

RISK FACTORS

An [REDACTED] in our Shares involves a high degree of risk. You should consider carefully all the information set out in this document and, in particular, should evaluate the following risks associated with the [REDACTED] in our Shares. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our Shares. You should also pay particular attention to the fact that we conduct our operations in China, as well as in the United States, the legal and regulatory environment of which in some respects may differ from that in Hong Kong and other jurisdictions. Any of the risks and uncertainties described below could have a material adverse effect on our business, results of operations, financial condition or on the [REDACTED] of our Shares, and could cause you to lose all or part of your [REDACTED]. The order in which the following risks are presented does not necessarily reflect the likelihood of their occurrence or the relative magnitude of their potential material adverse effect on our business, financial condition, results of operations, prospects or on the [REDACTED] of our Shares.

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

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

Our business will depend on the successful development, regulatory approval and commercialization of our current product candidates, including our Core Products, and our Key Product all of which are still in pre-clinical or clinical development, as well as other product candidates we are developing or may develop in the future. Our success depends on timely patient enrollment and completion of pre-clinical and clinical studies, safeguarding trial data in compliance with relevant laws and standards, obtaining regulatory approvals, securing scalable commercial manufacturing and reliable supplies for combination-use trials that ensuring CROs, CDMOs and other vendors comply with protocols and legal requirements to protect data integrity, acquiring the necessary intellectual property rights and licenses, successfully commercializing approved products, and maintaining acceptable post-approval safety profiles. If we do not achieve one or more of these factors in a timely manner or at all, we may experience significant delays in our ability or be unable to obtain approval for and/or to successfully commercialize our product candidates, which would materially harm our business, and we may not be able to generate sufficient revenues and cash flows to continue our operations.

AAV gene therapies entail inherent safety risks that could adversely affect development and regulatory timelines.

AAV-based therapies are subject to safety risks that could cause SAEs, including fatalities. While AAV vectors have historically been considered to have a favorable safety profile, AAV administration can be associated with severe and potentially life-threatening toxicities. These include hepatotoxicity, thrombotic microangiopathy (TMA), cardiotoxicity, tumorigenicity and other adverse events. The risk of such toxicities may be exacerbated by high vector doses, preexisting immunity, complement activation, concurrent infections, and patient-specific factors, and the underlying mechanisms remain incompletely understood.

Accordingly, any SAEs observed in our clinical trials or elsewhere in the field could result in clinical holds, delays in regulatory approvals, restrictive labeling, or reputational harm, which would have a material adverse effect on our ability to develop and commercialize our product candidates.

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The biological effects of our siRNA-based therapies may persist for a period of time, and currently available methods to rapidly reverse or precisely modulate such effects remain limited.

Small nucleic acid-based therapeutic products, such as small interfering RNA (siRNA), antibody-oligonucleotide conjugates (AOCs), and other modalities, achieve therapeutic effects by inducing degradation of specific mRNA and thereby mediating gene silencing. However, once an siRNA is delivered *in vivo* and becomes pharmacologically active, its biological effects may persist for a period of time, and currently available methods to rapidly reverse or precisely modulate such effects remain limited. As a result, if excessive or unintended gene silencing occurs, it may be difficult to promptly terminate or mitigate the associated effects. In addition, small nucleic acid-related technologies continue to face potential risks of off-target effects. Small nucleic acid molecules may partially hybridize with certain non-target mRNA sequences due to partial complementarity, resulting in unintended suppression of gene expression. Such off-target gene silencing may affect multiple biological pathways and could lead to adverse events that are difficult to predict. Although sequence optimization, bioinformatic prediction and *in vitro/in vivo* screening may reduce these risks to some extent, the possibility of such events cannot be fully eliminated at present. Given that small nucleic acid therapies often exhibit relatively durable pharmacological activity, uncertainty remains regarding their long-term safety outcomes. For example, long-term or cumulative gene silencing may have potential effects on target tissues or other physiological systems, and such effects may only become apparent after an extended period. Regulatory authorities may therefore require longer-term and more comprehensive safety follow-up studies, which could increase development timelines, clinical trial complexity and costs.

In light of the foregoing uncertainties and potential safety risks, regulatory authorities, clinicians or patients may be more inclined in clinical practice to position small nucleic acid therapies as later-line or alternative treatment options rather than first-line choices. If any of the above occurs, it could limit the market acceptance, patient coverage and commercialization potential of relevant products, and could materially and adversely affect our business, financial condition and results of operations.

Clinical development of biopharmaceutical products involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and early phases of clinical trials may not be predictive of future trial results.

Clinical trials can be expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies, investigator-initiated trials and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results and may be subject to adjustments. For example, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies, investigator-initiated trials and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, such as changes in trial procedures set forth in protocols and differences in the size and type of the patient populations, including genetic differences, adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries involved in such trials. Certain clinical trial results disclosed in this document are interim data. Some of such data and results of clinical trials are dependent on physicians' subjective judgment, for example, whether certain adverse events occurred to the trial patients were treatment-related or not. As a result, when preparing the final report of such clinical trials, it is possible that certain necessary adjustments may be made to the clinical data in accordance with judgments and relevant rules promulgated by the NMPA, the FDA and other comparable regulatory authorities, rendering the final data different from the interim clinical trial data. Therefore, you are cautioned not to place undue reliance on the interim data presented herein.

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A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may not be favorable, regardless of earlier results. If so, we would have expended a significant amount of capital and other resources to progress the relevant product candidates to that stage, but would not realize any revenue on such product candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects. Even if our future clinical trial results show favorable efficacy and impressive durability of anti-tumor responses, not all patients may benefit. For certain therapies, not all patients will respond, some responders may also relapse after a period of response.

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

We may fail to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in our clinical trials as required by the NMPA, the FDA or similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment.

We may be unable to enroll and retain enough patients for our clinical trials on a timely basis due to restrictive eligibility criteria and limited addressable patient populations, patients’ distance to study sites, trial design, our ability to recruit qualified investigators, competition from other trials in the same therapeutic areas, challenges in obtaining and maintaining informed consent and patient dropout before treatment completion.

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

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

We cannot predict accurately when or whether any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of clinical development.

