our research and development process, may be inaccurate or misleading. Moreover, we cannot assure you that our academic promotion and scientific focused commercialization strategy will continue to serve as an effective marketing strategy. Business partners may no longer want to collaborate with us and our marketing strategy may no longer be able to yield results that are commensurate with our efforts spent. If we are unable to develop new product candidates or generate returns from our relationships with business partners as anticipated, or at all, our business, financial conditions and results of operations may be materially and adversely affected.

We may face competition from drug manufacturers who may commercialize competing products that are more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier.

We face competition from existing drugs and drug candidates under development in the global renal disease market. Competition in therapeutic areas such as CKD diseases, indications and complications, to which our Core Product AP301, AP303 and AP306 belong, is increasingly intense given the abundance of existing CKD treatment options, the emergence of new CKD treatment options as well as the growing attention from multinational companies on renal diseases. For details, see "Industry Overview — Overview Of Chronic Kidney Disease And Therapeutic Landscapes."

Our commercial opportunities may be adversely impacted if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than any of the drug products that we may develop or commercialize. Our competitors may obtain approval from relevant regulatory authorities for their drugs more quickly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. This may render our product candidates obsolete or less competitive before we can recover the expenses of developing and commercializing our product candidates.

Many of the companies against which we are competing or against which we may compete in the future have greater financial, technical and human resources and expertise in research and development, manufacturing, clinical trials, obtaining regulatory approvals and marketing approved drug products than we do. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with requisite protocols depends, among other things, on our ability to enroll enough participants who remain in the trials until their conclusion. We may experience difficulties in participant enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population, the patient eligibility criteria defined in the clinical trial protocol, the resources we invest to facilitate timely subject enrollment in our clinical trials and the efforts made by trial execution personnel including our CROs to screen and recruit eligible subjects, among others.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our product candidates. Such competition will likely reduce the number and types of patients available to us, because some patients may instead opt to enroll in a trial being conducted by one of our competitors. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our product candidates.

We invest substantial human and capital resources in research and development to develop our product candidates, but we cannot guarantee that such efforts will lead to successful outcomes.

To keep pace with the vibrant development of the renal disease treatment industry, we have invested substantial capital, time, human and other resources to develop our product candidates, strengthen our technical capabilities in the development and manufacture of our product candidates, identify new technological and commercialization opportunities and obtain property intellectual property protection. For example, in 2024 and 2025, our research and development expenses were RMB235.4 million and RMB372.6 million, respectively. We intend to continue to strengthen our research and development, sales and marketing and management capabilities, which require substantial capital and time investment. We cannot assure you that we will be able to enhance such capabilities in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our product candidates, and harm our business and prospects.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval for our product candidates, including but not limited to: (i) we or our investigators may not be authorized to commence a clinical trial or conduct a clinical trial at a prospective trial site; (ii) clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; (iii) our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; (iv) drug candidates supplied by third parties for use in a clinical trial may have quality issues or result in severe adverse events ("**SAEs**"), leading to product liability; and (v) we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks.

Adverse events ("**AEs**") and undesirable side effects caused by our product and product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our product candidates, a delay or denial of regulatory approval by relevant regulatory authorities, or a significant change in our clinical protocol or even our development plan. Results of trials conducted by us or by our business partners with respect to our product candidates could reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, such trials could be suspended or terminated and relevant regulatory authorities could order us or our licensing partners, as applicable, to cease further development of, or deny approval of, our product candidates for any or all targeted indications. We may in the future be subject to actual or threatened liability claims related to perceived AEs and undesirable side effects related to our product candidates. Responding to such claims may divert our management's attention and resources, and there can be no assurance that our defenses will be successful. Actual or perceived AEs and undesirable side effects related to our product candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial. Any of these occurrences may significantly harm our reputation, business, financial conditions and prospects.

We may fail to sufficiently and promptly respond to and adapt to rapid scientific and technological changes, clinical demand and market changes in the industry, and we may be unable to establish strong market presence in this industry for a variety of reasons.

The global renal disease industry is characterized by advances in science and technology and the emergence of new treatment options. Our future success partially depends on our ability to launch new products that meet evolving market demands, in particular, new drugs that are effective in treating renal diseases. We cannot assure you that we will be able to respond to emerging or evolving trends by improving our product portfolio in a timely manner, or at all. In addition, we may need to adjust our research and development plan, production scale and schedule, product portfolio, and inventory levels based on market demand, sales trends and other market conditions. There can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future, and such failure may have an adverse effect on our business, financial conditions, results of operations and profitability.

All material aspects of the research and development, manufacturing and commercialization of our product and product candidates are heavily regulated. Any failure to comply with relevant laws and regulations may materially and adversely affect our business, financial conditions, results of operations and prospects.

We adopt a global development strategy, and all jurisdictions in which we operate or intend to conduct our pharmaceutical industry activities regulate these activities in great depth and detail. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they implement extensive regulations governing the development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. Efforts to adapt to the differences in these regulatory regimes impose a complex and costly regulatory compliance burden on us.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires spending of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our product candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements; the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors; or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material and adverse impact on our business, financial conditions, results of operations, and prospects.

Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include, but are not limited to, a regulator's refusal to approve

pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of manufacturing or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially and adversely affect our business, financial conditions, results of operations and prospects.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURING

The sales of our commercialized product accounted for all of our revenue during the Track Record Period. If we are unable to maintain the sales volume, pricing levels and profit margins, our business, financial conditions and results of operations could be materially and adversely affected.

During the Track Record Period, we generated revenue from the sales of Mircera® in China. We expect that the revenue from the sales of Mircera® will continue to contribute to a significant, if not the entire portion of our revenue, for the foreseeable years, before we commercialize our Core Product, AP301. If we fail to maintain the sales volume, pricing levels and profit margins of Mircera® to achieve or further promote the widespread market acceptance of the commercialized product, or to grow or retain our customer or consumer base, our business, results of operations and financial conditions may be materially and adversely affected.

As our revenue is, and we expect will continue to be, concentrated in the Mircera® before we launch other product candidates, including our Core Product AP301, we may be susceptible to factors adversely affecting the sales volume, pricing level or profitability of Mircera®, including (i) the exclusion from, or reduced coverage under, the government-sponsored or major commercial insurance programs; (ii) unfavorable government pricing regulations; (iii) sales and popularity of substitute products by competitors; (iv) interruptions in the supply of raw materials or increases in the cost of raw materials; (v) the failure to maintain an adequate and stable supply of our commercialized product; (vi) issues with product quality or side effects; and (vii) adverse changes in our sales and distribution network.

Many of these factors are outside of our control, and any factor adversely affecting the sales volumes, pricing levels and profit margins of our commercialized product could materially and adversely affect our operations, revenue and profitability.

We may not effectively leverage our experience in effectively marketing our product and product candidates. If we are unable to properly build and manage our commercial network or benefit from strategic external partnerships with business partners, we may be unable to generate sufficient revenue, or at all.

