

## RISK FACTORS

*An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. 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.**

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. 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.

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. 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.

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

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promising results at an earlier stage. The transition from Phase II to Phase III in gene therapy has a historical success rate of less than 40%. 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. Our research and development expenses were US\$20.6 million and US\$13.9 million for the years ended December 31, 2024 and 2025, respectively, and US\$7.1 million and US\$5.3 million for the six months ended June 30, 2025 and 2026, respectively. 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, such as the total size of the relevant patient population, design and eligibility criteria for the clinical trial in question, and perceived risks and benefits of the drug candidate under study.

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.

**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. However, we

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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].

**Our drug candidates may cause adverse side effects, such as triggering immune responses, or have other properties that could delay or prevent their regulatory approval, which may limit their commercial profile or result in 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.

Current clinical practices with gene therapies have revealed the potential to trigger immune responses including cytokine release syndrome and complement activation, and high-dose systemic administration ( $>1 \times 10^{14}$  vg/kg) is associated with severe hepatotoxicity that may progress to acute liver failure. Such safety risks have not been observed in the clinical trials of any of our drug candidates. However, we cannot guarantee that such risks will not arise in the future.

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, such as suspension of our marketing activities, revocation of licenses, liability to patients or participants, and reputation harms. 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.

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**The side effects of our drug candidates on patients, such as tumorigenesis induced by AAV genome integration and unintended off-target genomic modifications, may be irreversible, with limited effective remedial measures available should any SAEs occur.**

Our drug candidates pose theoretical risks of resulting in permanent and irreversible genomic modifications to the patient. The modification may not proceed as intended, and even if our therapies achieve the intended genomic modification, unintended and irreversible off-target effects and tumorigenesis induced by genome integration may occur, which could lead to SAEs, resulting in unpredictable health problems and an increased risk of cancer. Also, our gene therapies utilize continuous, high-level expression of the transgene, which carries a potential risk of retinal toxicity, and could manifest SAEs such as chronic inflammation. The current technologies do not allow for the precise turning off or downregulation of the transgene’s expression. This inability to modulate or halt gene expression in response to toxicity or other adverse events could exacerbate the condition, potentially leading to irreversible results like damage to retinal function and vision loss. We cannot guarantee that long-term follow-up of treated participants will not reveal such irreversible risks. If such unexpected events occur, we may not be able to reverse the genomic modification, and there may be limited effective remedial measures available.

**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.

**The safety and efficacy of our Core Products remain unconfirmed given the limited availability of clinical data pertaining to participants with the targeted indications.**

We have two Core Products, namely FT-002 and FT-003. For FT-002, we have completed Phase II clinical trials in China for XLRP and have received clearance from the FDA for Phase II trials in the United States for XLRP. For FT-003, we have completed Phase II clinical trials for nAMD in China, initiated Phase II clinical trials for DME in China, and obtained FDA clearance for Phase II trials in the United States for nAMD and DME. There is a limited number of trial participants. Additionally, data and information from our preclinical studies and clinical trials may not be accurate. See “— 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.” for further details. Thus, even though our Core Products have shown favorable safety and efficacy in the current clinical trials, their safety and efficacy have not been fully validated at this time.

**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,

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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.

**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.

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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.

**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.

**We face the risk of product cannibalisation arising from our drug products targeting similar indications.**

Some of our drug candidates target the same or similar indications. When we commercialize these candidates, if any of these candidates fail to deliver their unique value propositions, they may compete with one another for market share instead of helping us expand our overall market presence. This may cause a material adverse impact on our business prospects, financial condition and results of operations.

**If we fail to manage our inventories effectively, our business, financial condition and results of operations may be adversely affected.**

As of December 31, 2024 and 2025 and June 30, 2026, we had inventories of US\$1.4 million, US\$1.2 million and US\$0.8 million, respectively. Our inventory turnover days, calculated based on the inventory consumption for R&D purposes instead of cost of goods sold as we have not generated revenue, were 334 days, 623 days and 269 days in 2024 and 2025 and the six months ended June 30, 2026, respectively. Due to the COVID-19, we arranged a one-time bulk procurement prior to our Core Products advancing to Phase II clinical stages. This strategic move was designed to ensure the stability of clinical trial supplies. However, it also resulted in a substantial majority of our inventory balance being over two years. While we have formulated definitive plans for future trial usage and implemented robust inventory management mechanisms, we are unable to completely foresee volatility and fluctuations in inventory consumption throughout clinical trials. We made impairment provisions for inventories of US\$108 thousand, US\$21 thousand and US\$20 thousand as of December 31, 2024 and 2025 and June 30, 2026, respectively, all of which were at a low level. The scheduled inventory consumption for R&D purposes in 2026 is expected to consume most of the inventories reaching their expiration date this year, keeping potential impairments to a minimum. However, if there are any deficiencies arise, we still may be subject to inventory impairments. Any material inventory impairment could have adverse impacts on our business prospects, financial condition and results of operations. For further discussions of our inventories, see also “Financial Information — Discussion of Certain Key Items from the Consolidated Statements of Financial Position — Inventories.”