Unexpected events prior to, during, or after our clinical trials could delay, suspend, or prevent regulatory approval and commercialization, including disagreement from regulatory authorities over trial design, trial implementation or data interpretation, inability to obtain authorization from institutional review boards (“IRBs”) or ethics committee to commence a clinical trial, manufacturing problems relating to our own facilities or third-party CDMOs, negative or inconclusive results, unexpected safety issues, or unacceptable participant risk leading to trial suspension or termination, requirements to run additional studies or abandon programs, slower-than-expected enrollment, higher dropout rates, or larger-than-expected sample size needs, non-compliance of third-party vendor or performance failures, higher-than-expected trial costs, inadequate quality or supply of drug product, companion diagnostics, or other required materials, and changes in policies or regulations of the NMPA, the FDA or other regulatory authorities that render prior data insufficient.

To the extent that the results of our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the NMPA, the FDA or other regulatory authorities, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

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If we must conduct additional trials or testing, if we cannot complete our planned clinical trials, or if the results of these trials are negative, or are only modestly positive, or if they raise safety concerns, we may face delayed or failed regulatory approval, narrower-than-expected indications, post-approval withdrawal, additional post-marketing study requirements, distribution or use restrictions, or limited reimbursement.

Adverse events (“AEs”) and undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our product candidates, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. AEs related to our product candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our product candidates or allow our competitors to bring their products to market before we do. This could impair our ability to commercialize our product candidates and may have an adverse effect on our business and results of operations.

We may not be successful in developing, acquiring, enhancing or adapting to new technologies and methodologies.

We must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2024 and 2025, our research and development expenses were RMB145.0 million and RMB103.9 million, respectively. We must continue to commit substantial personnel and capital to improve the scale and quality of our clinical trials and to strengthen our discovery, development, and manufacturing capabilities, which are time- and capital-intensive. We may also pursue acquisitions of new technologies and methods to expand our R&D capabilities and product candidate portfolio when we identify suitable opportunities. We cannot assure you that we will be able to develop, acquire, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

We may not be able to discover or identify new product candidates, or to expand the therapeutic opportunities for our product candidates.

The success of our business depends in part upon our ability to discover or identify additional product candidates. There can be no assurance that we will be successful in identifying new product candidates in the future. Some product candidates may be technically challenging to develop and manufacture. Product candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential product candidates. However, there can be no assurance that such license and collaboration will deliver the expected results. Research programs to identify new product candidates and to develop our product candidates for additional indications require substantial technical, financial, and human resources. We may invest efforts and resources in potential product candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material and adverse effect on our business, results of operations and prospects.

The invasive delivery routes of certain of our product candidates may pose safety risks, which may negatively impact the clinical development of our product candidates.

Certain of our product candidates are administered through invasive delivery routes, including intrathecal or subretinal injection. Central nervous system or intraocular

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administration involves inherent procedural and anatomical risks, including infection, inflammation, bleeding, neurological or visual impairment, increased intraocular pressure, retinal injury or detachment, and other procedure-related complications. These risks may vary depending on operator expertise, patient-specific factors, and disease severity. If serious adverse events occur or if these delivery procedures are not well tolerated, patient enrollment and retention in clinical trials may be adversely affected, regulatory authorities may impose additional requirements or restrictions, and the development, approval, or commercialization of our gene therapy product candidates may be delayed, limited, or rendered unfeasible.

In addition, certain of our product candidates are administered via non-surgical or minimally invasive routes, including intravenous (IV) or intravitreal (IVT) injection. Although these delivery methods are generally less invasive than intrathecal or subretinal administration, they are still associated with risks. IV administration may result in local injection-site complications such as pain, swelling, infection, infiltration, phlebitis or hematoma, as well as systemic reactions including allergic or infusion-related reactions, fluid overload, blood pressure or heart rate changes, and other treatment-related adverse effects. For IVT administration, potential risks include intraocular inflammation and elevated intraocular pressure. The occurrence of any of these events could adversely affect patient safety, clinical trial outcomes, regulatory approval or the commercial adoption of our product candidates.

Our pre-clinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

Some of our product candidates are still in the pre-clinical development stage, and the risk of failure of pre-clinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive pre-clinical studies on safety and efficacy of product candidates to obtain regulatory clearance to initiate clinical trials on humans. We cannot be certain of whether we will be able to timely complete our pre-clinical studies or generate results that are adequate to support the initiation of subsequent clinical trials. There is also no assurance that the NMPA, the FDA or other comparable regulatory authorities will accept our proposed protocols for clinical programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our pre-clinical programs on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the NMPA, the FDA or other regulatory authorities allowing us to commence the contemplated clinical trials.

Our and/or others' failure to obtain or renew approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities causing operations to cease, and may include corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations. There is also no assurance that the relevant authorities would not take any enforcement action against us. In the event that such enforcement action is taken, our business operations could be disrupted.

Furthermore, interpretation or implementation of existing laws and regulations could change, or new regulations might come into effect requiring us and/or other related parties to obtain additional approvals, permits, licenses or certificates that were previously not required. In such circumstances, we cannot assure you that we and/or other such related parties would be able to successfully obtain such approvals, permits, licenses or certificates. Our or these parties' failure to obtain the additional approvals, permits, licenses or certificates could restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and prospects.

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Changes in government regulations or in practices relating to the biopharmaceutical industry may adversely affect our business.

The biopharmaceutical industry in China, the United States and other markets where we intend to enter is heavily regulated. Changes in government regulations or in practices relating to the biopharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures which lower entry barriers for potential competitors, or an increase in regulatory requirements that may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval and commercialize our product candidates and affect the prices we may set. For example, in China, a number of legislative and regulatory changes and proposed changes regarding healthcare and biopharmaceutical industry could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies that will affect the biopharmaceutical industry, including measures which may result in more rigorous coverage criteria and downward pressure on the price that we set for any approved product. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Recently, the Chinese government announced that they would further promote the reform of the drug purchase system and expand the centralized drug purchase program, which may result in a material adverse effect on drug prices.

Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may set limitations on our manufacturing and marketing activities, and we may incur additional costs and devote substantial resources to comply with such requirements.

