An [**REDACTED**] *in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an* [**REDACTED**] *in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could materially and adversely affect our business, financial condition, and results of operations. The* [**REDACTED**] *of our Shares could significantly decrease due to any of these risks, and you may lose all or part of your* [**REDACTED**]. *In particular, we are a biotech company seeking to* [**REDACTED**] *on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with* [**REDACTED**] *in companies such as ours, which may cause you to lose all or part of your* [**REDACTED**]. *These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information is given 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 "Forward-looking Statements" in this document.*

RISKS RELATING TO THE DEVELOPMENT AND REGULATORY APPROVAL OF OUR DRUG CANDIDATES

We depend substantially on the success of our drug candidates, all of which are in discovery stage, preclinical or clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be significantly harmed.

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates, all of which are still in discovery stage, preclinical or clinical development, and other new drug candidates that we may identify and develop. As of the Latest Practicable Date, our pipeline included two Core Products, one Key Product, and five other preclinical and early-stage rAAV gene therapy candidates. With respect to our Core Products, FT-002 and FT-003, we are conducting Phase II clinical trials of FT-002 and FT-003 in China and have received clearance from the FDA for Phase II clinical trials of the above in the United States. As for our Key Product, FT-001, we have completed Phase I/II clinical trials in China and our Phase III clinical trial plan has been approved by the CDE of the NMPA. Each of our drug candidates will require additional preclinical and/or clinical development, and regulatory approvals potentially in multiple jurisdictions. Substantial investments are required before we generate any revenue from product sales.

We cannot guarantee that we are able to complete clinical development, obtain regulatory approvals, and commercialize our drug candidates in a timely manner, or at all. The success of our drug candidates will depend on several factors, including the successful completion of preclinical studies and/or clinical trials, receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or product registrations, future manufacturing, commercialization of our existing drug candidates, hiring sufficient technical experts to oversee all development and regulatory activities and meeting of the prerequisite safety requirements.

If we do not achieve one or more of these in a timely manner or at all, we could experience significant delays in our ability to obtain approval for our drug candidates, which would materially harm our business. As a result, we may not be able to generate sufficient revenue or cash flow to continue our operations, and our financial condition, results of operations and prospects will be materially and adversely harmed.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We may encounter unexpected difficulties while executing our drug development plans and our current and future drug candidates are susceptible to the risks of failure inherent at any stage of drug development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials.

While we believe our drug candidates have the potential to be innovative and differentiated globally, we cannot guarantee that we will be able to realize such potential for any of our drug candidates, especially because they are still in clinical or preclinical development. Failure can occur at any time during the drug development process, which would result in a material and adverse effect on our business, financial condition and results of operations. For instance:

- regulators, ethics committees, or other designated review bodies may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including negative results or a finding that participants are being exposed to unacceptable health and safety risks;

- we may not be able to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation;

- we may encounter various manufacturing issues, including problems with quality control or ensuring sufficient quantities of our drug candidates for use in a clinical trial;

- participant enrolment may be insufficient or slower than we anticipate, or participants may drop out at a higher rate than anticipated;

- participant disputes or the failure to secure participants or other intellectual property protection for our drug candidates may affect the drug development process; and

- our drug candidates may cause undesirable side effects, which could result in a suspension or termination of an ongoing trial.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial clinical trials, and despite the level of scientific rigor in the design of such studies and trials and the adequacy of their execution. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including differences in the size and demographics of the enrolled participants, conditions of the individual participants and their adherence to the treatment regimen and other compounding factors, such as other medications or pre-existing medical conditions. Differences in the number of clinical trial sites and regions involved may also lead to variability between clinical trials.

Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results at an earlier stage. We cannot guarantee that the results from our future research and development efforts will be favorable based on currently available clinical and preclinical data, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.

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

The biopharmaceutical and gene therapy market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made significant efforts to develop our core technology platforms, including our proprietary EXACTE™ R&D platform and AAVANCE™ manufacturing platform, which allow us to continuously develop a strong pipeline of drug candidates. Our research and development expenses were US$27.6 million and US$20.6 million for the years ended December 31, 2023 and 2024, respectively, and US$17.3 million and US$11.0 million for the nine months ended September 30, 2024 and 2025, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products 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 technology platforms and drug candidates, and harm our business and prospects.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed and result in increased costs and longer development periods or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trials until their conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible participants to participate in these trials, or if there are delays in the enrollment of eligible participants as a result of the competitive clinical enrollment environment.

We may experience difficulties in participant enrollment in our clinical trials for a variety of reasons, including:

- total size and nature of the relevant patient population;
- severity of the disease under investigation;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible participants; and
- proximity and availability of clinical trial sites for prospective participants.

In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and participants who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates, which may further delay our clinical trial enrollments.

Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in participant enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

We may rely on third parties to monitor, support and/or conduct clinical trials of our drug candidates.

We may rely on third-party organizations that we do not control, including CROs, hospitals and clinics, to monitor, support, conduct preclinical studies and/or clinical trials of our drug candidates. As a result, we have less control over the quality, timing and cost of these studies and the ability to recruit trial participants than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll participants on a timely basis or otherwise conduct our trials in the manner we anticipate.

In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our future drug candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with

regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality and/or accuracy of their activities and/or the data they obtain, then clinical trials of our future drug candidates may be extended, delayed or terminated, or our data may be rejected by the NMPA, the FDA or other regulatory agencies.

If we cannot maintain or develop clinical collaborations and relationships with principal investigators, physicians and other industry experts, our results of operations and prospects could be adversely affected.

Our relationships with principal investigators, physicians and other industry experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with principal investigators, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products.

Preliminary and interim data from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with participant enrollment where more participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile prices of our Shares after this [**REDACTED**].

Moreover, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidate or product and us in general.

Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial profile or result in significant negative post-approval consequences.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval. Results of our trials could reveal a high and unacceptable level of severity or prevalence of side effects. In such event, our trials could be suspended or terminated and the regulatory authority may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. We cannot guarantee that undesirable side effects will not occur in clinical trials of our drug candidates. For details of the side effects of our product pipeline as observed during clinical trials, please see "Business — Our Drug Candidates." Side effects could affect participant recruitment or the ability of enrolled participants to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, operations, financial condition and prospects significantly.

Additionally, if one or more of our drug candidates receive regulatory approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including the following:

- we may suspend the marketing of the product;
- regulatory authorities may withdraw approvals or revoke licenses of the product;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop risk evaluation and mitigation strategies for the product or, if these strategies are already in place, to incorporate additional requirements under these strategies;
- we may be required to comply with additional post-market requirements;
- we could be sued and held liable for harm caused to patients or participants; and
- our reputation may suffer.

Any of these occurrences may prevent us from achieving or maintaining market acceptance of our particular drug candidate, and significantly harm our business, results of operations and prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry are

fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on CROs and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities.

The data and information we derive from future investigator-initiated trials may not be accepted by regulatory agencies.