Successful sales and marketing are crucial for us to increase the market penetration of our products and product candidates after they are commercialized, expand coverage of hospitals and other medical institutions and promote new products in the future. As of the Latest Practicable Date, we carry out sophisticated commercialization activities only for Mircera® and in China. For our product candidates, including our Core Product AP301, our commercialization strategy involves a combination of in-house capabilities and collaborations with renowned business partners. As a result, we rely on ourselves and our current and future business partners' willingness and ability to devote resources to the development and commercialization of such product candidates and to otherwise support our business as contemplated in our collaboration agreements. We may require a longer time frame or be less cost-efficient in the commercialization process best tailored to launching and marketing each of our product candidates. Although our core management team and sales team do possess deep experience in marketing CKD drug products and benefit from our experience commercializing Mircera® in China, we cannot guarantee that such experience translates perfectly into the successful commercialization of our product candidates. We may dynamically adjust our commercialization plan due to the low commercial value or high promotion difficulty of the relevant products after they are approved, which may have a material impact on our overall operations and financial conditions.

In addition, our sales and marketing efforts are scientific focused and consist of raising awareness and knowledge of our product and product candidates among medical professionals, hospitals, other medical institutions and pharmacies. Therefore, our sales and marketing force must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we or our commercialization business partners are unable to effectively train sales and marketing representatives, the sales and marketing of our pipeline products may be less successful than desired.

Furthermore, as we will pursue collaborative arrangements regarding the sales and marketing of our product candidates, 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, our business partners will have effective sales forces. We may have little or no control over the marketing and sales efforts of such third parties beyond contractual terms, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our product candidates. Therefore, we cannot assure you that we will be able to establish or maintain relationships with third-party partners to successfully and continuously commercialize any product. As a result, we may not be able to generate the anticipated product sales revenue.

Due to the similarities of therapeutic effect and applicable indication for certain product candidates, there may be an overlap of addressable market or risk of cannibalization.

In clinical practice, AP301 and AP306 can be applicable to a same group of hyperphosphatemia patients, thereby causing potential competition between the two products in a certain market. For example, both AP301 and AP306 target hyperphosphatemia caused by renal insufficiency of CKD patients. The two product candidates are positioned to target different clinical scenarios, with AP301 being a backbone therapy for the majority of the hyperphosphatemia patients based on classic phosphate binding effect and AP306 primarily targeting patients that need more efficacious drugs to contain extremely high hyperphosphatemia level or intolerance of other phosphate lowering therapeutics. The two product candidates are also expected to target different patient groups, with AP301 primarily targeting cost-sensitive patients for its high value for money and AP306 primarily targeting patients who are less price sensitive for its novel approach to therapeutic needs. Despite the differences and the fact that they can be applied simultaneously to deliver better treatment outcome, as we plan to commercialize both product candidates globally, depending on market feedback, there may be an overlap of addressable market and risk of cannibalization.

Counterfeit pharmaceutical products, illegal and/or parallel import of competing drugs may reduce demand for our product candidates and compromise our reputation, which may adversely affect our business.

Counterfeit pharmaceutical products are manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. Pharmaceutical product control and enforcement system, particularly in emerging markets, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic biopharmaceutical products but are generally sold at lower prices, they can quickly erode the demand for our existing commercialized product and future approved product candidates. In addition, thefts of inventory at warehouses, plants or while in-transit, could lead to our products being wrongfully stored and handled, and eventually sold through unauthorized channels. A patient who receives a counterfeit or unauthorized pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer as a result of counterfeit or unauthorized pharmaceutical products sold under our or our business partners' brand name(s).

The illegal importation of competing products from jurisdictions where government price controls or other market dynamics result in lower prices may adversely affect the demand for our product and product candidates and, in turn, may adversely affect our sales and profitability in jurisdictions where we commercialize our products upon approval. Any future legislation or regulations that increase consumer access to lower priced medicines from jurisdictions where we operate could have a material and adverse effect on our business.

Negative results from off-label uses of our product candidates could harm our reputation, product brand, business operations and financial conditions and expose us to liability.

Off-label drug use is the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, the FDA and other comparable regulatory authorities actively enforce laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions or AEs. Any of these occurrences can create negative publicity, expose us to liability, cause a delay in the progress of our clinical trials or ultimately result in failure to obtain regulatory approval for our product candidates, which may materially and adversely affect our business reputation, results of operations and financial conditions.

Our commercialized product and future approved product candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, which will lead to the possibility of our products not meeting sales expectations in the future.

Our ability to commercialize any approved product candidates successfully may depend in part on the extent to which reimbursement for our products when commercialized and related treatments will be available from government health administration authorities, private health insurers and other organizations. As of the Latest Practicable Date, our Mircera® have been included in the National Reimbursement Drug List ("**NRDL**"). We intend to seek the inclusion of our product candidates, following their commercial launch, in the NRDL and other insurance coverage and reimbursement programs. We did not experience any inability or impediments to enlist or obtain reimbursement coverage for our commercialized product during the Track Record Period. However, there can be no assurance that any of our future approved product candidates will be included in the NRDL or be continuously included in the NRDL. If we were to successfully launch commercial sales of our products but unable to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Patients may choose other drugs with similar or even less efficiency but lower price which have been included in the NRDL. In addition, even if our product candidates are successfully included in the NRDL, the drug procurement catalog under the central procurement scheme in China or any other reimbursement programs sponsored by government health administration authorities and third-party payers, our potential revenue from the sales of these products could still decrease as a result of the potential deeper-than-expected price reduction required for our products to be included in such reimbursement programs due to price control policies.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers, while patients primarily purchase commercial health insurance or participate in the Medicare program administered by the Center for Medicare & Medicaid Services, an agency within the United States Department of Health and Human Services. As a result, obtaining coverage and reimbursement approval of a drug from governments or other third-party payers is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our future approved product candidates on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for,

long-term follow-up evaluations required following the use of our future approved product candidates. Patients are unlikely to use any of our future approved product candidates unless coverage is provided, and reimbursement may be inadequate to cover a significant portion of the cost of the drugs.

We cannot be sure that reimbursement will be available for any approved product candidates that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any approved product candidates that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidates that we successfully develop.

The pricing of our products when commercialized may be subject to other downward pressure which may have a material and adverse effect on our business and results of operations.

We may experience downward pressure on the pricing of our product and product candidates mainly from governmental price control measures and some other sources, many of which may be beyond our control. For example, we may need to lower the price for our product and product candidates in light of the potential launch and commercialization of competing products that tackle similar indications with improved efficacy and safety profile. If we experience such downward pressure on the pricing of our product and product candidates, our revenue from the sales of our product and product candidates will decrease, which may have a material and adverse effect on our business and results of operations.

We have limited experience in manufacturing drug products on a large clinical or commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our product candidates.

We have limited experience in manufacturing pharmaceutical products on a commercial scale, which is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements. If problems arise during the manufacturing process of certain future products, such as the low quality or insufficient supply of Active Pharmaceutical Ingredients ("**APIs**"), any failure to follow specific protocols and procedures, altered manufacturing methods and formulations that cause product candidates to perform less effectively, equipment malfunction and man-made or natural disasters, or our products' failure to meet relevant industry or regulatory standards or specifications, a batch or several related batches of such product may have to be discarded. The occurrence of any such events could restrict our manufacturing capacity, the availability of our products for commercial sale, or render us unable to meet the increasing demand for our products, which may materially and adversely affect our results of operations and financial conditions. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

Delays in completing and receiving regulatory approvals for our manufacturing facilities, or potential damage to, destruction of or interruption of future manufacturing capabilities at such facilities, could delay our development plans or commercialization efforts.