Any product candidates we may eventually commercialize will remain subject to extensive ongoing regulation in China, the United States, and other jurisdictions, including requirements covering manufacturing, labeling, packaging, storage, promotion and advertising, sampling, record-keeping, post-marketing studies, and ongoing submissions of safety, efficacy, and other post-market data. Our manufacturing operations must comply with stringent GMP and related quality system requirements, including but not limited to quality control, documentation, reporting, and routine inspections, which requires significant time and expense. Promotional activities are generally limited to approved indications and label use, which may constrain commercial potential, and approvals may impose costly post-marketing surveillance and studies as well as continued compliance with GMP and GCP for any post-approval trials, increasing costs and potentially adversely affecting our results of operations and financial condition.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURE OF OUR PRODUCT CANDIDATES

If we experience material delays in obtaining, regulatory approvals from the NMPA, the FDA and other comparable regulatory authorities for our product candidates, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

The regulatory approval process, especially for novel products, including gene therapy-related candidates, is lengthy, costly, and inherently unpredictable, and outcomes depend in significant part on regulators’ determination. Authorities may require additional non-clinical or clinical data, mandate protocol changes, or delay acceptance, review, or approval of our submissions, which could increase development time, cost, and complexity

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and may force us to suspend or abandon programs. Trial delays can also postpone or reduce commercialization opportunities and may ultimately result in approval denial.

We have limited experience obtaining marketing approvals, and requirements differ across jurisdictions. Data from one country may not be accepted in another, and approval in one market does not ensure approval elsewhere, potentially requiring additional studies. Even after approval, certain manufacturing or labeling changes may need further regulatory review, and approvals may be withdrawn. Any inability to secure approvals or approvals with significant limitations could shrink our addressable markets which could in turn impair our ability to generate revenue, obtain sufficient funding and continue the development of our other product candidates.

One of our Core Product candidates EXG001-307 (SMA Type 1) targets the treatment of SMA Type 1, a rare disease with a relatively smaller patient population and lower prevalence rate, may constrain our commercial opportunity and adversely affect our results of operations.

One of our Core Product candidates EXG001-307 (SMA Type 1) is a differentiated product candidate for the treatment of SMA Type 1, which is a rare disease with a relatively smaller patient population and lower prevalence. As a result, the addressable market for our Core Product candidate EXG001-307 (SMA Type 1) may be inherently limited and may be smaller than we expect. The number of patients who can be identified, diagnosed and referred for treatment may be constrained by factors such as the availability and uptake of newborn screening and genetic testing, variations in diagnostic practices, geographic dispersion of patients and the limited number of specialized treatment centers. Even where patients are identified, actual treatment penetration may be affected by patient eligibility and disease characteristics, physician and patient preference, competitive therapies, and, importantly, pricing, reimbursement and broader payer coverage decisions, given that gene therapies can be costly. If the realized treatable patient pool, treatment uptake, or reimbursement access is lower than anticipated, we may not achieve our expected sales volumes or revenue growth, our results of operations could be materially and adversely affected.

We have no experience in launching or marketing products. If we are unable to establish adequate marketing and sales capabilities, or to effectively build and manage our sales network, we may not be able to generate revenue from our product candidates after they are approved for marketing.

We have not yet demonstrated an ability to launch and commercialize any of our product candidates. As a result, our ability to successfully commercialize our product candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing product candidates.

We are formulating commercialization plans for our product candidates, and we plan to develop internal sales and marketing capabilities for our product candidates. However, as currently there is no approved gene therapy for the treatment of SMA in China, we may face a greater risk as compared to commercializing other types of therapeutic solutions that have achieved wide market acceptance. In addition, assembling an in-house marketing organization and sales force, or establishing effective external marketing channels through distributors or CSOs, may require us to compete for talents with more established competitors as well as incurring significant capital expenditures, management resources and time.

We may also pursue collaborative arrangements regarding the sales and marketing of our product candidates. We may have little or no control over the marketing and sales efforts of such third parties. We cannot assure you that we will be able to establish or maintain relationships with third-party collaborators to successfully commercialize our product candidates, and as a result, we may not be able to generate product revenue.

Our projections of the number of patients who have the potential to benefit from treatment with our product candidates are based on our beliefs and estimates derived from a variety of sources, which may prove to be incorrect. The potentially addressable patient population and market size for our product candidates may be smaller than our estimates.

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Furthermore, there is no guarantee that any of our product candidates, even if approved, would be approved for the line of therapy we are aiming for. For example, certain therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments received. For indications with well-established standard of care therapies, the NMPA, the FDA and other comparable regulatory authorities may approve new therapies initially only for later lines of therapy. As a result, even if we obtain market approval for our product 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.

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 financial results.

Regulatory requirements for approval, pricing, and reimbursement vary significantly by country, and in some markets, a drug’s sale price must be approved before it can be marketed or remains subject to ongoing government control after approval. As a result, we may obtain regulatory approval but still face pricing reviews or price caps that delay commercialization and reduce revenue, which could limit our ability to recoup development investments. The Opinions of the State Council on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) issued by the PRC State Council in August 2015 requires that enterprises applying for new drug approval undertake that the selling price of a new drug in the PRC market shall not be higher than the comparable market prices of the product in its country of origin or the PRC’s neighboring markets, as applicable.

Our commercial success will also depend on the availability and level of reimbursement from government programs and private payors, which determine coverage and payment rates and increasingly pursue cost-containment measures that restrict coverage and pressure prices. In China, demand for a product is often heavily influenced by whether it is included in the National Reimbursement Drug List (the “NRDL”) or provincial reimbursement catalogs and by any usage restrictions, and listing decisions and subsequent revisions depend on multiple factors, such as clinical need, safety, efficacy, utilization, and price, many of which are outside our control. We cannot assure you that our products will be listed, remain listed in the reimbursement catalogs, or maintain favorable reimbursement terms. Reimbursement may be delayed, may be narrower than the approved label, and may not cover our full costs, and interim or provisional payments may be inadequate or not made permanent. Payment rates can vary by indication, setting of care, and benchmarks against lower-cost alternatives, and net prices may be further reduced by required discounts, rebates, or other concessions demanded by government programs or private payors. If we cannot secure timely coverage and commercially reasonable reimbursement, we may be unable to successfully or profitably commercialize our products, which could materially and adversely affect our business, operating results, and financial condition.