We maintain close collaboration with principal investigators. We have derived and plan to continue to derive results from investigator-initiated trials of our drug candidates to expedite our clinical development activities. There is no assurance that the clinical data from these trials will be accepted or considered by the NMPA, the FDA, or other regulatory agencies. If our IIT clinical data is not accepted by these regulatory agencies, we will need to conduct additional data stripping and correction in our development activities, which may cause delays to our clinical development timeline, research and development cost overruns, loss of market window opportunities, and may even adversely affect the approval outcome of our product marketing applications, thereby adversely harming our business, financial condition and results of operations.

Regulatory approval processes are time-consuming and may be delayed due to evolving standards and limited familiarity with our rAAV gene therapies. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

Our business is substantially dependent on our ability to complete development, obtain regulatory approval, and successfully commercialize our drug candidates in a timely manner. We cannot commercialize our drug candidates without obtaining regulatory approval to market each product from the NMPA, the FDA, and other regulatory agencies. The time required to obtain approval from these regulatory agencies is unpredictable but typically takes years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In particular, our area of focus, rAAV gene therapies, is a relatively novel therapeutic approach with which regulatory agencies may have limited familiarity. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. One of our Core Products, FT-002, has received Orphan Drug Designation and Fast Track Designation from the FDA, which are expected to streamline the regulatory approval process for FT-002. However, if the FDA revokes either of these designations, we may incur increased time and costs in securing regulatory approvals. Moreover, changes in regulatory requirements and guidance during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could increase our costs, delay the timeline for or reduce the likelihood of regulatory approval for our drug candidates. It is possible that none of our existing drug candidates or any drug candidates we may discover and seek to develop in the future will ever obtain regulatory approval, and any such failure could adversely affect our business, financial condition, results of operations and prospects.

In particular, our drug candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;

- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

The NMPA, the FDA, or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may increase our costs, be time-consuming or even prevent us from initiating or completing the clinical trial. In addition, changes in government regulations or in practices relating to the pharmaceutical industry, such as heightened standards imposed due to regulatory requirements, may increase the difficulty for us to reach such standards, and have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate product sales revenue from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate related revenue for that candidate. Any of such occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Even if we obtain marketing approvals for our drug candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Any of our future approved drug candidates will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China and other countries.

As a general rule, manufacturers and manufacturers' facilities are required to comply with extensive rules promulgated by the NMPA in China and comparable regulatory authority requirements in other relevant jurisdictions ensuring that quality control and manufacturing procedures conform to cGMP regulations. As a consequence, our operation of our

manufacturing facility in Suzhou will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any new drug application, other marketing application, and previous responses to any inspection observations. Accordingly, we must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We may not be able to identify and discover novel and suitable drug candidates.

We may fail to identify and discover novel and suitable drug candidates for a number of reasons. For example, with respect to identifying and discovering new drug candidates for in-house development, our research methodology may not be successful in identifying potential drug candidates; those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval; or we may face competing products with similar profiles that advance more rapidly during the R&D process, depriving our identified and discovered drug candidates of their novelty.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources regardless of whether we are ultimately successful. Our research and development efforts may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including: (i) potential drug candidates may, after further study, be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective products; or (ii) it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our product portfolio.

Accordingly, we cannot assure you that we will ever be able to identify additional therapeutic opportunities for our drug candidates or develop suitable potential drug candidates through internal research programs, any of which could materially and adversely affect our future growth and prospects.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

As we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, collaboration or royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement, which could materially adversely affect our future growth and prospects.

RISKS RELATING TO THE COMMERCIALIZATION OF OUR DRUG CANDIDATES

Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Gene therapy is a novel treatment and in relatively early commercialization stage. Even if one of our drug candidates receive approvals from the NMPA, the FDA, or other regulatory agencies, the commercial success of any of our drug candidates might be lower than expected and will depend significantly on the broad procurement, adoption and use of the resulting product by physicians and patients for approved indications. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our drug candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the time required for manufacture and the timing of market introduction of our product candidate as well as competitive products;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors and other third-party payors for any of our drug candidates that may be approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies for a particular indication;
- proper training and administration of our drug candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our drug candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our drug candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the prevalence and severity of side effects;

In particular, given the high research and development costs, complex manufacturing processes, and specialized technical requirements associated with gene therapies, gene therapy products typically have relatively high prices compared with other treatment options. If the cost of treatment with our drug candidates is too high relative to the willingness to pay on the part of insurance companies, other third-party payers, physicians and patients, market acceptance of our products may be significantly limited.

Some of our drug candidates have also adopted injection methods with a relatively high operational threshold, which may limit the number of qualified hospitals or institutions during commercialization. Insufficient qualifications and restricted cooperation scope may prevent our drug candidates from rapidly reaching a broad patient base, and further adversely impact their commercialization and market acceptance.

We cannot assure you that our drug candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our drug candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The gene therapy industry in which we operate is intensely competitive and subject to rapid and significant technological changes. While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we continue to face competition with respect to our current drug candidates, and any drug candidates that we may seek to develop or commercialize in the future.

Our competitors include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of our competitors have substantially greater financial, technical, and other resources than we do, such as those with larger research and development staff and established marketing and manufacturing infrastructure. Collaborations, mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may be able to advance their drug candidates and obtain regulatory approval from the regulatory authorities more rapidly than we do, and become more effective in selling and marketing their products. Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Smaller or early-stage companies may also be significant competitors, particularly through collaborative arrangements with large, established companies.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or

achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. To compete with an approved product, we must demonstrate compelling advantages in efficacy, safety or other aspects in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

The actual markets for our drug candidates may be smaller than our estimates.

The size of the potential market for our drug candidates is difficult to estimate. Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

We do not have experience in launching and marketing drug candidates. If we are unable to maintain sufficient distribution, marketing, and sales capabilities, we may not be able to generate product sales revenue.

We have yet to demonstrate our capabilities in launching and commercializing any of our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, additional commercialization efforts, and cost more than it would if we were a company with experience launching and marketing drug candidates.

We have not demonstrated our capability to price products at appropriate levels to balance cost recovery and market acceptance. In particular, some of our products, if approved, would compete with other treatment options that are less costly than gene therapy treatments. If the pricing of our products is perceived to be too high, or if our products are perceived as not offering sufficient value relative to alternative treatment options, our products may receive limited market acceptance. On the other hand, we may not be able to generate sufficient revenue and recover our prior investments if our products are not priced at a sufficient level.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates

ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates. In addition, we cannot assure you that we will be able to maintain marketing and sales capabilities sufficient to support our future approved products. As a result, we may not be able to generate product sales revenue.

We may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at a premature stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

There are other risks associated with strategic collaboration with third party partners. Disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources. Our collaborations may be terminated and, if terminated, may have adverse effect on the development or commercialization of our drug candidates.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or potential license of products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis or acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable

terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, there may be material adverse impact on our business prospects, financial condition and results of operations.