As of the Latest Practicable Date, we owned our manufacturing facility in Yangzhou. For details, see "Business — Manufacturing". If the commencement, receiving of/renewing regulatory evaluation and/or approval of our facilities are delayed, we may not be able to manufacture sufficient quantities of our product candidates, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources. Any failure to comply with applicable regulations on our part or by our CDMOs could also result in sanctions being imposed, including fines, injunctions, penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our product and/or product candidates, operating restrictions and criminal prosecutions, any of which could materially and adversely affect our business.

If our or our CDMOs' manufacturing facilities, or the equipment in them are damaged or destroyed, we may not be able to quickly or economically replace the manufacturing capacity or at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party in a timely and cost-effective manner. In addition, we may be unable to obtain regulatory agency approval before selling any products manufactured at that facility. Any such disruption that impedes our ability to manufacture our product candidates in a timely manner could materially and adversely affect our business, financial conditions and operating results.

We may engage in the expansion of the manufacturing facilities which may not be as successful as planned.

As we bring our product candidates to the commercial stage, we may engage in the expansion of our manufacturing facilities to meet the increasing demand for our products. The completion of such expansion of the manufacturing facilities may involve obtaining additional regulatory approvals and reviews by various authorities, including, but not limited to, urban planning, construction, safety and environmental protection authorities. We cannot assure you that we will be able to obtain all of such required approvals, permits and licenses. Expansion of the manufacturing facilities also may not be completed on the anticipated timetable or within budget. We may also be unable to fully utilize the manufacturing capacity after the expansion of our manufacturing facilities. Any of the foregoing factors could materially and adversely affect our results of operations and prospects and result in loss of business opportunities.

Guidelines, recommendations and studies published by various organizations could disfavor our commercialized product and/or product candidates.

Government agencies, professional societies, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' product and product candidates. Currently, there are not any unfavorable guidelines, recommendations and studies published by various organizations in relation to our commercialized product. However, any such guidelines, recommendations or studies that reflect negatively on our commercialized product and product candidates, when commercialized, either directly or relative to competing drug products, could result in current or potential decreased use and/or sales of, and revenue from our product and product candidates. Furthermore, our success depends in part on the ability to educate healthcare providers and patients about our product and product candidates, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we or our partners are unable to obtain and maintain adequate intellectual property protection for our product and product candidates throughout the selected markets in the world, our ability to successfully commercialize our product and product candidates may be adversely affected.

We seek to protect our product candidates and technologies that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions as well as relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. However, filing, prosecuting, maintaining and defending patents in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. We or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all relevant jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that leads us to believe that any of the pending patent applications will be rejected. However, we cannot assure you that all of our patent applications will be granted. Patent applications may not be granted for a number of reasons, including a late application date, known or unknown prior art, deficiencies in the patent application or the lack of novelty or non-obviousness of the underlying invention or technology. China, the U.S. and Europe have adopted the "first-to-file" system, under which the first inventor to file a patent application will be awarded the patent if all other patentability requirements are met, which will typically not be published until an 18-month waiting period after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our business partners were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our business partners were the first to file for patent protection of such inventions.

In addition, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid and will be paid to applicable patent agencies in several stages over the lifetime of a patent. Such applicable patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by the payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, non-payment of fees, and the failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material and adverse effect on our business.

Our patent rights may be challenged and invalidated. We may become involved in lawsuits to protect or enforce our intellectual properties, which could be expensive, time-consuming and unsuccessful. This may lead to unfavorable publicity which may harm our reputation and result in additional distraction of our personnel. This may further cause the [REDACTED] of our H Shares to decline.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other jurisdictions. We may be subject to claims that former employees, business partners or other third parties have an interest in our patents or other intellectual property or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. If we are unsuccessful in any interference proceedings or other priority, inventorship or validity disputes (including any patent oppositions) to which our intellectual properties are subject, we may lose valuable intellectual property rights through the loss of one or more patents, loss of exclusive ownership or our patent claims may be narrowed, invalidated, or held unenforceable. We may also be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our product candidates. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material and adverse effect on our business, financial conditions, results of operations or prospects. 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.

If our patent terms expire before or soon after our product candidates are approved, our business may be materially harmed.

The life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Patent extensions may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years, and after the new drug is approved for marketing, the total effective term of the patent shall not exceed 14 years. In the U.S., products candidates designated as orphan drugs or which are approved for designated orphan indication may be granted seven years of market exclusivity.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the relevant governmental authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may fail to obtain the extension due to our failure to satisfy applicable requirements, such as failing to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, or apply prior to the expiration of relevant patents. Once the patent life has expired, we may be open to competition from competitive medications. In addition, a lower-cost generic drug can emerge into the market much more quickly, leading to early generic competition that may have a material and adverse effect on our financial conditions and business prospects.

We may become subject to intellectual property infringement or misappropriation claims, which could expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.

We may receive in the future, notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused other parties' intellectual property rights. Whether third-party intellectual property claims are with or without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction may hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates or technologies covered by the asserted third-party patents. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and thus it could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could result in a substantial diversion of management resources and burden us with substantial unanticipated costs. Moreover, some of our competitors are larger than we are and are able to mobilize substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material and adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research projects, in-license needed technologies, or enter into strategic partnerships that would help us bring our product candidates to market.

Changes in patent law in the jurisdictions that we operate could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The laws and regulations governing patents could be revised from time to time that would affect our ability to obtain or enforce new or existing patents. Such revisions may impact the value of our patent or other intellectual property rights. For instance, the U.S. has enacted wide-ranging patent reform legislation and its court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. The changes in patent law may thus create uncertainty with respect to the value of patents once obtained, if any.

We may not have the right to control the preparation, filing, prosecution, maintenance, extension, enforcement and defense of patents and patent applications covering the product and product candidates that we license from third parties, which could have a material and adverse effect on us. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the product candidates that we have in-licensed or may in-license from third parties in the future. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. In addition, our future licensing partners may not be the sole and exclusive owners of the intellectual property rights we in-license in some cases. They may breach or otherwise violate any such agreements, their rights thereunder may be terminated and our licensing partners may no longer be able to sublicense such rights to us. If we continue to enter into in-licensing agreements in the future, and such future licensing partners fail to prosecute, maintain, enforce or defend the patents we license in, or lose rights to those patents or patent applications, the rights we will have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such potential licensed rights could be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patents, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates. We seek to protect our trade secrets and confidential information, in part, by controlling the scope of knowledge and entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets or confidential information. However, we may not be able to properly monitor and prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. We are not aware of any threatened or pending claims concerning the agreements with our employees or senior management, but in the future litigation may be necessary to enforce such agreements. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our product candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming. The outcome is unpredictable and we may be unable to obtain adequate remedies for such violation. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, it would be hard for us to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

As of the Latest Practicable Date, we held six registered trademarks in Chinese Mainland, and three registered trademarks in Hong Kong. We are also the owner of one domain name. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in any conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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

Our intellectual property rights may not be sufficient to prevent third parties from developing or commercializing competing products or technologies, and our patent applications may not result in issued patents or provide meaningful competitive protection. If we fail to maintain or enforce effective intellectual property protection, our competitive position, business, financial condition, results of operations and prospects could be materially and adversely affected.