Our future approved product candidates may fail to achieve or maintain the degree of market acceptance by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community necessary for commercial success.

Even if we obtain regulatory approval for commercialization of our current or future product candidates, such drug products may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. If our drug products do not achieve an adequate level of acceptance, the commercialization of such drug products may become less successful or profitable than we had expected. Market acceptance of any approved products will depend on multiple factors, including the indications approved and any labeling limitations or warnings, perceptions of safety and efficacy among physicians, hospitals, and patients, and the product’s potential advantages over alternative therapies. Adoption may also be affected by the incidence and severity of side effects, the timing of launch relative to competitors, convenience and ease of administration, and publicity about our products or competing treatments. In addition, pricing and affordability, including price

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controls, NRDL or PRDL negotiations, reimbursement availability, and patients’ willingness to pay out of pocket, together with the effectiveness of our sales and marketing efforts, will materially influence demand. If any approved product candidates that we commercialize in the future fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centers or others in the medical community, we will not be able to generate revenue as we expect. Our failure to achieve or maintain market acceptance for our future approved product candidates would materially adversely affect our business, financial condition, results of operations and prospects.

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ product candidates. Any such guidelines, recommendations or studies that reflect negatively on our product candidates, either directly or relative to our competitive product candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our product candidates. Furthermore, our success depends in part on our, or our partners’ ability to educate healthcare providers and patients about our product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties’ guidelines, recommendations or studies. As a result, our business, reputation, financial condition and results of operations could be adversely affected.

The manufacturing process of biopharmaceutical products is highly complex, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

As of the Latest Practicable Date, we had not commercialized any product candidates. As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process, in part due to strict regulatory requirements. We cannot assure you that issues relating to the manufacturing of our product candidates will not occur in the future.

Issues may arise during the manufacturing process for reasons including: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, (iii) problems with raw materials, (iv) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (v) changes in the type of products produced, (vi) advances in manufacturing techniques, (vii) physical limitations that could inhibit continuous supply, and (viii) the occurrence of natural disasters. If problems arise during the production process of future products, one or more batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and supply of quality materials and products in sufficient quantities and at acceptable quality and price levels for our drug development and commercialization needs.

To date, we have relied primarily on third-party service providers, including CDMOs, to manufacture our product candidates. See “Business — Manufacturing” for details. Going forward, we intend to continue to engage third-party CDMOs to manufacture our product candidates for our research and development activities and commercial sales, while gradually re-establishing our in-house manufacturing capabilities. Our reliance on third-party CDMOs exposes us to risks including: limited availability of qualified manufacturers; capacity constraints affecting production timelines; regulatory compliance issues beyond our control; potential failures in manufacturing quality, quantity, or timelines; improper execution of

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procedures or breach of agreements; inadequate protection of our intellectual property or infringement of third-party rights; supplier substitution difficulties; and supply chain disruptions from weather events or disasters. In addition, during the Track Record Period, we and our CDMO relied on third parties to supply certain raw materials and products used in our research and development and clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our product candidates. Any disruption in production or the inability of our suppliers or suppliers of our CDMO to provide adequate quantities to meet our or our CDMO's needs could impair our operations and the research and development of our product candidates. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our product candidates, but there is no assurance that current suppliers have the capacity to meet our demand. The quality of the raw materials procured and products manufactured by our CDMO will depend significantly on the effectiveness of our quality control and quality assurance and that of our CDMO. We cannot assure you that these quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, jeopardize our drug approvals or licenses and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

We engage CROs to conduct clinical trials. If the CROs do not successfully carry out their contractual duties, comply with good clinical practice and ethical standards of clinical trial conduct, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed.

We rely on third-party CROs to conduct clinical trials in North America and China. While we remain responsible for ensuring compliance with applicable protocols, GCP regulations, and scientific standards enforced by the FDA, NMPA, and other regulatory authorities, we cannot fully control our CROs' performance. Non-compliance by our CROs or clinical investigators may render clinical data unreliable, requiring additional trials and delaying regulatory approval.

Our reliance on third-party CROs exposes us to risks including: difficulty replacing CROs on commercially reasonable terms; lack of control over CROs' resource allocation; potential protocol deviations or data quality issues causing trial delays, extensions, or termination; and challenges in obtaining regulatory approval or commercializing products. Switching or adding CROs increases costs and delays, which may potentially affect our clinical timelines, business operations, financial condition, and revenue generation ability.

We rely, and expect to continue to rely, on independent principal investigators and other third parties to conduct the clinical trials for our product candidates. We do not have full control over the conduct of such trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We rely on top-tier hospitals and independent principal investigators in China, the United States and other regions to conduct clinical trials, including both investigator-initiated trials and clinical trials initiated by us. Termination of these arrangements for any reason, including third-party performance failures, would delay product development. Principal investigator misconduct or reputation issues, even if unrelated to our trials, may delay trials, affect regulatory perception of data reliability, and damage our reputation. While we use investigator-initiated trials to expedite development, regulatory authorities may not accept such data.

Our reliance on third parties, particularly in investigator-initiated trials, limits our control over trial conduct, investigator behavior, and data integrity, though we remain responsible for compliance with investigational plans, protocols, and regulations. Our reliance on independent principal investigators and other third parties to conduct the clinical trials

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exposes us to risks, including but not limited to missed deadlines, protocol deviations, patient safety issues, communication difficulties, procedural delays, and data interpretation differences, all of which may potentially harm our product candidates’ prospects. We must comply with GLP and GCP standards for conducting, recording, and reporting preclinical and clinical trials, and register trials and post results within required timeframes. Non-compliance by third parties may result in regulatory refusal, enforcement actions, sanctions, and adverse publicity.

Additionally, principal investigators serving as our advisors or consultants may create perceived or actual conflicts of interest. If regulatory authorities question these financial relationships, trial data integrity may be compromised, which may potentially cause delays or rejections that prevent commercialization of our product candidates.

Risks Relating to Our Intellectual Property Rights

If we are unable to obtain, maintain and defend adequate intellectual property protection for our product candidates and technologies, our business may be materially and adversely affected.