Delays or failures in obtaining, maintaining and renewing regulatory approvals for our manufacturing facility may affect our ability to develop, manufacture and commercialize our drug candidates as we expect.

As of the Latest Practicable Date, we had an in-house commercialization-ready manufacturing facility in Suzhou, Jiangsu province, China, which was designed to be fully GMP-compliant and meet the regulatory requirements of the FDA, EMA and NMPA. However, we cannot assure you that we will be able to obtain, maintain and renew all the regulatory approvals for our manufacturing facility in a timely manner, or at all. Any such delay or failure would adversely affect our abilities to develop, manufacture and commercialize our drug candidates.

The manufacture of biologics is a complex process which requires significant expertise and capital investment, and if we encounter problems in manufacturing our future products, our business could suffer.

The manufacturing of biologics is an exacting and complex process, and our business, financial condition and results of operations could be materially and adversely affected if we encounter problems in manufacturing our products. Since our facility in Suzhou, Jiangsu province, China has a relatively short operational history and has not yet engaged in large-scale production of any commercialized drug products, future problems may arise for a variety of reasons, including equipment malfunction, failure to follow Chinese or U.S. protocols and procedures, problems with raw materials, delays related to the reconfiguration and/or expansion of the facility, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, physical limitations that could inhibit continuous supply, natural disaster, and environment factors.

If any problems arise during our production of a certain batch of product, that batch of product may have to be discarded, for which we may experience product shortage or incur increased expenses. Such incident could, among other things, lead to increase of our costs, decline in revenue, damage to customer relations, and increase in time and expenses spent on investigating the causes for the incident. If any of those problems was not discovered prior to the product's release to the market, we might also incur costs related to product recall or product liability disputes and our business prospects may be seriously harmed.

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

The quality of our products, including drug candidates we used for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the specific expertise of managerial persons, production processes and the quality and reliability of equipment used. We operate a comprehensive quality control system, which is established and refined in accordance with the rigorous regulations and guidelines. See "Business — Manufacturing —

Quality Management." However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol, such as failure to sufficiently investigate and address critical deviations, could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

We may not be successful in achieving commercial-scale manufacturing that provides for an attractive margin.

We cannot assure you that we can successfully scale up our manufacturing volume to support commercialization or at all. Local production of drug products will be subject to standards and requirements by various regulatory authorities, including the FDA, the NMPA or other comparable regulatory agencies to ensure compliance with cGMP. We may underestimate the cost and time required to scale up our manufacturing volume, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may not be able to successfully manage the cost of our drug candidates to levels that will allow for a margin in line with our expectations and return on investment, if and when those drug candidates are commercialized.

Even if we are able to commercialize any approved drug candidates, the products may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, according to a statement, the Opinions of the State Council on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》), issued by the PRC State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of a new drug in the PRC market shall not be higher than the comparable market prices of the product in its country of origin or PRC's neighboring markets, as applicable.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other

organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

Specifically, under the medical insurance programs in the PRC, patients are entitled to full or partial reimbursement of costs for pharmaceutical products listed in the National Reimbursement Drug List or relevant provincial medical insurance catalogs, or included in provincial insurance schemes regarding special medications for the treatment of major diseases, or other medical insurance reimbursement lists. The inclusion or exclusion of a pharmaceutical product in or from any of such medical insurance catalogs, or any limitation imposed on the coverage of a pharmaceutical product, will significantly affect the demand for such product in the PRC. The selection of pharmaceutical products for listing in medical insurance catalogs is based on a variety of factors, including clinical needs, frequency of use, effectiveness, safety and price, many of which are outside our control. Moreover, the relevant government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that are already listed in any medical insurance catalog. There can be no assurance that any of our drug products which will commercialize in the future will list in these medical insurance catalogs, will remain listed, or continuant changes in the scope of reimbursement will not negatively affect our drug products.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, the FDA, or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of products from countries where they may be sold at lower prices compared to the others. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates and any new products that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China, the United States and other countries and regions where we commercialize our products in the future. Illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. In addition, governmental authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products. Cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower priced medicines could have a material adverse effect on our business.

Furthermore, certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits could quickly erode the demand for our drug candidates approved in the future. In addition, thefts of our 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 harm as a result of counterfeit or unauthorized pharmaceutical products sold under our or our collaborators' brand name(s).

Negative results from off-label use of our future marketed drug products could harm our reputation, product brand, business operations and financial condition 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. While regulatory authorities including the NMPA, the FDA, and other comparable agencies strictly enforce regulations against the promotion of off-label use, physicians may legally prescribe drugs for unapproved uses under certain circumstances. Though a recognized aspect of medical practice, the prescription of our drug products outside their approved indications, patient populations, or dosing parameters could lead to potential risks arising from insufficient safety/efficacy data, regulatory compliance challenges, reimbursement issues, and the need for enhanced monitoring and documentation. Off-label use could also render our products less effective or entirely ineffective and may cause unexpected adverse drug reactions

or adverse effects. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, business operations and financial conditions. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are a clinical-stage biotech company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical stage biotech company with a 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 drug candidates, organizing and staffing our operations, business planning and raising capital. We have not yet demonstrated an ability to successfully obtain marketing approvals for, or commercialize, our drug candidates. To date, we have no products approved for commercial sale and have not generated any revenue from product sales.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate 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 commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Investment in the development of biopharmaceutical products is highly uncertain as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. We have not generated any revenue from commercial product sales to date, and we continue to incur significant research and development costs and other expenses related to our ongoing operations. As a result, we have incurred net losses of US$35.9 million and US$26.5 million for the years ended December 31, 2023 and 2024, respectively, and US$20.7 million and US$13.3 million for the nine months ended September 30, 2024 and 2025, respectively.

Our net losses during the Track Record Period were primarily attributable to expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials. Our research and development expenses were US$27.6 million and US$20.6 million for the years ended December 31, 2023 and 2024, respectively, and US$17.3 million and US$11.0 million for the nine months ended September 30, 2024 and 2025, respectively. See "Financial Information — Description of Major Components of Our

Results of Operations" for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing these drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur net losses in the foreseeable future, and that these net losses may increase as we carry out certain activities relating to our development, including, but not limited to, the following:

- continue our ongoing and planned research and development activities;
- seek to discover, identify or develop additional drug candidates and further expand our product pipeline;
- continue to scale up our business to meet the requirements for our R&D activities, clinical trials and potential commercialization;
- hire additional drug discovery, clinical, quality control and administrative personnel;
- develop, maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;
- establish sales, marketing and distribution infrastructure to commercialize any drug candidate for which we may obtain regulatory approval; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a [**REDACTED**] following the completion of this [**REDACTED**].

The size of our future net losses will depend, among other factors, on the rate of the future growth of our expenses, our ability to generate revenue and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our business, financial condition and results of operation.

We had net cash outflow from operating activities during the Track Record Period and may need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development of our major drug candidates.