RISKS RELATING TO OUR FINANCIAL POSITION

We have incurred significant net operating losses since our inception, and expect to continue to incur losses and may never achieve or maintain profitability.

Investment in the development of innovative biopharmaceutical products can be highly speculative as it entails substantial upfront expenditures and significant risks that a product candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, while we generated revenue from the sales of Mircera®, we continue to incur significant research and development in relation to, among others, our preclinical studies and clinical trials and other expenses related to our product candidates. As a result, we are not profitable and have incurred operating losses since our inception. In 2024 and 2025, our total losses were RMB335.1 million and RMB751.8 million, respectively. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing innovative product candidates into later stages of clinical development, obtaining regulatory approvals for each product candidate, and successfully commercialize them in jurisdictions where we operate. which we may not be able to do in a timely manner or at all.

We incurred net operating cash outflows, net current liabilities and net liabilities during the Track Record Period and may need to obtain substantial additional financing to fund our operations and expansion, which may not be available on commercially reasonable terms, or at all. If we are unable to secure such financing, we may be forced to delay, reduce or unable to complete the development and commercialization of our product candidates.

Since our inception, our operations have consumed substantial amounts of cash. We had net cash used in operating activities of RMB249.9 million and RMB287.9 million in 2024 and 2025, respectively. As of December 31, 2024 and 2025, we had net liabilities of RMB1,341.2 million and net assets of RMB503.2 million, respectively. As of December 31, 2024 and 2025, we recorded net current liabilities of RMB1,555.2 million and net current assets of RMB318.9 million, respectively. As we conduct the [**REDACTED**], we may require substantial additional capital to meet our continued operating needs, especially to fund our research and development activities, commercialize our product candidates, expand our manufacturing capabilities and repay our project loans. Therefore, we may seek additional funding through public or private offerings, debt financing, collaboration and licensing arrangements and other sources. However, certain factors beyond our control may affect our ability to raise capital. Failure to secure additional funding on favorable or commercially reasonable terms to us, or at all, may materially and adversely impact our business prospects, financial conditions and results of operations.

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

Future growth will impose significant additional responsibilities on our management. Managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global pharmaceutical market, effective coordination and integration of our teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased sales and marketing activities, enhanced quality control, and proper management of our suppliers and business partners. If we are not able to effectively manage our growth or execute our growth strategies, our business, financial conditions, results of operations and prospects could be adversely affected.

Share-based payments may have a material and adverse effect on our financial performance and cause shareholding dilution to our Shareholders.

We have granted share-based payments to, among others, attract and retain outstanding individuals. We believe the granting of share-based payment is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based payment to employees in the future. In 2024 and 2025, we incurred equity-settled share-based payment compensation of RMB21.9 million and RMB260.8 million, respectively. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the payments under our currently effective share incentive plans and any subsequently adopted employee stock ownership plan from time to time. If we choose to do so, we may experience substantial change in our share-based payment charges. In addition, such past and future payments may dilute the shareholding percentage of our existing Shareholders and could result in a decline in the value of our H Shares.

Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.

Valuation of our selected property interests as of March 31, 2026 prepared by AVISTA Valuation Advisory Limited, an independent property valuer, are set forth in the valuation report set out as Appendix III to this Document. The valuation is made based on assumptions which are subjective and uncertain and may differ from actual results. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the valuation of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value.

The expiration or discontinuation of any of government grants or preferential tax treatment currently available to us could adversely affect our financial conditions, results of operations, cash flows and prospects.

We have received and currently benefit from government grants and preferential tax treatments that reduce our overall tax obligations. These benefits include reduced tax rates, tax refunds, or other favorable tax policies provided by governmental authorities in certain jurisdictions where we operate. However, these preferential tax treatments are typically subject to review and renewal by the relevant tax authorities and are dependent on our compliance with applicable rules and regulations or satisfaction of certain conditions. There is no assurance that we will continue to properly comply with relevant rules and regulations or satisfy all relevant conditions to qualify for such preferential tax treatment or that these benefits will be renewed upon expiration. In addition, changes to existing laws, regulations, or interpretations of tax policies could result in the reduction or elimination of these benefits. The occurrence of any of the foregoing events could significantly increase our tax obligations and adversely affect our business, financial conditions, and results of operations.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Fluctuations in exchange rates between the Renminbi and the U.S. dollar and other currencies may be affected by, among other things, trade tensions between the U.S. and China, as well as international economic and political developments. Due to the economic situation and financial market developments in the PRC and abroad, the PRC government has decided to proceed further with reform of the Renminbi exchange rate regime and to enhance the Renminbi exchange rate flexibility. Changes in exchange rates have in the past, and could in the future continue to, materially and adversely affect our financial conditions and results of operations.

RISKS RELATING TO OUR OPERATIONS

We have limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a biopharmaceutical company with limited operating history. Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our product candidates, organizing and staffing our operations, business planning and raising capital. To date, we have one product approved for commercialization, from the sales of which we generated all our revenue.

Our limited operating history, particularly in light of the rapidly evolving pharmaceutical industry in which we operate, the inherent uncertainties in the research and development of the pharmaceuticals, and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting sophisticated commercial activities. If we do not address these risks and difficulties successfully or act properly in anticipation of certain uncertainties, our business may suffer and you may lose all of your [**REDACTED**] in us.

Any failure to obtain, amend or renew various filings, approvals, licenses, permits and certificates could materially and adversely affect our reputation, business, results of operations and prospects.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties. If the interpretation or implementation of laws and regulations is adjusted in the future or new regulations come into effect, or the criteria used in reviewing applications for, or renewals of permits, licenses and certificates change to adapt to new developments, we may be required to obtain additional approvals, permits, licenses or certificates. We cannot assure you that we will be able to do so, which may restrict the conduct of our business, increase our costs, and in turn, adversely affect our results of operations and prospects.

Our future success depends in part on our ability to retain our Directors, senior management, key scientific employees and other qualified personnel. If we are unable to retain our key employees or to attract and retain skilled and experienced personnel, our business operations and prospects could be materially impaired.

We depend on the continued contributions of our Directors, senior management and other key employees, many of whom may be difficult or costly to replace. The industry experience, management expertise, professional knowledge and contributions of the key members of our senior management and R&D team such as Dr. Tian (co-founder, executive Director, chief medical officer) and Dr. Shu Chutian (chief technology officer) are crucial to the success of our operations and clinical development. See "Business — Research and Development" and "Directors and Senior Management" for details. Replacing executive officers, scientific employees, and other qualified personnel may take an extended period of time because of the limited number of individuals in our industry with the breadth of skillset and experience required to successfully develop, gain regulatory approval of and commercialize product candidates like those we develop. The loss of the services of any of our executive officers or other key employees could impede the achievement of our research and development and commercialization objectives.

We believe that there has been, and will continue to be, intense competition for highly skilled management, technical, sales and other personnel with experience in our industry. Our need to significantly increase the number of our qualified employees and retain key employees may cause us to materially increase compensation-related costs, including share-based compensation. We must provide competitive compensation packages and a high-quality work environment to hire, retain and motivate employees. If we fail to achieve any of the above, we may be unable to manage our business effectively, including the development, manufacturing, marketing and sale of our product candidates, which could adversely affect our business, operating results and financial conditions, and the [**REDACTED**] of our H Shares could suffer.