If we are unable to obtain, maintain and enforce adequate patent and other intellectual property protection for our product candidates and technologies, or if the scope of such intellectual property rights is not sufficiently broad, third parties may be able to develop and commercialize products, product candidates or technologies that are similar to or competitive with ours and compete directly against us, which could adversely affect our competitive position and our ability to successfully develop and commercialize any of our product candidates or technologies. In addition, if the terms of our patents expire before, or shortly after, any of our product candidates obtain regulatory approval, or if competitors successfully challenge the validity, enforceability or scope of our patents or other intellectual property rights, we may not be able to prevent others from marketing competing products, which could materially harm our business, financial condition and results of operations. Further, our intellectual property rights may be subject to priority disputes, inventorship disputes and similar proceedings, including inter partes, opposition, derivation, interference or other administrative and judicial proceedings. If we are unsuccessful in any such proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of one or more of the product candidates we may develop, any of which could have a material adverse impact on our business.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming, and unsuccessful, leading our patent or other intellectual property rights to be found invalid or unenforceable, and could prevent us from developing or commercializing our product candidates, or delay the development or commercialization process.

We may become involved in lawsuits, claims, oppositions, invalidation actions or other proceedings to protect, enforce or defend our intellectual property rights, which could be expensive and time-consuming, divert management attention and other resources, and may not be successful. In the course of such proceedings, our patents or other intellectual property rights could be challenged and found to be invalid, unenforceable, narrowed in scope or otherwise not to provide meaningful protection, which could adversely affect our ability to maintain our competitive position and to commercialize our product candidates. In addition, third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, and the outcome of any such proceedings is inherently uncertain. Defending against these claims could require significant financial and managerial resources, and could result in injunctions or other relief that may prevent us from developing or commercializing our product candidates, or could otherwise delay, disrupt or increase the cost of our development and commercialization efforts. During the Track Record Period, Shanghai Jiayin filed a lawsuit with the Suzhou Court, alleging that the inclusion of the words “嘉因” and “嘉因生物” in the enterprise name of Hangzhou Jiayin constitutes trademark infringement and unfair competition, and seeking damages of RMB60.0 million. As of the Latest Practicable Date, the case had not commenced trial. Please refer to “Business — Legal Proceedings and Compliance — Legal Proceedings” for details.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, USPTO, and various other patent agencies 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 failure to respond to examination reports or office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, result of operations and prospects.

We rely substantially on our trade secrets and other confidential information, including unpatented know-how, and if we are unable to successfully protect the confidentiality of our trade secrets, information and know-how, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors 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 patents, we rely on trade secrets, confidential information, and unpatented know-how to maintain our competitive position. We use non-disclosure and confidentiality agreements with employees, collaborators, contract manufacturers, and third parties to protect such information. However, we cannot prevent unauthorized disclosure or use, and monitoring violations is difficult. Parties may breach agreements without adequate remedies available to us, potentially resulting in loss of trade secrets and competitive use by third parties. We cannot guarantee agreements exist with all parties who have accessed our confidential information. Enforcing trade secret claims is difficult, expensive, time-consuming, and has unpredictable outcomes. If competitors lawfully obtain or independently develop our trade secrets, we have no legal recourse to prevent their competitive use, which may harm our competitive position.

Furthermore, some of our employees were previously employed at other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, executed proprietary rights, non-disclosure or non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. Inability to incorporate or enforce such intellectual property rights would harm our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates and technologies, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

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In addition, we may be unsuccessful in executing agreements assigning intellectual property to us with each party who in fact, conceives inventions or develops technologies or intellectual property that we regard as our own. Furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting our ownership of inventions developed by that individual. 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 any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable.

The issuance of a patent does not guarantee inventorship, scope, validity, or enforceability, and our patent rights may be challenged in courts or patent offices. We face potential claims from former employees or third parties regarding ownership interests, and may become involved in opposition, derivation, revocation, reexamination, post-grant review, inter partes review, or interference proceedings. Unsuccessful outcomes could result in loss of patent rights, narrowed, invalidated, or unenforceable claims, loss of exclusive ownership and requirements to obtain third-party licenses that may be unavailable, commercially unreasonable, or non-exclusive. Without such licenses, we may need to cease development, manufacturing, or commercialization of product candidates. Loss of exclusivity or narrowed claims would limit our ability to prevent competitive use of similar or identical drugs, materially adversely affecting our business, financial condition, operations, and prospects. Even successful disputes impose substantial costs and management distraction.

Any of our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from CNIPA or made a misleading statement, during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate.

Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Any loss of patent protection could have a material adverse impact on our business. On the other hand, if third parties file counterclaims against us, we may need to exert significant time and expenses to defend such counterclaims, and failure to successfully defend counterclaims could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

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

We own a number of trademarks and trademark applications. Our registered or unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among medical professionals, patients, potential partners and other relevant parties in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market

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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 unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective, could divert management attention and our limited resources from other more productive activities, or result in substantial costs. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

Our future programs may involve additional product candidates that may require the use of proprietary rights held by third parties, and we may need to acquire and maintain licenses or other rights to use these proprietary rights. However, we may be unable to acquire or in-license any compositions, methods of use or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

Intellectual property rights do not necessarily address all potential threats.

Our intellectual property rights have inherent limitations and may not adequately protect our business or maintain competitive advantage. Risks faced by us include: others making similar products or using similar technologies not covered by our patents; licensors or us potentially not being first to invent or file patent applications; independent development of similar technologies without infringement; pending applications not resulting in issued patents; granted patents providing no competitive advantage or being invalidated through legal challenges; competitors conducting R&D in jurisdictions lacking our patent coverage and using resulting information in our major markets; patents expiring before or shortly after product commercialization due to the gap between patent grant and marketing approval; failure to develop additional patentable technologies; harm from third-party patents; and third parties potentially patenting trade secrets or know-how we chose not to patent. Any of these events could materially adversely affect our business, financial condition, operations, and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION AND OUR NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since our inception, and we anticipate that we will continue to incur net losses for the foreseeable future and may not achieve or maintain profitability.