During the Track Record Period, our operations consumed a substantial amount of cash. We recorded net cash used in operating activities of US$26.8 million, US$23.1 million and US$10.4 million in 2023, 2024 and the nine months ended September 30, 2025, respectively. In addition, we might expect to incur significant development expenses relating to our current drug candidates and future pipeline. Transitioning to becoming a [**REDACTED**] is also expected to incur substantial costs and expenses.

We expect that we will continue to experience net cash outflows from our operating activities for the foreseeable future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations, or out-licensing or sale arrangements for our drug candidates or other sources. Although we believe that we have sufficient working capital to fund our operations, if in any case we fail to maintain adequate liquidity on commercially reasonable terms, we could be forced to delay, reduce or terminate our research and development projects or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations.

We may need to obtain substantial additional financing to fund our operations, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we funded our operations primarily through equity financing. We expect our expenses to experience modest increases in connection with our ongoing activities, as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our preclinical stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, if we obtain regulatory approvals for any of our drug candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a [**REDACTED**]. Accordingly, we may need to secure substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources.

In the near future, we expect to fund our operations primarily with existing cash and cash equivalents, and [**REDACTED**] from the [**REDACTED**]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

We cannot assure that we will continue to receive government grants.

We have historically received various government grants primarily relating to the innovative nature of our business and as compensation for our capital expenditure. We recognized government grants as other income of US$0.8 million and US$0.5 million for the the years ended December 31, 2023 and 2024, respectively, and US$80 thousand and US$0.4 million for the nine months ended September 30, 2024 and 2025, respectively. There is no assurance that we could maintain or continue to receive the government grants described above at the historical levels, or at all. Any change, suspension, withdrawal or termination of these government grants to us may have an effect on our business, financial condition and results of operations.

We have granted, and may continue to grant, certain awards under our share incentive plan, which may result in increased share-based compensation expenses.

We have adopted a share incentive plan for the purpose of granting share-based compensation awards to employees, officers, or directors to incentivize their performance and align their interests with ours. We incurred share-based compensation expenses relating to share options granted under our share incentive plan of US$36 thousand and US$0.2 million for the years ended December 31, 2023 and 2024, respectively, and US$0.1 million and US$0.4 million for the nine months ended September 30, 2024 and 2025, respectively. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the arrangements under our currently effective employee stock option plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this [**REDACTED**].

Fluctuations in exchange rates could result in foreign currency exchange losses.

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. For the years ended December 31, 2023 and 2024, we recorded exchange differences arising on translation of foreign operations, an item under other comprehensive income, of US$1.3 million and US$0.9 million, respectively. For the nine months ended September 30, 2024 and 2025, we recorded exchange differences arising on translation of foreign operations, an item under other comprehensive expense, of US$0.4 million and US$1.2 million, respectively. There is no assurance that we will continue to incur foreign exchange related income in the future. The value of the Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that the Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

The [**REDACTED**] from the [**REDACTED**] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [**REDACTED**] from the [**REDACTED**]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the SAFE before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates, all of which are still in discovery stage, preclinical or clinical development. Each of our drug candidates will require additional preclinical and/or clinical development, and regulatory approvals potentially in multiple jurisdictions. Substantial investments are required before we generate any revenue from product sales. If we are unable to access funding from investors due to a financial crisis, a disruption of the credit markets, extreme volatility in security prices, or other financial, economic, social or political conditions that discourage long-term investments, we will be unable to bear the costs necessary to complete the development and approval of some or all of our drug candidates. If we have to downscale or discontinue our operations, our financial condition, results of operations and prospects will be materially and adversely harmed, and you may lose part or all of your [**REDACTED**].

RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our drug candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain robust patent coverage, as well as other forms of intellectual property and proprietary information protections, for the key technologies, inventions, and know-how fundamental to our pipeline and technology platforms. Equally important is our capacity to defend and enforce these patents, preserve the confidentiality of our trade secrets, and ensure our freedom to operate without infringing upon, misappropriating, or otherwise violating the valid and enforceable intellectual property rights held by third parties.

We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China, the U.S. and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that patents that may be issued or granted in the future will not later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates, or otherwise fail to provide us with any competitive advantage. Patent applications we apply for may not be granted in the end, and we cannot predict whether the patent applications we are currently pursuing and may pursue in the future will be issued as patents in any particular jurisdiction. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future are issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, otherwise provide us with any competitive advantage or even last until the successful commercialization of our drug candidates. In addition, the patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been a common subject of litigation in recent years. As such, we do not know the degree of future protection that we will have on our drugs and technology, if any. If we are unable to obtain or maintain patent protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met and no objection are raised by other parties. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we may be granted in the future may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. 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 countries. We may be subject to a third-party pre-issuance submission of prior art to the patent office in a jurisdiction, or become involved in opposition, derivation, revocation, re-examination, post-grant review, *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates, and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights.

Moreover, we may have to participate in interference proceedings declared by the patent office of a jurisdiction to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

We could be unsuccessful in maintaining adequate patent protection for one or more of our drug candidates.

Although various extensions may be available, the life of a patent and the protection it affords is limited. Even if we successfully obtain patent protection for a product candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Even if our patent applications are granted in the

future, such patents are expected to expire on various dates as described in "Business — Intellectual Property" of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior facts, deficiencies in the patent application, or the lack of novelty of the underlying invention or technology. In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration (the "**CNIPA**"), for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The scope of patent protection in various jurisdictions is uncertain, and the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The laws and regulations governing patents could be revised from time to time in ways that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Changes in either the patent laws or their interpretation in China, the United States or other countries may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights. For instance, the United States has enacted wide-ranging patent reform legislations. United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

We may enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner in all desirable territories. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to

jurisdictions where we have patent protection. Consequently, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions into our target markets or other jurisdictions. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

As we intend to sell our successfully commercialized drugs in various jurisdictions around the world, we are dependent on the laws of a wide range of jurisdictions to protect, maintain and enforce our intellectual property rights throughout the world. We may not obtain adequate intellectual property protection in all jurisdictions where we ultimately intend to sell our products, and as a result of commercial pressures or otherwise, we may significantly expand our business into such jurisdictions without the benefit of clear, enforceable intellectual property protections. The laws of these jurisdictions may also be insufficient to protect our intellectual property rights to the same extent or in the same manner as the laws of the jurisdictions in which we currently have sought intellectual property protections or of the jurisdictions where investors may be located. Many companies have encountered significant problems in protecting, obtaining and defending intellectual property rights in certain jurisdictions. In particular, the legal systems of certain developing countries do not favor or consistently enforce patents, trade secrets, trademarks and other forms of intellectual property protection, which could make it difficult and time-consuming to stop the infringement, misappropriation or other violation of our intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and sell or import products made using our inventions in and into our markets of interest. These products may compete with our products, and our existing patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years from the date of application 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. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates could expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable 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. For example, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which 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. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Similarly, depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it, may be extended. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable drug candidates, if approved, could be reduced, possibly materially.

Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. On the other hand, if we launch our drug candidates prior to the expiration of patents for any competing products, we may face potential claims for patent infringement.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the United States Patent and Trademark Office (the "**USPTO**") and other applicable patent authorities over the lifetime of a patent. The CNIPA, the USPTO and other applicable patent authorities require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the 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, but not limited to failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our drug candidates or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved. In addition, according to the PRC Patent Law and related regulations, we must file the patent license agreements with the CNIPA within three months after the effective date thereof, otherwise we may lose our exclusive right to use our in-licensed patents if the licensor grants a bona fide third party a right to use the patent. Before such filings become effective, we may not be able to protect ourselves against challenges brought by bona fide third parties to whom the licensors may, for any reason, grant a right to use the same patents we have in-licensed.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. Our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the United States Patent and Trademark Office or comparable non-U.S. authority.

Litigation relating to patents and other intellectual property rights in the biopharmaceutical and pharmaceutical industries is common, including patent administrative proceedings, patent ownership and patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Third parties could resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future. Some claimants may be able to sustain the costs of complex intellectual property proceedings to a greater degree and for longer periods of time than we could. Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. Though we have not been a party to any actual or threatened material legal proceedings, we may be involved in legal proceedings where third parties may challenge our intellectual property rights. In such instances, we may need to take action to enforce or defend our intellectual property rights.

Failure to successfully defend against such claims may result in adverse court rulings affecting our ownership of certain patent rights. Such outcomes could result in limitations to our control over the affected patents, including allowing others to utilize our patent rights, which could potentially affect our competitive position and prospects and adversely affect our business operations and financial condition. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is subject to uncertainty.

In addition, competitors or other third parties may challenge, infringe or misappropriate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover and protect our drug candidates. In any infringement proceeding, a court or governmental authority may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages. In addition, if the breadth or strength of protection provided by our patents and other intellectual property rights is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our drug candidates. Any loss of intellectual property protection could have a material adverse impact on one or more of our drug candidates and our business.

Also, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Numerous U.S., China, and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties could allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing.

It is possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. It is also possible that we could infringe upon certain patents that we are aware of but do not believe we infringe upon, or that we are aware of and believe we have valid defenses to any claim of patent infringement related thereto. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our planned products. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use. Generative artificial intelligence resources that are publicly available also present a risk that a company may inadvertently obtain, incorporate or use a third party's intellectual property.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause

us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

We may be subject to claims that former employees, collaborators, contractors or other third parties have an interest in our patents or other intellectual property, for example as an inventor or co-inventor. Inventorship disputes may arise from conflicting obligations of consultants or others who are involved in developing drugs and drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our drug candidates and our technology we may develop.

An adverse result in any litigation proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or investors perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our Shares. There is no assurance that our drug candidates will not be subject to the same risks.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our current and any future drug candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in China, the United States and other countries may diminish the value of our intellectual property and may increase the

uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws in China, the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in the PRC. For example, on October 17, 2020, the Standing Committee of the National People's Congress of the PRC (the "**SCNPC**") promulgated the Amendment to the PRC Patent Law effective from June 1, 2021, which provides that, among others, the patentee of an invention patent relating to a new drug that has been granted the marketing authorization in the PRC is entitled to request the patent administration department under the State Council to grant a patent term extension of up to five years, in order to compensate the time required for the regulatory evaluation and approval for the commercialization of such a new drug; provided that, the total remaining patent term of such a new drug approved for commercialization shall not exceed 14 years after such approval. As a result, the terms of our PRC patents may be eligible for extension and allow us to extend patent protection of our products, and the terms of the patents owned by third parties may also be extended, which may in turn affect our ability to commercialize our products candidates, if and when approved, without facing infringement risks. The length of any such patent term extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new competitor products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Evolving judicial interpretation of patent law could also adversely affect our business. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued numerous precedential opinions in recent years narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce or defend patents that we have licensed or that we might own or license in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our current and future owned and licensed patents.

We may not be successful in obtaining necessary rights to our drugs or drug candidates we may develop through acquisitions and in-licenses.

The field of gene therapy, including rAAV gene therapy, is competitive, and intellectual property around the technology of gene therapy is complex. Third party companies or academic institutions may have filed or be planning to file patent applications, and may obtain patents, that are potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our drug candidates we may develop.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and other companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. Such companies may have a competitive advantage over us due to size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to third party intellectual property rights we require or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We also may be subject to claims that our employees, consultants, or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. If we rely on third parties to manufacture or commercialize our current or any future drug candidates, or if we collaborate with third parties for the development of our current or any future drug candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure, confidentiality and similar agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, CROs, consultants, advisers and other third parties. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Moreover, 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.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, financial condition, and results of operations. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not wrongfully use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property.

Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We own a number of trademarks and may register more trademarks in China and other jurisdictions. Our trademarks or trade names may be challenged, infringed, circumvented or

declared generic or determined to be infringing on other marks, and may not be registered in all the necessary or desirable jurisdictions and categories in which we intend to sell our future products or provide our future services. Our trademarks may not be approved by one or more governmental trademark offices or may not be approved for use on our products or services by regulatory authorities. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. In the future, we may license our trademarks and trade names to third parties, such as business partners and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel. If we lose any of them and are unable to find proper replacements in a timely fashion, our business prospects could be adversely affected.

Our future success depends heavily upon our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. In particular, the industry experience, management expertise, professional knowledge and contributions of key members of our senior and middle management are crucial to our success. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us with relatively short notice. We have had senior management departures in the past. If we lose the services of any of these individuals or one or more of our other members of senior management, we may not be able to locate suitable or qualified replacements, and may incur additional expenses to recruit and train new personnel, which could severely disrupt our business and prospects. We also rely on other key personnel for, among other things, research and development, production, and sales and marketing, to develop new products, technologies and applications, enhance our existing products, ensure quality and safety control in production and enhance sales of our products both at home and abroad.

To incentivize valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical companies for similar personnel. We have had senior management departures in the past. Although we have not historically experienced undue difficulties attracting and retaining qualified employees, we could encounter such problems in the future for various reasons. We may not be able to retain the services of our senior management or key scientific personnel, or offer competitive packages to attract or retain experienced senior management or key personnel, which could have a material adverse impact on our business and prospects. In addition, with our expansion of commercialization and manufacturing capability in the future, we will need to hire additional employees and may not be able to attract and retain qualified employees on acceptable terms.