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### 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 due to several factors, including the unavailability of long-term treatment outcomes, long-term follow-up required and the concern of long-term safety, and limited market accessibility and negative public sentiment owe to high pricing.**

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. The degree and rate of physician and patient adoption of our drug candidates, if approved, will depend on a variety of factors including competitive landscape, pricing or physician preference, and reimbursement by insurers.

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 costs of treatment with our drug candidates are too high relative to the willingness to pay on the part of insurance companies, other third-party payers, physicians and patients, market accessibility of our products may be significantly limited. Beyond practical obstacles, high pricing and limited accessibility may also trigger negative public sentiment, which could further adversely affect our reputation and market acceptance of our products.

Even if the costs of treatment with our drug candidates match the market expectations, they may still be reluctant to use our drug candidates due to the lack of long-term treatment outcome data and long-term follow-up required, which results in their concern of long-term safety. Some impacts of gene therapies might be long-term and future manifestation. We are conducting the five-year long-term follow-up in accordance with regulatory requirements to monitor long-term safety. Currently, our drug candidates are still limited by the scarcity of long-term data regarding treatment durability. Furthermore, as newly commercialized products, there is a lack of precedents regarding the potential delayed adverse effects of gene therapies, and information can only be derived from limited clinical data and results. These uncertainties may significantly hinder patient trust and market acceptance.

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.**

The gene therapy industry in which we operate is intensely competitive and subject to rapid and significant technological changes. 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. For

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example, Ixo-vec, one of our peer gene therapies, has reported reduced injection frequency by as high as 95% at Week 26 of its Phase II clinical trial, which is higher than that of our FT-003 at a similar stage. Also, some of our competitors may become more effective in selling and marketing their products. 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.

### **The potential market for FT-002 may be limited in the future.**

FT-002 is one of our Core Products, being investigated to treat XLRP. According to Frost & Sullivan, the XLRP drug market is anticipated to decline after 2034. This market is primarily constrained by two factors: the relatively limited patient population and the one-time treatment nature of gene therapies. Consequently, the potential market for FT-002 may be limited, which could affect our business prospects, financial condition and results of operations.

### **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

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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.

**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.

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.

**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. 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 gene therapy products is a complex process which requires significant expertise and capital investment, and if we encounter problems in manufacturing, our business could suffer.**

The manufacturing of gene therapy products 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

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factors. In particular, the manufacturing of gene therapy products entails stringent requirements for specialized equipment, professional personnel and high capital expenditure, as well as possible substantial production losses and significant challenges in scalable production. The manufacturing of gene therapy products suffers from low conversion rates and high costs associated with large-scale production. Moreover, the technical difficulties of production create substantial hurdles in maintaining product purity and batch stability. See “Industry Overview — The Gene Therapy Market — Challenges and Entry Barriers to the Gene Therapy Market” for more details.

**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 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.

**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.

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.

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

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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.

**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.

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### 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.**

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.**

We incurred net losses of US\$26.5 million and US\$19.5 million for the years ended December 31, 2024 and 2025, respectively, and net losses of US\$8.2 million and US\$4.7 million for the six months ended June 30, 2025 and 2026, 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\$20.6 million and US\$13.9 million for the years ended December 31, 2024 and 2025, respectively. Our research and development expenses were US\$7.1 million and US\$5.3 million for the six months ended June 30, 2025 and 2026, 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, such as scaling up our business to meet the requirements of our R&D activities and potential commercialization. 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\$23.1 million, US\$16.3 million and US\$6.5 million in 2024 and 2025 and the six months ended June 30, 2026, 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.

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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 and debt financing. We expect our expenses to experience modest increases in connection with our ongoing activities. 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.

**Our extended cash conversion cycle exerts pressure on our financial position.**

Our cash conversion cycle is relatively extended primarily due to our prolonged inventory turnover days. Although we believe this situation is not indicative of our long-term inventory and cash position, the significant tie-up of working capital heightens liquidity risks and the potential for cash flow disruptions. If any liquidity issues or cash flow disruptions arise, they could have adverse impacts on our business prospects, financial condition and results of operations.

**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\$0.5 million and US\$0.4 million for the years ended December 31, 2024 and 2025, respectively, and US\$0.3 million and US\$1.7 million for the six months ended June 30, 2025 and 2026, 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

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align their interests with ours. We incurred share-based compensation expenses relating to share options granted under our share incentive plan of US\$0.2 million and US\$0.5 million for the years ended December 31, 2024 and 2025, respectively, and US\$0.2 million and US\$0.4 million for the six months ended June 30, 2025 and 2026, respectively. 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, [REDACTED] 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, 2024 and 2025, we recorded exchange differences arising on translation of foreign operations, an item under other comprehensive income, of US\$0.9 million and US\$1.8 million, respectively. For the six months ended June 30, 2025 and 2026, we recorded exchange differences arising on translation of foreign operations of US\$0.8 million and US\$1.7 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.

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]. 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.