As of the Latest Practicable Date, none of our product candidates had been approved for commercial sale by any relevant regulatory authorities, and therefore we had not generated

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any revenue from sale of our product candidates. We are not profitable and have incurred losses and net operating cash outflows in each year since our inception. For the years ended December 31, 2024 and 2025, we recorded losses of RMB219.8 million and RMB826.9 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs, clinical trials, CMC, and from administrative expenses associated with our operations. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our research and development of, and seek regulatory approvals for, our product candidates, and build up our commercialization and sales workforce in anticipation of the future roll-out of our product candidates.

Gene therapy and oligonucleotide product development requires substantial capital expenditures and considerable time from initial stages to patient treatment. Future net losses depend on the number and scope of development programs, associated costs, commercialization expenses, and revenue generation ability. Achieving profitability requires successfully completing preclinical studies and clinical trials, obtaining regulatory approval, manufacturing, marketing and selling approved products, and developing additional candidates. We may never succeed in these activities or generate sufficient revenue for profitability. Even with successful commercialization, we expect continued losses due to substantial R&D expenditures, public company operating costs, and growth-related expenses. Unforeseen expenses, difficulties, complications, and delays may adversely affect our business. Historical and expected losses may adversely affect shareholders' equity and working capital. Due to uncertainties in research, development, manufacturing, delivery, and commercialization of complex therapies, we cannot predict timing or amount of expenses or when profitability may occur. Even if achieved, sustained profitability is uncertain. Failure to achieve or maintain profitability would depress share value, impair capital raising ability, limit business expansion, constrain R&D efforts and commercialization plans, and potentially threaten operations, potentially causing total or partial investment loss.

We had net operating cash outflow and recorded net current liabilities and net liabilities during the Track Record Period.

We had net cash used in operating activities of RMB67.6 million and RMB71.8 million for the years ended December 31, 2024 and 2025, respectively, and record net current liabilities of RMB1,599.9 million and RMB2,344.4 million as of December 31, 2024 and 2025, respectively. We record net liabilities of RMB1,491.6 million and RMB2,293.4 million as of December 31, 2024 and 2025, respectively. If we continue to experience net operating cash outflows, net current liabilities and net liabilities, we may be unable to maintain adequate working capital, we may default on our payment obligations and may not be able to meet our operating cash and capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

The discontinuation of any government grants or preferential tax treatment currently available to us may adversely affect our business, financial condition and results of operations.

We have historically benefited from government grants and other preferential policies as incentives for drug research and development activities and other development activities. We recorded government grants of RMB44.7 million and RMB4.4 million for the years ended December 31, 2024 and 2025, respectively. The fluctuation in government grants was primarily attributable to (i) the Group's receipt in 2024 of the full amount of special support policy 11i subsidies for the period of 2022 in an aggregate amount of RMB27,009,000, together with technology-specific incentive awards of RMB13,657,000, while (ii) in 2025, the Group only received a partial amount of “special support policy” subsidies for the period of 2023 in an amount of RMB1,513,000. In addition, we have benefited from the VAT refund policy. The local government authorities have the discretion to determine the timing, amount and criteria of such financial incentives. We generally do not have the ability to influence local government authorities in making these decisions. Local authorities may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including

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compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, otherwise we may be deprived of all or part of the incentives, which may have an adverse effect on our business, financial condition and results of operations.

Raising additional capital may cause dilution to our shareholders, restrict our operations or, when licensing of intellectual property rights is deployed as a means of financing our operations, require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

We adopted the Pre-[REDACTED] Equity Incentive Plan for the benefit of our employees to incentivize and reward the eligible persons who have contributed to the success of our Group. For further details, see “Appendix IV — Statutory and General Information — D. Pre-[REDACTED] Equity Incentive Plan” in this document. For the years ended December 31, 2024 and 2025, we incurred RMB37.8 million and RMB25.2 million, respectively, in share-based compensation expenses. To further incentivize our employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your investment.

The value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. A substantial amount of our operating costs and our financial assets are denominated in RMB and USD. However, the [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rate of the Hong Kong dollar against RMB, of the Hong Kong dollar against USD, or of RMB against USD may give rise to foreign exchange gains or losses that would impact our results of operations, and any significant change in value of Hong Kong dollar against RMB or of Hong Kong dollar against USD may materially and adversely affect the value of, and any dividends payable on, our Shares in Hong Kong dollars.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, motivate and retain highly qualified and skilled personnel.

We are highly dependent on the principal members of our management and scientific teams. The employment agreements with our executive officers do not prevent our executives

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from terminating their employment with us at any time. We do not maintain key-person insurance for any of our executives or other employees and we currently do not plan to purchase key-person insurance in the near future which is in line with what we believe is the biotech industry norm. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Our future success depends on attracting qualified employees and retaining key personnel, particularly drug development and technology professionals. Intense competition exists for skilled management, technical, and sales personnel in our office locations. Increasing headcount and retention may substantially raise compensation costs, including stock-based compensation. We must offer competitive packages and quality work environments. Hiring talents from competitors may trigger allegations of improper solicitation or disclosure of confidential information. Failure to retain existing employees or attract qualified candidates for critical positions could impair effective business management, including research and development, marketing, and sales, which may adversely affect our business, operating results, financial condition, and share price.

Our reputation is key to our business success. Negative publicity and allegations involving us, our Shareholders, Directors, officers or employees may adversely affect our reputation, business and growth prospects.

Any negative publicity concerning us, our affiliates such as our Shareholders, Directors, officers, employees, or any entity that shares the “Exegenesis” name, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicities about us or any of our affiliates or any entity that shares the “Exegenesis” name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. In addition, referrals and word of mouth have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us or any of our affiliates or any entity that shares the “Exegenesis” name could adversely affect our ability to maintain our existing collaboration arrangements or attract new partners.

We are or may become subject to a variety of privacy and data security laws, policies and contractual obligations, and failure of our third-party vendors or contractors to comply with them could harm our business.

We collect, generate, maintain, and process sensitive information including confidential business data, personal information, and health data from preclinical and clinical studies and employees. Third-party vendors and contractors also process such information on our behalf. Non-compliance by third parties could result in enforcement actions including fines, imprisonment of officials, public censure, damage claims, reputational harm, and goodwill loss, which may materially adversely affect our business, financial condition, operations, and prospects.