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

We aim to discover, develop and deliver innovative rAAV gene therapies. Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global and Chinese pharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

Our reputation is important to our success. Negative publicity with respect to us, our management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations and prospect.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CROs and CSOs, to expand our commercialization network and increase

market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrongdoing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

If our commercial manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

Our commercial manufacturing facility is located in Suzhou, Jiangsu Province. We have relied on this facility for the production of rAAV gene therapy products for our clinical trials in China and the U.S., and expect it to support the commercial launch and global distribution of our products upon regulatory approval. Natural disasters or other unanticipated catastrophic events, including power outage, water shortage, storms, fire, earthquakes, terrorist attacks and wars, as well as changes in governmental planning for the land underlying our facility, could significantly impair our ability to develop and manufacture products and disrupt our business operations. Although we maintain property insurance for our production facility and equipment, the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production facilities or our business operations. If our facility was damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to search for alternative measures to continue our business and operations. In such event, we would be forced to identify alternative premises for relocation. We may incur substantial expenses as a result of such events, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Not only might our facility and equipment be difficult to be replaced on a timely basis, but catastrophic events might destroy inventories stored in the facility. The occurrence of any such an event could significantly disrupt our business and materially reduce our revenue and profitability.

Any disruption or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialize our drug candidates or meet market demand for our products, which would adversely affect our business and results of operations.

In conducting drug discovery and development, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury 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. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drug candidates; damage to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals, or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved product candidate; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we have purchased clinical trial insurance in the conduct of our clinical trials. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

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 PRC laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain liability insurance covering our clinical trials. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

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

We may be exposed to fraud, bribery, kickback or other misconduct committed by our employees or third parties including independent contractors, consultants, commercial partners and vendors that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, kickback or other misconduct involving employees and other third parties that

had any material and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct by our employees or third parties. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business, results of operations and reputation.

If we obtain approval of any of our drug candidates and begin commercializing those products in the PRC, the United States or other applicable jurisdictions, we will become subject to enhanced requirements that impact, among other things, our current activities with principal investigators and research participants, as well as future sales, marketing and education programs. In particular, the promotion, sales and marketing of our products will be subject to extensive laws designed to prevent fraud, bribery, kickbacks or other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. We may incur increased costs associated with compliance with such laws and regulations.

Our information technology systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. 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 drug candidates could be delayed.

Our risk management and internal control systems may not be thorough or effective in all respects.

We seek to establish risk management and internal control systems consisting of an organizational framework, policies, procedures and risk management methods that are appropriate for our business operations, and seek to continue to improve these systems. See "Business — Risk Management and Internal Control" for further details. However, due to the inherent limitations in the design and implementation of risk management and internal control systems, we cannot assure that our risk management and internal control systems will be able to identify, prevent and manage all risks. Our internal procedures are designed to monitor our operations and ensure their overall compliance. However, our internal control procedures may be unable to identify all non-compliance incidents in a timely manner or at all. It is not always possible to timely detect and prevent fraud and other misconduct

committed by our employees or third parties, and the precautions we take to prevent and detect such activities may not be effective.

Furthermore, we cannot assure you that our risk management and internal control systems will be effectively implemented. Since our risk management and internal control systems depend on their implementation by our employees, we cannot assure you that all of our employees will adhere to such policies and procedures, and the implementation of such policies and procedures may involve human errors or mistakes, which may materially and adversely affect our business and results of operations. Moreover, as we are likely to offer a broader and more diverse range of services and solutions in the future, the expansion and diversification of our service offerings will require us to continue to enhance our risk management capabilities. If we fail to adapt our risk management policies and procedures to our evolving business in a timely manner, our business, financial condition and results of operations could be materially and adversely affected.

Changes in international trade policies and political tensions may adversely impact 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 condition, 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. There can be no assurance that our existing or potential service providers or collaboration 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 condition, results of operations, cash flows and prospects.

Rising trade and political tensions, as well as changes in relevant government policies could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions. Such political tensions and policy changes would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies. In particular, tensions between the United States and China in recent years have led to additional or higher tariffs imposed by the United States on products imported from China and restrictions on the sale of certain products into the United States. China has responded by imposing, and proposing to impose, additional or higher tariffs on products imported from the United States, among other measures. We currently import some of our manufacturing equipment and materials from the United States, and increasing trade barriers between China and the United States may make it more difficult for us to obtain necessary equipment and materials, resulting in disruptions, delays, and/or increased costs associated with our manufacturing activities. While we are actively looking for alternative suppliers within China, we cannot assure you that we will be able to secure alternative supplies on a timely basis to fully mitigate the impact of increasing trade barriers, or at all.

While we have not started commercialization of our drug candidates, any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products. In addition, rising trade and political tensions, heightened government scrutiny or unfavorable government policies may also affect our existing and future relationships with shareholders and business partners, including our suppliers and CROs, the provision of research and development and other services, the supplies of materials and products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. Any failure in confirming and continuing business relationships with our existing partners or any delay in identifying and entering into commercially reasonable business relationship with a new partner could harm our ability to develop, manufacture and distribute our drug candidates as planned or within budget, which could materially adversely affect our business, financial condition and results of operations.

We may be subject to natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control.

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

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs.

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

RISKS RELATING TO GOVERNMENT REGULATIONS

Gene therapy products are subject to stringent regulation across multiple jurisdictions, and the regulations or restrictions governing the development and commercialization of our drug candidates may change from time to time.

Gene therapies may be associated with undesirable or unacceptable side effects, and unexpected characteristics. Multiple jurisdictions have expressed interest in further regulating gene therapies and related products, and such regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. For example, agencies at both the federal and state level in the U.S., as well as the U.S. congressional committees and other governments or governing agencies, have expressed interest in further regulating gene therapies. In January 2020, the FDA issued several new guidance documents on gene therapy products, and in March 2022, the FDA published a draft guidance document providing recommendations for human genome editing gene therapy products. The FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research to consolidate the review of gene therapies and related products and established the Cellular, Tissue and Gene Therapies Advisory Committee to advise this review. In September 2025, the FDA released three new draft guidance documents aimed at streamlining the development, approval, and post-market monitoring of cell and gene therapy products. These documents reflect the FDA's ongoing commitment to accelerating the safe and efficient advancement of gene therapies while maintaining rigorous scientific and regulatory standards. In China, the CDE has issued several guidance documents to further regulate gene therapies and related research activities in recent years. In December 2021, the CDE issued two guidance documents providing technical guidelines for preclinical studies and long-term followup clinical studies for gene therapy products. In May 2022, the CDE issued a guidance document providing technical guidelines for pharmaceutical research of in vivo gene therapy products. In January 2024, the CDE issued a guidance document providing technical guidelines for clinical trials of gene therapy products for rare diseases. In December 2024, the CDE issued a guidance document providing technical guidelines for preclinical studies of rAAV-related gene therapy products.

As we advance our potential drug candidates, we will be required to consult with relevant regulatory agencies and committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue the development of our drug candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our potential drug candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our drug candidates in a timely manner, if at all.