We had only one distributor during the Track Record Period, the loss of which could disrupt our operations.

During the Track Record Period, we generated revenue from sales to only one customer which acts as our logistics partner and distributor. We expect to continue such sales pattern in the near future, before the launch of our product candidates. Our reliance on this customer subjects us to the concentration and counterparty risk from this customer. We believe that we have established long and stable relationship with such customer and there are ample logistics partners and distributors to choose from in the market. However, we cannot assure you that we will be able to maintain relationship with our customer in the future. If it scales back or terminates its business relationship with us, or if we are unable to continue to negotiate favorable contractual terms with them, our short-term sales will be affected before finding alternative logistic provider/distributor in the market. We also cannot guarantee that we may be able to secure collaboration with a new distributor or logistic partner in a timely manner, on favorable or comparable terms, or at all. If this occurs, our business, financial conditions, results of operations and prospects could be materially and adversely affected.

Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize distribution network that ensures timely delivery of our products across China and in jurisdictions where we intend to operate. However, we may not be able to establish business relationships with new distributors to support the continued growth of our business. In the event that our distributor terminates its relationship with us and we are unable to find a capable and cost-effective alternative, our business, results of operations and financial conditions could be materially and adversely affected. Even if we successfully expand our distribution network, we cannot assure you that our distributors and sub-distributors (if any) will at all times comply with our sales policies. If they fail to distribute our products to their customers in a timely manner, overstock, or carry out actions which are inconsistent with our business strategy, it may affect our future sales. Any such deviation from our sales policies and development strategies may materially and adversely affect our business, financial conditions, results of operations and prospects.

We will mitigate the occurrence of channel stuffing, cannibalization and competition within our distribution network through various measures as we expand our distribution network. However, we cannot assure you that the measures would be effective in preventing channel stuffing, cannibalization and competition within our distribution network. The failure in avoiding such occurrences may adversely affect our financial conditions and results of operation.

Negative publicity or the failure to maintain and enhance our recognition and reputation may materially and adversely affect our business and growth prospects.

Our brand is important to attracting and retaining partners and our success depends on our ability to maintain and enhance our brand image and reputation. Maintaining, promoting and growing our brands depend largely on the success of our ability to provide consistent, high-quality services, our marketing efforts and our ability to successfully secure, maintain, and defend our rights to use our brands and trade names. Our brand could be harmed if we fail to achieve these objectives.

Our brand value also depends on our ability to maintain a positive perception of our corporate integrity, purpose and brand culture. Any negative publicity concerning us, our management, employees, affiliates and partners, even if untrue, could adversely affect our reputation and business prospects. There can be no assurance that negative publicity about us or any of our management, employees or affiliates and partners would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition.

We, our Directors and management may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business, which would be costly and time-consuming to defend.

We, our Directors and management may from time to time become party to litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and intellectual property rights. For example, we may be sued if our product candidates cause or are perceived to cause injury, significant AEs, or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties.

Involvement in litigation, legal disputes, claims or administrative proceedings may distract our Directors' or management's attention, time and other resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate due to the various factors involved, such as the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us. If we cannot react quickly and successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our product and product candidates.

If our principal investigators, distributor, CROs or other business partners fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences that could have a material and adverse effect on our business.

We and our business partners are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. Manufacturing facilities can only continue to operate after the relevant administrative authorities in charge of environmental protection and health and safety have approved, reexamined and renewed licenses and permits for our relevant facilities. As requirements imposed by laws and regulations may change and become more stringent, we or our business partners may not be able to adapt to, comply with, or accurately predict any potential substantial cost of complying with these laws and regulations. Failure to comply with such regulations may subject us to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial conditions, results of operations and prospects.

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

We maintain insurance policies that are required under applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. We also maintain product liability insurance covering our clinical trials. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any uninsured risks may result in substantial costs and the diversion of resources, which could adversely affect our business, financial condition, and results of operations.

We are subject to risks associated with our leased properties.

As of the Latest Practicable Date, our interests in two leased properties may be defective, as the ownership certificates or other similar proof of certain leased properties have not been provided to us by the relevant lessors. Therefore, we cannot assure you that such lessors are entitled to lease the relevant real properties to us or that the ownership nature of these properties is suitable for leasing purposes. If the lessors are not entitled to lease the real properties to us and the owners of such real properties decline to ratify the lease agreements between us and the respective lessors, or if any third party or governmental authorities challenges our right to use such properties, we may not be able to enforce our rights to lease such properties under the respective lease agreements against the owners and be forced to vacate the relevant properties and seek alternative properties.

As of the Latest Practicable Date, we were not aware of any claim or challenge brought by any governmental authorities or third parties concerning the use of our leased properties. Although we, as the lessee, will not be penalized or claimed for indemnity for the defectives of the nature or ownership of leased properties, we could be required to vacate the properties, in the event of which we could only initiate the claim against the lessors under relevant lease agreements for indemnities for their breach of the relevant leasing agreements. We cannot assure you that we will receive sufficient indemnity to cover all of our losses, or readily find suitable alternative locations available on commercially reasonable terms, or at all, and if we are unable to relocate our operations in a timely manner, our operations may be interrupted.

Pursuant to applicable PRC laws and regulations, all lease agreements are required to be registered with the local land and real estate administration bureau. As of the Latest Practicable Date, six lease agreements were not registered and filed with the relevant land and real estate administration bureaus in the PRC. While non-registration does not void the leases, failure to cure within the prescribed deadline after official notice may result in a penalty of RMB1,000-RMB10,000 per lease. The occurrence of the foregoing could have an adverse effect on our results of operations and financial conditions. In the event that any fine is imposed on us for our failure to register our lease agreements, we may not be able to recover such losses from the lessors. As of the Latest Practicable Date, we were not aware of any notice or allegation of penalty from PRC government authorities for our failure on the registration of lease agreements.

Our information technology systems, or those used by our business partners, may fail or suffer security breaches, data losses or other unauthorized or improper access, which could significantly disrupt our ordinary business activities, compromise sensitive information related to our business or subject us to costly and protracted litigation, which may cause significant reputational harm and impact our ability to operate our business effectively.

We make use of information technology systems to obtain, process, analyze and manage data. Despite the implementation of security measures, our information technology systems and those of our CROs, CMOs, CDMOs, consultants and other service providers may be vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

There can be no assurance that we will be able to effectively handle any failure of our information systems, or that we will be able to restore our operational capacity in a timely and effective manner to avoid disrupting our business. The occurrence of any of these events could adversely affect our ability to effectively manage our business operations. In addition, if the capacity of our information systems fails to meet the increasing needs of our expanding operations, our ability to expand may be constrained.

We may be subject to natural disasters, health epidemics, acts of war, terrorism, civil and social disruptions and other force majeure events, which may have a material and adverse effect on our business.

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions in which we conduct our business. Our operations may be under the threat of natural disasters, such as floods, earthquakes, storms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, SARS, Ebola, Zika and COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and other unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

Increased labor costs could slow our growth and adversely affect our operations.