### **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 [REDACTED] 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 [REDACTED], 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**

**We have not yet obtained granted patents relating to our Core Products in all relevant jurisdictions, which may pose risks to uniqueness and competitive advantage of our drug candidates.**

We have not yet obtained granted patents relating to our Core Products in all relevant jurisdictions. To date, we have obtained a granted patent relating to one of our Core Products, FT-003, in Japan, and have received notice of allowance for both FT-002 and FT-003 in the

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United States. The Directors, based on their best estimates, believe that granted patents relating to both of our Core Products in all relevant jurisdictions are expected to be obtained by end of 2027 according to our consultation with our IP counsel. However, there can be no assurance that patents will be granted within this timeframe, or that the examination procedures will not encounter unexpected delays. If our Core Products fail to secure patent protection prior to commercialization, our drug candidates may be at risk of being imitated by competitors, which could consequently result in the loss of our exclusivity period and market share. Consequently, our significant investments in costs may not be recoverable, which could significantly harm our business, financial condition and results of operation.

**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.**

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. 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, 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.

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 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.

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,

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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 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.

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. 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, 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. 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

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may grant more limited extensions than we request. 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.

**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.**

The CNIPA, the United States Patent and Trademark Office (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. 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, 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. 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. In such instances, we may need to take action to enforce or defend our intellectual property rights. Failure to successfully defend against such claims 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

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lack of novelty, obviousness, or non-enablement. 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.

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.**

The field of gene therapy, including rAAV gene therapy, is competitive, and intellectual property around the technology of gene therapy is complex. 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. 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. 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

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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. 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. 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 [REDACTED], securities analysts or [REDACTED] 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.

**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 non-public 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. Any of the parties that have access to our trade secrets and confidential information such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, CROs, consultants, advisers and other third parties, may breach non-disclosure, confidentiality and similar agreements we entered into with them and disclose our non-public information, and we may not be able to obtain adequate remedies

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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 confidential 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. 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 intellectual property 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 non-public 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 non-public information, of any such individual’s former employer.

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.**

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. 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.

## RISK FACTORS

### 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.**

Our future success depends heavily upon our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. 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.

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.

**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.**

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

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catastrophic events, 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. 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. 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.

**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.

It is possible that our liabilities could exceed our insurance coverage or that our clinical trial 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.**

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 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 non-public information, we could incur liability and the further development of our drug candidates could be delayed.

**Changes in international trade policies and political tensions may adversely impact our business and results of operations.**

Rising trade and political tensions, as well as changes in relevant government policies could reduce levels of trades, investments, technological exchanges and other economic

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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.

### 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, while the development and application of human stem cell and gene diagnosis and therapy technologies (the “**Relevant Businesses**”) is still subject to the relevant special administrative measures for foreign investment access in China, in September 2024, the Ministry of Commerce, the National Health Commission and the National Medical Products Administration jointly issued a notice that allowed foreign-invested enterprises to engage in the Relevant Businesses in four Free Trade Zones and/or Ports. We now conduct our gene therapy R&D business within these Free Trade Zones and/or Ports pursuant to the notice. To the extent that there are further changes to the notice or other applicable laws and regulations, we may be required to adjust our business practices which may result in additional costs and/or disruptions to our business operations.

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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.

**Our R&D activities of gene therapy are confined to the entity located within a free trade zone under the current regulatory framework of mainland China.**

Under the current regulatory framework, our gene therapy R&D activities are restricted to specific free trade zones in mainland China. We now conduct our gene therapy R&D activities in the Shanghai Free Trade Zone, while we are allowed to engage in the production, sales and marketing of gene therapy drugs outside of free trade zones and collaborate with clinical trial sites, CROs, SMOs and CDMOs outside of free trade zones. Notwithstanding the above, we could face difficulties in trying to hire R&D talents residing in cities outside of free trade zones. In addition, many provinces and cities across mainland China have introduced favorable policies for R&D-focused enterprises incorporated locally, including but not limited to generous government grants, rental concessions, and tax incentives. As our R&D activities are restricted to free trade zones, we are unable to incorporate new entities in these provinces or cities for the purpose of engaging in R&D activities, and cannot take advantage of these benefits.

**All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated.**

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. We are required to obtain 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.

**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**”) stipulates that

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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. 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》) 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 (《网络安全法》). The SCNPC 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 (《数据安全法》). On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law (《个人信息保护法》). 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 (《网络安全审查办法》) with effect from February 15, 2022, according to which, the data processing activities of a network platform operator that affect or may affect national security will be subject to a 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.

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. 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

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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.

**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. Our current insurance may not provide adequate coverage against all potential liabilities.

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

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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.

**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

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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.**

Pursuant to applicable 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-listed 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 offerings, 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. Under these rules, any 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 applicable rules, both lessors and lessees are required to file the lease

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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. 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 [REDACTED] for our Shares prior to the [REDACTED]. An active [REDACTED] for our Shares may not develop or be sustained, and the [REDACTED] and [REDACTED] of our Shares may be volatile.**

Prior to the completion of the [REDACTED], there has been no [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED], 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.

**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

## RISK FACTORS

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

**We cannot assure you 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.

**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.