All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated. Any failure to comply with relevant laws, regulations and industry standards or any adverse actions by the regulatory authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

All jurisdictions in which we operate or intend to conduct our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products in great depth and detail. For example, China and the United States, the two largest pharmaceutical markets in the world, strictly regulate the pharmaceutical industry, and in doing so employ a broad range of strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

We are required to obtained and maintain certain licenses and permits for conducting our business. The process of obtaining regulatory approvals and compliance with appropriate laws, regulations and guidance requires the expenditure of substantial time and financial resources. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or permits or promulgates new laws and regulations that require additional approvals or licenses or imposes additional restrictions on the operation of any part of our business, it has the power, among other things, to levy fines, confiscate our income, revoke our business licenses, and require us to discontinue our relevant business or impose restrictions on the affected portion of our business. In particular, failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an approval, license revocation; clinical hold, voluntary or mandatory product recalls, product seizures; total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution and disgorgement, or other civil or criminal penalties. Failure to comply with these laws, regulations and guidance could have a material and adverse effect on our business and prospects.

We are subject to stringent privacy and cybersecurity laws, information security policies and contractual obligations related to data privacy and security in both the PRC and the U.S.; failure by us or our business partners to adequately protect clinical trial participant data, or other personal or sensitive data could result in reputational damage, regulatory sanctions, fines or other penalties.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), which provide that enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term "state secret" is not clearly defined, if and to the extent any data collected or generated in connection with our R&D of drug candidates will be subject to these measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China.

In addition, the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) (the "**HGR Regulation**"), which was promulgated on May 28, 2019 and further amended on March 10, 2024, stipulates that foreign organizations, foreign individuals and the institutions established or actually controlled thereby shall not collect or preserve China's human genetic resources within the PRC, and shall not provide China's human genetic resources abroad. Where a foreign organization or an institution established or actually controlled by a foreign organization or foreign individual needs to use China's human genetic resources to conduct scientific research activities, it shall comply with the applicable laws, administrative regulations and relevant provisions in the PRC, and cooperate with China's scientific research institutions, universities, medical institutions and enterprises provided therein. In this regard, utilization of China's human genetic resources for international cooperation in scientific research, as well as transporting China's human genetic resources materials abroad shall be subject to the approval of the administrative department for health under the State Council. However, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials for obtaining the licensing for the listing of relevant drugs and medical devices in the PRC market, provided that the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department for health under the State Council before conducting the clinical trials. If we are unable to obtain necessary approvals, complete the filings or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered. Further, the Biosecurity Law (《生物安全法》), which was promulgated on October 17, 2020, became effective on April 15, 2021, and amended on April 26, 2024, reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. If the relevant government authorities consider the transmission of our scientific data or usage of human genetic resources to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

The landscape of cybersecurity and data privacy and security laws is constantly evolving. For example, on November 7, 2016, the SCNPC promulgated the Cybersecurity Law (《網絡安全法》), effective on June 1, 2017, which requires network operators to safeguard security of the network and follow the principles of legitimacy in collecting and using personal information. The SCNPC has also promulgated its Decision on Revising the Cybersecurity Law on October 28, 2025, which will come into effect on January 1, 2026. On June 10, 2021, the SCNPC promulgated the Data Security Law (《數據安全法》), effective on September 1, 2021, which imposes data security and privacy protection obligations on entities and individuals which carry out data activities, and introduces a data classification and hierarchical protection system. On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law (《個人信息保護法》), effective on November 1, 2021, which further detailed the general rules and principles on personal information processing and further increased the potential liability of personal information processor. Complying with new laws and regulations could substantially increase the costs or require us to change our business practices in a manner materially adverse to our business. Additionally, to the extent we are found by the PRC regulators to be not in compliance with these laws and requirements, we may be subject to fines, regulatory orders to suspend our operations or other regulatory and disciplinary sanctions.

On December 28, 2021, the CAC, together with other relevant administrative departments, jointly promulgated the revised Cybersecurity Review Measures (《網絡安全審查辦法》) with effect from February 15, 2022, according to which, the purchase of network products and services by a critical information infrastructure operator (the "**CIIO**") or the data processing activities of a network platform operator that affect or may affect national security will be subject to a cybersecurity review. In addition, an online platform operator who possesses personal information of over one million users and intends for listing in a foreign country (國外上市) must be subject to the cybersecurity review. Moreover, when relevant government authorities under the cybersecurity review mechanism identify network products, services, or data processing activities that affect or may affect national security, the Cybersecurity Review Office of the CAC will, upon approval by the Central Cyberspace Affairs Commission, initiate a cybersecurity review. However, there has been no further explanation or interpretation for "affect or may affect national security" under the aforementioned regulation. We cannot rule out the possibility that the relevant government authorities may conduct cybersecurity review on us according to the Cybersecurity Review Measures. If a cybersecurity review for any of our activities is required, we will actively cooperate with the CAC to conduct such cybersecurity review. Any failure to obtain such approval or clearance from the regulatory authorities could materially constrain our liquidity and have a material adverse impact on our business operations and financial results, especially if we need additional capital or financing.

On September 30, 2024, the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (the "**Data Security Regulations**") was promulgated by the State Council, which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. In particular, the Data Security Regulations provide that cyber data processors whose cyber data processing activities affect or may affect national security shall be subject to national security review in accordance with

the relevant regulations. However, the Data Security Regulations provide no further explanation or interpretation for the criteria on determining the risks that "affect or may affect national security". Additionally, since the Data Security Regulations are still relatively new, the interpretation and implementation of these regulations may further evolve and develop.

Moreover, the regulatory framework on cross-border transfer of personal information and data worldwide is rapidly evolving and is likely to remain uncertain due to lack of clear explanation and instruction on enforcement. For example, in recent years, China has promulgated several laws and regulations on cross-border data transfer, including but not limited to the Data Security Law, the Personal Information Protection Law, the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), 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》) and the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》). The Measures for the Certification for Cross-Border Transfer of Personal Information (《個人信息出境認證辦法》 was promulgated by the CAC and the State Administration for Market Regulation on October 14, 2025, and will come into effect on January 1, 2026. These regulations have provided that, amongst others, CIIO that provides any personal information or important data to an overseas recipient, and other data processors that provides any important data, sensitive personal information or certain amount of non-sensitive personal information to an overseas recipient shall be subject to security assessment, standard contract filing or personal information protection certification for outbound data transfer activities, unless otherwise provided under the relevant laws and regulations. We cannot guarantee if these rules or regulations promulgated will impose additional compliance requirements, including any approval, filing, certification and/or other administrative measures thereunder, and we cannot guarantee that the measures we have taken or will take in the future will always be effective or fully satisfy the relevant regulatory requirements under the relevant laws and regulations, including obtaining such approval, filing and other administrative measures in a timely manner, or at all.

In addition, our presence in the United States also subject us to a variety of U.S. laws and regulations that involve privacy, data protection and personal information, data security, and data retention and deletion. The United States has several federal laws that protect specific types of data, such as the Privacy Act of 1974, the Health Insurance Portability and Accountability Act, and the Health Information Technology for Economic and Clinical Health Act, but the United States does not have a comprehensive federal data protection law that covers all types of private data. However, more states are passing data privacy laws, and the federal government may also pass comprehensive laws in the future. U.S. federal and state laws and regulations, which in some cases can be enforced by private parties in addition to government entities, are constantly evolving and can be subject to significant change. In such circumstances, we must exercise heightened diligence in protecting, processing and transferring clinical trial participants data, as well as other personal or sensitive data in our daily operation.