Our operations depend in part on the skills and know-how of our employees. In recent years, the average labor cost in the global pharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for the same pool of qualified employees has become more intense. We face intense competition in recruiting and retaining qualified personnel and our remuneration packages may not be as competitive as those of our competitors. We cannot assure you that there will be no further increase in labor cost, which may adversely affect our operations and financial conditions.

RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

We are subject to changes in government regulations or in practices relating to the biopharmaceutical industry, which may increase compliance costs, risk of non-compliance, and adversely affect our business.

The biopharmaceutical industry in China, the U.S. and other markets in which we intend to enter is heavily regulated. Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product and any product candidates for which we obtain regulatory approval. For example, in China, there have been and will likely continue to be efforts to enact administrative or legislative changes, including measures which may result in more rigorous coverage criteria and downward pricing pressure.

We may be exposed to risks of conducting our business and operations in international markets, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns between China and other countries or regions may adversely affect our business, financial conditions, results of operations, cash flows and prospects. China's political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. Changes to trade policies, treaties and tariffs, or the perception that these changes could occur, could adversely affect the financial and economic conditions in the jurisdictions in which we operate. There can be no assurance that our existing or potential service providers or other business partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and

adversely affect our business, financial conditions, results of operations, cash flows and prospects. Rising trade and political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

In February 2024, the U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against certain Chinese biopharmaceutical companies over alleged ties to the Chinese military. The BIOSECURE Act, first introduced in the U.S. Senate in late 2023 and the U.S. House of Representatives in early 2024 and amended on October 9, 2025, would prohibit the U.S. government from procuring biotechnology equipment or services from designated biotechnology companies of concern ("**BCOC**"), and would prohibit government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated BCOC. The latest amendment defines BCOC as including those that are an extension of the Chinese military as well as firms that answer to a "foreign adversary" or otherwise pose a national security risk to the U.S. We are of the view that the BIOSECURE Act, if enacted in its current form, would not have a material and adverse impact on our business, primarily because, to our best knowledge, we are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future. Furthermore, to our best knowledge, none of our licensing partners in existence are using any services provided by us under the respective licensing arrangements in connection with any federal contracts, loans, grants or funding. However, future amendment to the BIOSECURE Act may revise and expand the name list of BCOC and we cannot guarantee that our business partners or their collaborators will not be named by the regulation. If any such things happen, our results of operations, financial conditions and business prospects may be materially and adversely affected.

In addition, over the years, the U.S. government has imposed rounds of tariffs on imports from China and other countries. Recently, in September 2025, the U.S. President Trump announced that the U.S. would impose a 100% tariff on imports of branded or patented pharmaceutical products from October 1, 2025, unless a pharmaceutical company is building a manufacturing plant in the U.S. On October 1, 2025, the Trump administration announced the 100% tariff had not gone into effect and that the administration had begun preparing tariffs on manufacturers that do not build in the U.S. or enter into a most-favored-nation drug pricing agreement with the Trump administration, casting uncertainty over the future of the proposed 100% pharmaceutical tariffs. Meanwhile, China has implemented measures in response to the heightened tariffs against Chinese products initiated by the U.S. government. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry.

During the Track Record Period, we have initiated clinical trials in the U.S. Although most of the items imported by our suppliers and CDMOs are available in general markets, if the U.S. were to further increase the tariff on any of the abovementioned items imported from China or other countries, we might not be able to find substitutes with the same quality and price in China or from other countries. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China's political relationships with those foreign countries and regions may affect the prospects of conducting clinical trials in such countries and regions.

There can be no assurance that our clinical trials will be able to carry out smoothly as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial conditions, results of operations, cash flows and prospects. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual property transfer, our business, financial conditions and results of operations could be negatively impacted.

We may be subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with future capital raising activities, including this [REDACTED], and, if required, we cannot predict whether we will be able to obtain such approval or complete such filing.

Pursuant to 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》) and certain supporting guidelines (together, "**Trial Measures**"), domestic companies that seek to [**REDACTED**] should fulfill the filing procedure and report relevant information to the CSRC. The filing is required to be conducted within three business days after the submission of the [**REDACTED**] for [**REDACTED**] and [**REDACTED**] overseas to the overseas regulators. The CSRC will review the filing [**REDACTED**] and may have queries and may consult with other relevant regulators. Further follow-up [**REDACTED**] after overseas [**REDACTED**] also require a filing or a report submitted to the CSRC in accordance with the Trial Measures, and the [**REDACTED**] companies will need to report to the CSRC upon the occurrence and public disclosure of certain significant matters. If a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as orders to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

Our PRC Legal Adviser is of the view that this [**REDACTED**] shall be deemed as a direct overseas [**REDACTED**] by PRC domestic enterprise, and we are required to submit filings with the CSRC within three business days after we submit filings to Hong Kong Stock Exchange for this [**REDACTED**]. We cannot assure you that we could meet such requirements or complete such filing in accordance with the Trial Measures in a timely manner. Any failure may restrict our ability to complete the [**REDACTED**] or any future equity capital-raising activities.

Existing or future laws and regulations related to privacy, data protection and information security are subject to rapid and evolving changes, imposing significant compliance requirements on us. Compliance with such laws may require significant resources and increase the costs of our products, which may negatively affect our operating results and business.

We are subject to privacy, data protection and information security laws and regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure to comply with any of these laws and regulations could result in enforcement actions, fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to reputation and loss of goodwill, any of which could have a material and adverse effect on our business, financial conditions, results of operations or prospects. However, our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies and procedures.

Pursuant to Article 2 of the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**MCR**"), if a critical information infrastructure operator purchases network products and services or a network platform operator conducts any data processing activity that affects or may affect national security, a cybersecurity review shall be carried out according to the MCR. In accordance with Article 7 of the MCR, a network platform operator possessing personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when [**REDACTED**] abroad.

As of the Latest Practicable Date, (i) we had not been notified of the results of any determination that we have been identified as a critical information infrastructure operator by the relevant governmental authorities; (ii) we did not hold the personal information of more than 1 million users; (iii) we had not received any notification of cybersecurity review from the relevant governmental authorities, nor had we been involved in any investigations on cybersecurity review initiated by CAC or received any inquiry, notice, warning, or sanctions in such respect; and (iv) the [**REDACTED**] is a [**REDACTED**] in Hong Kong, rather than a [**REDACTED**] abroad. Therefore,

as advised by our PRC Legal Adviser, taking into consideration the above and provided that there is no material change to our current business and no further rules are introduced and no significant changes to the MCR is made by the relevant governmental authorities, our Directors believe we are not required to voluntarily apply for a cybersecurity review under the MCR as of the Latest Practicable Date.

However, the MCR was released recently, and relevant government authorities may issue additional regulations. If we are deemed having conducted any data processing activity that "affects or may affect national security" by the relevant regulatory authorities, we may be subject to cybersecurity review under the MCR. We may fail to pass such cybersecurity review, in which case our [**REDACTED**] may be impeded, our business operations may be adversely affected, and/or we may be subject to other penalties and/or actions by the competent governmental authorities.