Data protection law interpretation and application in China and elsewhere are uncertain and evolving. Governments frequently amend existing laws and implement new regulations, requiring ongoing attention to changing requirements. We cannot determine the impact of future data privacy and security laws and regulations. New laws, amendments, or reinterpretations may increase costs and restrict operations. Uncertain, contradictory, and evolving interpretation and application of health-related and data protection laws may result in inconsistent application with our practices, and compliance efforts may fail. This could trigger government fines or orders requiring practice changes, adversely affecting our business. Privacy regulations vary by country, and our operations may not comply with each jurisdiction’s requirements.

Any future litigation, legal disputes, claims or administrative proceedings against us could be costly and time-consuming to defend.

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement

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activity. Litigation to which we subsequently become a party might result in substantial costs and divert management’s attention, time and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake, and the parties involved.

Our insurance might not cover claims brought against us, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if the claim is outside the scope of the indemnification arrangement we have with our collaborators, our collaborators do not abide by the indemnification arrangement as required, or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

We may not be able to renew our current leases or locate desirable alternatives for our offices and laboratories.

We lease properties for our offices and laboratories in China and the U.S.. See “Business — Land and Properties.” We may not be able to extend or renew such leases on commercially reasonable terms, or if at all, as we will have to compete with other businesses for premises at desired locations. Rental payments may significantly increase as a result of high demand for the leased properties. Moreover, we may not be able to extend or renew such leases upon expiration of the current term and may therefore be forced to relocate the affected operations. This could disrupt our operations and result in significant relocation expenses. We may not be able to locate desirable alternative sites for our offices and laboratories. The occurrence of such events could materially and adversely affect our business, financial condition, results of operations and prospects.

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

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns between China and other countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China’s political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flows and prospects. Rising trade and political tensions, as well as changes in relevant government policies could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions. For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo entitled the “America First Investment Policy” (the “**America First Memo**”), outlining the ongoing review and consideration of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, and directed energy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments and other limited partner investors. Such political tensions and policy changes would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

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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, CROs and CDMOs, 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 product candidates as planned or within budget, which could materially adversely affect our business, financial condition and results of operations. In particular, if any new tariffs, legislation and/or regulations, including the recently proposed BIOSECURE Act aiming at discouraging federal funding to, and contracting with, entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies, are implemented, or if existing trade agreements are renegotiated, such changes could limit our ability to expand into certain markets and have an adverse effect on our business, financial condition and results of operations. In addition, our results of operations could be adversely affected if any such tensions or unfavorable government trade policies harm the Chinese economy or the global economy in general.

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

We face significant competition seeking appropriate partners, and negotiations are time-consuming and complex. We may fail to identify suitable partners or establish partnerships because candidates may be deemed too early-stage for collaboration, or third parties may question their safety, efficacy potential, or commercial viability. Collaborating with third parties requires relinquishing some or all control over product candidate success. We may face non-compete provisions with licensors or partners, limiting our ability to compete or pursue new opportunities. In-licensing candidates from third parties involves competition from better-resourced biopharmaceutical companies, and agreements may not deliver anticipated benefits.

Third-party collaborations carry additional risks. Disputes may delay or terminate research, development, or commercialization, or result in costly litigation or arbitration diverting management attention and resources. Collaborations may be terminated with adverse effects on product candidate development or commercialization.

We may fail to realize collaboration, partnership, or licensing benefits if we are unable to successfully integrate products with existing operations and culture, which may delay timelines or adversely affect our business. We cannot ensure post-transaction revenue or net income will justify transactions. Without timely agreements on acceptable terms, we may curtail candidate development, reduce or delay development programs, delay commercialization, reduce sales or marketing scope, or increase expenditures undertaking activities independently. Independent development or commercialization requires additional expertise and capital, which may be unavailable on acceptable terms or at all. Failure to enter collaborations without sufficient funds or expertise for necessary activities may materially adversely impact business prospects, financial condition, and results of operations.

RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

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

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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.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data 《科學數據管理辦法》, or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, 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. Currently, as the term “state secret” is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, in particular when coordination and information exchange with our Houston office is pivotal, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to specific administrative penalties imposed by those government authorities.

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, and 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.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its 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 subsidiary is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a our PRC subsidiary may allocate a portion of its after-tax profits based on PRC accounting standards to a discretionary reserve fund, or a staff welfare and bonus fund. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which currently anticipates.

The Enterprise Income Tax Law (中華人民共和國企業所得稅法) and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.

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Pursuant to the Arrangement Between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income, or the “Hong Kong Tax Treaty” (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income, and our Hong Kong subsidiary directly holds a 25% or greater interest in our PRC subsidiary throughout the 12 months prior to receiving the dividends. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (關於稅收協定中“受益所有人”有關問題的公告), also known as SAT Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to SAT Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

There are regulations restricting the conversion of foreign currencies into RMB in China and, in certain cases, the remittance of currency out of China. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

We are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. We cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes could have an adverse effect on our business, financial condition and results of operations.

Our business benefits from certain tax preferences, financial incentives and preferential policies granted by local governments. Expiration of, or changes to, these incentives, tax preferences or policies would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not

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have the ability to influence local governments in making these decisions. Governments authorities may decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations. In addition, according to relevant PRC tax laws and regulations, enterprises in the PRC are entitled to tax preferences when certain requirements and qualifications are satisfied. Our relevant PRC subsidiaries may not continue to be entitled to relevant tax preferences if relevant tax preferences expire or the relevant PRC subsidiaries fail to continue to satisfy certain requirements and qualifications. For example, enterprises in the PRC qualified as “high and new technology enterprises” are entitled to a preferential rate of 15%. CARsgen Therapeutics currently qualifies as a “high and new technology enterprise” until November 2023. If any of our PRC subsidiaries fails to continue to enjoy such tax preferences, financial incentives or preferential policies in the future, tax expenses would increase, which may have a material adverse effect on our results of operations.

It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.

Most of our operating subsidiaries are incorporated in China. Some of our management reside in China from time to time. Almost all of our assets are located in China. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the “Arrangement”), pursuant to which a party with an enforceable final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with an enforceable final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong.