Changes in political and economic policies, as well as the interpretation and enforcement of laws, rules and regulations, may affect our business, financial condition, results of operations and prospects.

As a substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources; however, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations may also be amended from time to time, and the application, interpretation and enforcement of such evolving laws, rules and regulations may affect our business operations. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

You may experience difficulties in effecting service of process upon or enforcing foreign judgments against us or our Directors or officers.

Most of our assets are situated in the PRC and most of our directors and officers reside in the PRC. Therefore, there remains the possibility that it may be difficult to effect service of process outside the PRC upon our directors and officers, including with respect to matters arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the United States and many other countries. Consequently, you may experience difficulties in enforcing against us or our directors or officers in the PRC any judgments obtained from courts outside of the PRC.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People's Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《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》), which has come into effect on January 29, 2024 and superseded the Arrangement, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However,

we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous materials, including chemicals and biological materials, and may produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We maintain work-related injury insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We also maintain certain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Governmental regulations on currency exchange may affect us.

The convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency into and out of China are subject to PRC foreign exchange regulations. Under existing PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate governmental 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.

In July 2014, the SAFE promulgated the SAFE Circular 37. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals with a habitual residence in China due to economic interests) to register with SAFE or its local branches in connection with their direct or indirect offshore investment

activities. SAFE Circular 37 further requires amendment to the SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as changes of the offshore special purpose vehicle's name and operational term, or any significant changes with respect to the PRC individual shareholder, such as the increase or decrease of capital contributions, share transfer or exchange, or mergers or divisions. If our shareholders who are PRC residents fail to make the required registration or to update the previously filed registration, our PRC subsidiaries may be prohibited from distributing their profits or the proceeds from any capital reduction, share transfer or liquidation to us, and we may also be prohibited from making additional capital contributions into our PRC subsidiaries. In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) ("**Notice 13**"), effective from June 2015, and further amended by SAFE on December 30, 2019. Under Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE. We cannot assure you that all our Shareholders will at all times comply with the registration procedures as required under these regulations. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities, including the Ministry of Commerce, the State Administration for Market Regulation and SAFE or their local counterparts. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial condition and results of operations.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have. Any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business or financial condition.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity that may be paid by our subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to the holders of our Shares and service any debt we may incur. If any of our subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside 10% of its after-tax profits each year, after making up previous years' accumulated losses, if any, to fund certain statutory reserve funds, until the aggregate amount of such a fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends.

Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

Failure to comply with PRC regulations regarding the registration requirements for employee share ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In 2012, SAFE promulgated the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》). Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year and participate in any stock incentive plan of an overseas publicly listed company are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures, unless certain exceptions are available. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our executive officers and other employees who are PRC citizens or non-PRC citizens living in China for a continuous period of not less than one year and have been granted options will be subject to these regulations when our company becomes an overseas-[**REDACTED**] company upon the completion of the [**REDACTED**]. Failure to complete SAFE registrations may subject them or us to fines or supervision measures. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees.

In addition, the State Taxation Administration has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiary has obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes for those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

If we fail to complete the CSRC filing and other procedures for future offshore [REDACTED], we may be subject to sanctions imposed by the relevant PRC government authority.

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures have comprehensively improved and reformed the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities. Any such domestic company that is deemed to conduct overseas offering and listing activities, including both the [**REDACTED**] and any further capital raising, shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

We have obtained the CSRC filing notice for the [**REDACTED**] on [**REDACTED**], and intend to file with the CSRC for any further offshore offerings within the specific time limit as required by the Overseas Listing Trial Measures. However, it is uncertain whether we can or how long it will take us to complete the CSRC filing for future offerings. Any failure to complete the CSRC filing may subject us to sanctions by the CSRC. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.

We have leased certain properties in China as our offices and R&D and manufacturing facilities. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, our lease agreements in China had not been registered. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. If any of our leases is terminated or becomes

unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. Any relocation could lead to disruptions to our operations and adversely affect our business, financial conditions and results of operations.

As our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our Shares prior to the [REDACTED]. An active trading market for our Shares may not develop or be sustained, and the [REDACTED] of our Shares may be volatile.

Prior to the completion of the [**REDACTED**], there has been no public market for our Shares. There can be no guarantee that an active [**REDACTED**] for our Shares will develop or be sustained after completion of the [**REDACTED**]. The [**REDACTED**] is the result of negotiations between us and the [**REDACTED**] (for themselves and on behalf of the [**REDACTED**]), which may not be indicative of the price at which our Shares will be traded following the completion of the [**REDACTED**]. The [**REDACTED**] of our Shares may drop below the [**REDACTED**] at any time after completion of the [**REDACTED**].

The actual or perceived sale or availability for sale of substantial amounts of our Shares, especially by our directors, executive officers, and substantial Shareholders, could adversely affect the [REDACTED] of our Shares.

Save for existing Shareholders who are subject to certain lock-up periods, our existing Shareholders may dispose of our Shares that they may own now or in the future. Sales of substantial amounts of our Shares in the public market, or the perception that these sales may occur, could materially and adversely affect the prevailing [**REDACTED**] of our Shares.

You will incur immediate and substantial dilution and may experience further dilution in the future.

As the [**REDACTED**] of our Shares is higher than the net tangible book value per share of our Shares immediately prior to the [**REDACTED**], purchasers of our Shares in the [**REDACTED**] will experience an immediate dilution. If we issue additional Shares in the future, purchasers of our Shares in the [**REDACTED**] may experience further dilution in their shareholding percentage.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we have not yet adopted a dividend policy with respect to future dividends. Therefore, you should not rely on an [**REDACTED**] in our Shares as a source for any future dividend income.

Our Board has discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends either out of profits or share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, 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 condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [**REDACTED**] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value or even maintain the price at which you purchased the Shares. You may not realize a return on your [**REDACTED**] in our Shares and you may even lose your entire [**REDACTED**] in our Shares.

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

Without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

We cannot assure you of the accuracy or completeness of certain industry facts, statistics, and forecasts that were obtained from government publications contained in the document.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, the information from official government sources has not been independently verified by us, the Joint Sponsors, [**REDACTED**], any of their respective directors, employees, agents or advisers or any other person or party involved in the [**REDACTED**], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate or not comparable to statistics produced for other economies. Accordingly, the information from official government sources contained herein should not be unduly relied upon. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

You should read the entire document carefully and should not rely on any information contained in press articles or other media regarding us and the [REDACTED].

We strongly caution you not to rely on any information contained in press articles or other media regarding us and the [**REDACTED**]. Prior to the publication of this document, there has been press and media coverage regarding us and the [**REDACTED**]. Such press and media coverage may include references to certain information that does not appear in this document, including certain operating and financial information and projections, valuations, and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness, or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this document, we disclaim responsibility for it, and you should not rely on such information.

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

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.