The Data Security Law of the PRC (《中華人民共和國數據安全法》), stipulates data security obligations on entities and individuals carrying out data processing activities, introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, and the degree of harm it will cause to national security, public interests or legitimate rights and interests of individuals or organizations when such data are tampered with, destroyed, leaked, or illegally acquired or used, and provides for a national security review procedure for those data processing activities which may affect national security as well as regulates the export of certain data and information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), clarifies the scope of application, the definition of personal information and sensitive personal information, the legal basis of personal information processing and the basic requirements of notice.

According to the State Council promulgated the Regulation on Network Data Security Management (《網絡數據安全管理條例》), if the activities of cyber data processors affect or may affect national security, a national security review is required. If it is necessary to provide important data collected or generated domestically to entities abroad, it shall be subject to the security assessment of outbound data transfer organized by the Cyberspace Administration of PRC.

The Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), which required that the data processors providing data overseas and falling under any of the circumstances provided in Article 4 of the Measures for the Security Assessment of Cross-border Data Transfer shall apply for the security assessment of cross-border data transfer. In addition, the Measures for the Administration of Standard Contractual Clauses for the Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》), attach the prescribed template for the standard contract on the cross-border transfer of personal information that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law. According to the Provisions on Facilitating and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》), where a data processor transfers any data overseas and falls under any of the following circumstances, it shall apply to the CAC for security assessment: (i) where a critical information infrastructure operator provides personal information or important data overseas; or (ii) where a data processor other than critical information infrastructure operator transfers overseas the personal information of more than one million individuals (excluding sensitive personal information) or the sensitive personal information of more than 10,000 individuals on a cumulative basis starting from January 1 of the said year. As of the Latest Practicable Date, as our business operations had not fallen under any of the above-mentioned circumstances, our Directors believe that the security assessment of cross-border data transfer under the Measures for the Security Assessment of Cross-border Data Transfer shall not be applicable to us currently.

Up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions in accordance with applicable PRC laws and regulations with respect to data privacy and protection. As confirmed by our PRC Legal Advisor, up to the Latest Practicable Date, we had complied with laws and regulations related to cybersecurity, personal information, data protection and cross-border data transfer in all material aspects.

Laws in all 50 U.S. states require businesses to provide notice under certain circumstances generally to governmental authorities and affected individuals in connection with certain breaches of personal information, and, in the future, we may be required to notify applicable governmental authorities and affected individuals in the event of a data breach or other data security incident. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. Other states also have enacted laws and regulations relating to privacy, information security and comprehensive privacy laws. The laws are not consistent, as certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international, or other state laws, and such laws may differ from each other, which may complicate compliance efforts. These laws may apply directly to our business or indirectly by contract when we enter into collaboration arrangements with other companies. If we become subject to these new or additional privacy laws, the risk of enforcement actions against us could increase.

We may be restricted from using human genetic resources collected in China.

According to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) and the PRC Biosecurity Law (《中華人民共和國生物安全法》), if any scientific data falls within the scope of Chinese human genetic resources, any transfer of such data outside of China will be subject to the prior approval of the PRC National Health Commission. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all.

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

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approval. As we currently have one commercialized product in China and expect to pursue additional marketing approvals in China and the U.S., our operations have been subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and the PRC Criminal Law (《中華人民共和國刑法》), and after receiving marketing approvals from the FDA, our operations will be subject to federal and state fraud and abuse laws in the U.S., including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Federal Physician Payment Act, among others.

Furthermore, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (FCPA) of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material and adverse effect on our business, financial conditions, results of operations and prospects.

If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments, or bringing original actions based on foreign laws against us and our management in the PRC.

A significant portion of our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our Directors and senior management. Pursuant to Arrangements for Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Cases between Courts of the Chinese Mainland and Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) effective on January 29, 2024, promulgated by the Supreme People's Court, a party with an enforceable final court judgment rendered by the competent People's Court of the PRC or the High Court of Hong Kong with respect to any civil and commercial cases excluding certain types of which, may apply for recognition and enforcement of the judgment in the relevant Intermediate People's Court of the PRC or the High court of Hong Kong. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

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

Procedures on the remittance of Renminbi into and out of the PRC are required under the relevant PRC laws and regulations. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may affect our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under the relevant PRC laws and regulations, foreign exchange transactions under the current account conducted by us do not require advance approval from China's State Administration of Foreign Exchange ("**SAFE**"), but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

Holders of H Shares may be subject to PRC income taxes.

Non-PRC resident individuals are required to pay PRC individual income tax at a 20% rate for the income derived in China under the PRC Individual Income Tax Law (the "**IIT Law**") and its implementation guidelines. Accordingly, we are required to withhold such tax from dividend payments, unless applicable tax treaties between China and the jurisdiction in which the foreign individual resides reduce or provide an exemption for the relevant tax obligations. However, pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《財政部、國家稅務總局關於個人所得稅若干政策問題的通知》) (Cai Shui Zi [1994] No. 020), the income gained by individual foreigners from dividends and bonuses of enterprises with foreign investment are exempted from individual income tax for the time being. As of the Latest Practicable Date, no aforesaid provisions had expressly provided that individual income tax shall be levied on non-PRC resident individual holders on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges, and to our knowledge, no such individual income tax was levied by PRC tax authorities in practice. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individual holders on gains from the sale of H shares.

For non-PRC resident enterprises that do not have establishments or premises in China, and for those that have establishments or premises in China but whose income is not related to such establishments or premises, under the PRC Enterprise Income Tax Law and its implementation regulations, dividends paid by us and gains realized by such foreign enterprises upon the sale or other disposition of H Shares are subject to PRC enterprise income tax at a 10% rate. In accordance with the Circular on Issues Relating to Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-PRC Resident Enterprise Shareholders of H Shares (《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), the withholding tax rate for dividends payable to non-PRC resident enterprise holders of H Shares will be 10% and we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including [**REDACTED**]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and the payment of such refund will be subject to the PRC tax authorities' approval.

Despite the arrangements mentioned above, the interpretation and application of applicable PRC tax laws and regulations by the competent tax authorities shall be in accordance with the then effective laws and regulations, and new taxes may be imposed which may materially and adversely affect the value of your [**REDACTED**] in our H Shares.

Payment of dividends is subject to restrictions under PRC law and regulations.

Under PRC law and the constitutional documents of our Company and our PRC operating subsidiaries, dividends may be paid only out of distributable profits, which refer to after-tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. As a result, our Company and our PRC operating subsidiaries may not be able to pay a dividend in a given year if our Company or our PRC operating subsidiaries do not have distributable profits as determined under PRC GAAP even if they have profits as determined under IFRS. During the Track Record Period, no dividend had been paid or declared by us. As of the Latest Practicable Date, we did not have a formal dividend policy. We currently intend to retain all available funds and earnings and not to declare or pay any dividends in the foreseeable future. See "Financial Information — Dividend" for further details.

There can be no assurance that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, after taking into account our results of operations, financial conditions, cash requirements and availability and other factors as they may deem relevant, and subject to the approval at Shareholders' meeting. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable.

We are subject to risks in relation to our social insurance and housing provident fund contributions.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees.