On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), which has come into effect on January 29, 2024 and superseded the Arrangement, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

Any failure by the Shareholders or beneficial owners of our Shares to comply with PRC foreign exchange or other regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities,

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including Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by domestic Residents in China via Special-Purpose Companies (關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知), or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (國家外匯管理局關於發佈境內機構境外直接投資外匯管理規定的通知) (SAFE Circular 30) and other regulations, if our shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

We may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other regulations. We cannot assure you that all of our Shareholders or beneficiaries will at all times comply with, or in the future make or obtain all applicable registrations or approvals required by SAFE rules or other regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

We are subject to PRC laws and regulations relating to indirect transfers by a non-resident enterprise of assets of a PRC resident enterprise.

On February 3, 2015, the PRC State Administration of Taxation, or the SAT, issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (關於非居民企業間接轉讓財產企業所得稅若干問題的公告), or SAT Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (關於加強非居民企業股權轉讓所得企業所得稅管理的通知), or SAT Circular 698, which was previously issued by the State Administration of Taxation on December 10, 2009, as well as certain other rules providing clarification on SAT Circular 698. SAT Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities' scrutiny over,

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indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets.

For example, SAT Circular 7 specifies that when a non-resident enterprise transfers PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company which directly or indirectly holds such PRC Taxable Assets, the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purpose.

Except as provided in SAT Circular 7, transfers of PRC Taxable Assets under the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the value of the equity interest of the overseas enterprise is directly or indirectly attributable to the PRC Taxable Assets; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of PRC Taxable Assets, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of PRC Taxable Assets; (iii) the overseas enterprise and its subsidiaries directly or indirectly hold PRC Taxable Assets and have registered with the relevant authorities in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

SAT Circular 7 contains certain exemptions. However, it remains unclear whether any exemptions under SAT Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will, at their discretion, reclassify such transactions by applying SAT Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

Provisions of SAT Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for SAT Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the SAT Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this document and the [REDACTED]” in this document, potential investors should consult their professional advisors if they are in any doubt as to the tax implications of subscribing for, purchasing, holding, disposing of and dealing in the Shares.

Under China’s Enterprise Income Tax Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under China’s Enterprise Income Tax Law, or the “EIT Law,” an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. A tax circular issued by the SAT on April 22, 2009, or SAT

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Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, SAT Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more than half of senior management or directors having voting rights. On July 27, 2011, the SAT issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (境外註冊中資控股居民企業所得稅管理辦法(試行)), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of SAT Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

The SAT may take the view that the determining criteria set forth in SAT Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow.

Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiaries, which could restrict our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.

There are regulations restricting the conversion of foreign currencies into RMB in China. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with certain government authorities, including the State Administration for Market Regulation (“SAMR”) through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) and the SAFE.

In August 2008, SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign Invested Enterprises (國家外匯管理局綜合司關於完善外商投資企業外匯資金支付結匯管理有關業務操作問題的通知), or SAFE Circular 142, providing that the Renminbi capital converted from foreign-currency-registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC.

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On March 30, 2015, SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知), or SAFE Circular 19, which came into force and superseded SAFE Circular 142 from June 1, 2015. On June 9, 2016, SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (關於改革和規範資本項目結匯管理政策的通知), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions under SAFE Circular 142 are expected to be lifted. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

The Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (關於外國投資者併購境內企業的規定), or the M&A Rules, and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. The M&A Rules require that the Ministry of Commerce, or the MOFCOM, be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

The Anti-Monopoly Law (中華人民共和國反壟斷法) promulgated by the Standing Committee of the National People's Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with MOFCOM. Without the clearance from MOFCOM, no concentration of undertakings shall be implemented and effected. Mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold under the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, (關於經營者集中申報標準的規定) or the Prior Notification Rules, issued by the State Council in August 2008 is triggered.

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises, issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors relating to national security are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions.

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We cannot preclude the possibility that the MOFCOM or other government agencies may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

Failure to comply with relevant regulations relating to social insurance and the housing provident fund may subject us to penalties and adversely affect our business, financial condition, results of operations and prospects.

PRC laws and regulations require us to pay several statutory social welfare benefits for our employees, including social insurance and housing provident funds. The amounts of our contributions for our employees under such schemes are calculated based on certain percentage of salaries, including bonuses and allowances, up to a maximum amount specified by the local government from time to time at locations where we operate. For details relating to the relevant laws and regulations, see “Regulatory Overview.”

During the Track Record Period, we did not make full payment for social insurance and housing provident fund contributions for a few employees. In addition, the required contribution under the relevant laws to some of our employees were paid by third parties on behalf of the relevant subsidiaries of the Company. If the local governments determine the payment from the third-party payors are invalid or the third-parties failed to make the required contributions, we may be ultimately liable for the unpaid social insurance contribution and fines and penalties associated with the non-compliance. We cannot assure you that we will not be subject to any order in the future to rectify such non-compliance or that there will not be any employee complaints or claims regarding social insurance payments or housing provident fund contributions made against us. We may also incur additional costs to comply with such laws and regulations by the PRC Government or relevant local authorities. Any such payment could adversely affect our business, financial condition, results of operations and prospects.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares, an active trading market for our Shares may not develop and the market price for our Shares may decline.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (for itself and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will not decline following the [REDACTED].

The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting

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the biopharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

Future sales or perceived sales of our Shares in the [REDACTED] market by major Shareholders following the [REDACTED] could materially and adversely affect the price of our Shares.

Prior to the [REDACTED], there has not been a [REDACTED] market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing market price of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the [REDACTED] market or the perception that these sales may occur could significantly decrease the prevailing market price of our Shares and our ability to raise equity capital in the future.

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

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

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

Under Rule 18A.10 of the Listing Rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or any series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Rule 18A.10. If some investors find our Shares less attractive as a result of our limited capability to conduct relevant transactions or arrangements, there may be a less active [REDACTED] market for our Shares and our share price may be more volatile. 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.

RISK FACTORS

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles of Association and by the Cayman Companies Act and the common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III — Summary of the Constitution of our Company and Company Law of the Cayman Islands” in this document.

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Controlling Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

Facts, forecasts and statistics in this document relating to the biopharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the biopharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of this information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. 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. The information from official government sources has not been independently verified by us, the Sole Sponsor, [REDACTED] or any other party involved in the [REDACTED] and no representation is given as to its accuracy. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the biopharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

RISK FACTORS

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your investment decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to invest in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].