During the Track Record Period and as of the Latest Practicable Date, we have made proper payment of social insurance premium and housing provident funds for the substantially all of our employees. We engaged a third-party human resource agent to pay social insurance premium and housing provident funds for certain employees on behalf of us in locations where we do not have substantial presence in accordance with customary industry practice. We might also be subject to additional contribution, late payment fee and/or penalties imposed by relevant authorities if the third-party human resource agency failed to pay the social insurance or housing provident funds for

the relevant employees in full amount and/or in a timely manner, or if the validity of such arrangements are challenged by relevant authorities. We might also be subject to potential labor disputes arising from such arrangements with the relevant employees. In addition, certain of our foreign employee voluntarily waived our contributions to social insurance and housing provident funds on behalf of such employee and signed a waiver form. Such form may be deemed invalid by the court if such employee files a lawsuit against us in the court alleging our failure to pay social insurance premiums. For details relating to the legal basis for such lawsuit, see "Regulatory Overview — Regulations on Labor Protection — Social Insurance and Housing Provident Funds."

As of the Latest Practicable Date, we had, and the third-party human resource agent confirmed they had made full and timely contributions for substantially all employees. As of the Latest Practicable Date, there had been no disputes between us/the third-party human resource agent and employees with regard to such arrangement, and we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement. As of the Latest Practicable Date, there had been no dispute between us and any employee for the voluntary waiver of the contribution of social insurance and housing provident funds. As advised by our PRC Legal Adviser, the risks that we are required by the relevant authorities to make additional payment of social insurance and housing provident funds and be subject to administrative penalties during the Track Record Period are remote.

RISKS RELATING TO THE [REDACTED]

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

Prior to the [**REDACTED**], there was no [**REDACTED**] for our H Shares. We cannot assure you that a [**REDACTED**] for our H Shares with adequate liquidity will develop and be sustained following the completion of the [**REDACTED**]. The initial [**REDACTED**] for our H Shares to the [**REDACTED**] will be the result of negotiations between us and the Overall Coordinators (for themselves and on behalf of the [**REDACTED**]), and the [**REDACTED**] may differ significantly from the [**REDACTED**] of the H Shares following the [**REDACTED**].

We have applied to the Hong Kong Stock Exchange for the [**REDACTED**] of, and permission to [**REDACTED**] in, the H Shares (including any H Shares which may be [**REDACTED**] pursuant to the exercise of the [**REDACTED**]). A [**REDACTED**] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid [**REDACTED**] market for the H Shares will develop, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the H Shares will not decline following the [**REDACTED**]. If an active [**REDACTED**] for our H Shares does not develop following the completion of the [**REDACTED**], the [**REDACTED**] and liquidity of our H Shares could be materially and adversely affected.

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

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

Our Single Largest Shareholders Group has substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately upon the completion of the [**REDACTED**], without taking into account any H Shares which may be issued pursuant to the exercise of the [**REDACTED**], our Single Largest Shareholders Group will collectively control approximately [**REDACTED**]% of the voting power at our general meetings. Our Single Largest Shareholders Group will thus have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional Shares or other equity securities, timing and amount of dividend payments, and our management. This concentration of ownership may discourage, delay or prevent a change in the control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of shares of our Company and might reduce the [**REDACTED**] of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Single Largest Shareholders Group may differ from the interests of our other Shareholders. We cannot assure you that our Single Largest Shareholders Group will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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

The [**REDACTED**] of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the [**REDACTED**], or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or anticipated sales, of substantial amounts of our securities, including any future [**REDACTED**], could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. In addition, our Shareholders may experience dilution in their holdings if we issue more securities in the future. New shares or shares-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the H Shares.

In addition, while [**REDACTED**] subscribing shares in the [**REDACTED**] are not subject to any restrictions on the disposal of the H Shares they subscribed (except otherwise disclosed in this Document), they may have existing arrangements or agreement to dispose part or all of the H Shares they hold immediately or within certain period upon completion of the [**REDACTED**] for legal and regulatory, business and market, or other reasons. Such disposal may occur within a short period or any time or period after the [**REDACTED**].

Any sale of the H Shares subscribed by such [**REDACTED**] pursuant to such arrangement or agreement could adversely affect the [**REDACTED**] of our H Shares and any sizeable sale could have a material and adverse effect on the [**REDACTED**] of our H Shares and could cause substantial volatility in the [**REDACTED**] volume of our H Shares.

Raising additional capital or entering into certain other arrangements may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

The [**REDACTED**] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [**REDACTED**]. Therefore, purchasers of the H Shares in the [**REDACTED**] will experience an immediate dilution. In order to expand our business, we may consider [**REDACTED**] and issuing additional Shares in the future. Purchasers of the H Shares may experience dilution 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. Furthermore, we may issue Shares through share incentive scheme and employee shareholding scheme, which would further dilute Shareholders' interests in our Company.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on [REDACTED] appreciation of our H Shares for a return on your [REDACTED].

We intend to retain most, if not all, of our available funds and any future earnings after the [**REDACTED**] to fund the development and commercialization of our product candidates. 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.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board declares and pays dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiary, our financial conditions, contractual restrictions and other factors deemed relevant by our Board. For details, see "Financial Information — Dividend." Accordingly, the return on your [**REDACTED**] in our H Shares will likely depend entirely upon any future [**REDACTED**] appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [**REDACTED**] or even maintain the [**REDACTED**] at which you purchased the Shares. You may not realize a return on your [**REDACTED**] in our H Shares and you may even lose your entire [**REDACTED**] in our H Shares.

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 spend the net [**REDACTED**] from the [**REDACTED**] in ways with which you may not agree or which do not yield a favorable return to our Shareholders. We plan to use the net [**REDACTED**] from the [**REDACTED**] to fund the pre-clinical studies, clinical trials, manufacturing and commercialization of our product candidates. For details, see "Future Plans and Use of [**REDACTED**] — Use of [**REDACTED**]." However, our management will have discretion as to the actual application of our net [**REDACTED**]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [**REDACTED**] from this [**REDACTED**].

Certain facts, forecasts and statistics in this Document relating to the industry we compete in are derived from third-party reports or publicly available sources.

Certain statistics, information and data contained in this Document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications or other third-party reports. In particular, we have extracted and disclosed in this Document certain statistics, information and data from publications and other publicly available sources relating to the products and product candidates of third parties, scientific research, theories and mechanisms. We have taken reasonable care in the reproduction or extraction of the official government publications for the purpose of disclosure in this Document. However, we cannot guarantee the quality or reliability of official government publications. They have not been prepared or independently verified by us, any of our Directors, the Joint Sponsors, the Overall Coordinators, [**REDACTED**] or any of their respective affiliates or advisers and, therefore, we make no representation as to the accuracy of such statistics, information and data from the official government publications, which may not be consistent with other information compiled within or outside the PRC. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between the official government publications and market practice, such statistics, information and data in this Document may be inaccurate or may not be comparable to statistics, information and data produced with respect to other economies. Further, there is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. In all cases, [**REDACTED**] should give consideration as to how much weight or importance they should attach to or place on such facts.

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

Prior to the publication of this Document, there has been coverage in the media regarding us and the [**REDACTED**], which contained among other things, certain financial information, projections, valuations and other forward-looking information about us and the [**REDACTED**]. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any responsibility for the accuracy or completeness of any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this Document. Accordingly, prospective [**REDACTED**] are cautioned to make their [**REDACTED**] decisions on the basis of the information contained in this Document only and should not rely on any other information.