

## RISK FACTORS

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

*The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] price of our Shares could decline, and you may lose all or part of your [REDACTED]. You should seek professional advice from your relevant advisers regarding your prospective [REDACTED] in the context of your particular circumstances.*

### KEY RISKS RELATING TO OUR BUSINESS

**We depend substantially on the success of our drug candidates. If we are unable to successfully complete research and development, obtain regulatory approval and commercialize our drug candidates, or if we experience significant delays in doing any of the foregoing, our business, financial condition, results of operations and prospects will be materially harmed.**

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future. The success of our drug candidates will depend on a number of factors, such as safety and efficacy results from preclinical studies and clinical trials, and competition with other drug products.

Some of our drug candidates represent a potentially new approach to achieve therapeutic needs. For example, we have built a differentiated portfolio of oral small molecule assets, including ECC5004 for obesity/overweight and T2D with vast market potential. Our clinical and preclinical assets, given their novelty and differentiated features, may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Furthermore, a substantial amount of education and training may need to be provided to patients and medical personnel in connection with our drug candidates, which potentially increases our sales and marketing expenses. This may have a material and adverse effect on future profits generated from our drug candidates. We may not be able to generate additional meaningful economic value, taking into consideration the potentially significant efforts to develop our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

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

While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we continue to face competition with respect to our current drug candidates, and any drug candidates that we may seek to develop or commercialize in the future. For instance, our Key Products, ECC5004 and ECC0509, and Core Product, ECC4703, and other pipeline products may face competition from other therapies directed against the same targets and indications and approved for the same target indications upon potential marketing approval in the future.

---

## RISK FACTORS

---

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

**Adverse events could delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved drug, or result in significant negative consequences following any regulatory approval.**

Undesirable adverse events caused by our product candidates, or caused by our product candidates when used in combination with other drugs, could cause significant negative consequences. These may include, among others, delays, interruptions, or termination of clinical trials, regulatory delays, restrictions, or loss of approvals, increased development and compliance costs, changes to product labeling or administration, slower patient enrollment or higher dropout rates; product recalls, litigation, or regulatory investigations, as well as potential harm to our reputation. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, and could significantly harm our business, results of operations and prospects.

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

If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed targets or if they raise safety concerns, we may (i) be subject to substantial liabilities, (ii) be delayed in or even prevented from obtaining regulatory approval for our drug candidates, (iii) obtain approval for indications that are not as broad as intended, (iv) have the product removed from the market after obtaining regulatory approval, (v) be subject to additional post-marketing testing requirements, (vi) be subject to restrictions on how the product is distributed or used, or (vii) be unable to obtain reimbursement for use of the product. In addition, conditional regulatory approval may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn. Having expended a significant amount of capital to progress our product candidates, failure to demonstrate safety and efficacy to the satisfaction of regulatory authorities or to obtain regulatory approval could prevent us from realizing any revenue on such product candidates and materially and adversely affecting our business, financial condition, results of operations and prospects.

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

Besides the continued clinical testing, potential approvals and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to discover or identify additional drug candidates. We cannot guarantee that we will successfully identify potential drug candidates as expected. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have

---

## RISK FACTORS

---

also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential drug candidates. However, there can be no assurance that such license and collaboration will deliver the expected results. We may also invest efforts and resources in potential drug 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.

**We have licensed rights to a third party and may form or seek additional collaborations with third parties in the development, manufacturing and commercialization of our drug candidates, which is subject to various risks.**

Our existing and any future collaboration and licensing arrangements expose us to significant risks, including early termination by our partners, failure to receive anticipated milestone payments and royalties, and limited control over the development and commercialization of our drug candidates in certain territories. We have entered into the AstraZeneca Agreement in November 2023, pursuant to which we granted AstraZeneca exclusive global rights for the development and commercialization of ECC5004 in all territories except Greater China, where we retained the right to co-develop and co-commercialize. We may also form or seek additional collaboration or strategic partnerships with other companies in the future. See “Business — Our Collaboration and Licensing Agreement” for more details on the AstraZeneca Agreement, and “Business — Our Strategies — Maximize the Value of Our Assets Through Accretive Partnerships” for more details on our collaboration and licensing strategies. Our results of operations have been, and may continue to be, affected by our collaboration and licensing arrangements. As a licensor of intellectual property rights to AstraZeneca, and as a potential licensor or collaborator with other third parties in the future, we are subject to a broad range of risks under our existing and any future arrangements.

The AstraZeneca Agreement may be terminated for various reasons, including at AstraZeneca’s sole discretion. If AstraZeneca were to terminate the agreement, we would lose the benefit of AstraZeneca’s development and commercialization capabilities for ECC5004 on a global scale, and there is no guarantee that we would be able to find an alternative partner on comparable terms or at all. Any such termination could materially and adversely affect the development timeline and commercial prospects of ECC5004 and our business as a whole. Similar termination risks may apply to any future collaboration or licensing arrangements we may enter into.

We cannot guarantee that we will receive the milestone payments and royalties contemplated under the AstraZeneca Agreement or any future collaboration or licensing agreements. The receipt of such payments is typically contingent on the achievement of specified clinical, regulatory and commercial milestones, which may not be achieved on the anticipated timeline or at all. Any failure to achieve such milestones, or any dispute with AstraZeneca or future partners regarding the interpretation or satisfaction of milestone conditions, could result in us receiving less consideration than anticipated under the relevant agreement.

The broader global development of ECC5004 in AstraZeneca Territory is led by AstraZeneca, and we are subject to risks arising from AstraZeneca’s development decisions, execution and resource allocation in territories outside Greater China. Any failure by AstraZeneca to conduct development activities in a timely and effective manner, or any disagreement between the parties regarding development strategy or other material matters, could delay or otherwise adversely affect the clinical and regulatory progress of ECC5004. Furthermore, regulatory authorities in different jurisdictions may impose requirements or conditions that neither we nor AstraZeneca anticipated, which could further complicate or delay the development of ECC5004.

AstraZeneca may own or co-own certain intellectual property rights covering ECC5004 or future approved products that result from the collaboration. In such cases, we would not have the exclusive right over such intellectual property, which could limit our ability to develop, commercialize or license ECC5004 independently, regardless of whether the AstraZeneca Agreement remains in effect, is terminated or expires. If AstraZeneca fails to prosecute, maintain, enforce or defend such patents, or loses rights to such patents or patent applications, our rights with respect to ECC5004 could be reduced or eliminated, and our ability to research, develop and

---

## RISK FACTORS

---

commercialize ECC5004 could be adversely affected. In addition, AstraZeneca and any future collaboration partners may themselves rely on third-party collaborators or upstream licenses from third parties in connection with the development and commercialization of ECC5004. We do not have control over such arrangements (if any), and any disruption to AstraZeneca’s or a future partner’s relationships with their own third-party collaborators or licensors could indirectly affect the development and commercialization of our drug candidates. We also rely on AstraZeneca to supply and manufacture ECC5004 for development and future commercialization in the Licensor Territory. We have limited control over AstraZeneca’s manufacturing processes, supply chain arrangements and related decisions. Any failure by AstraZeneca to manufacture ECC5004 in sufficient quantities, in compliance with applicable regulatory requirements, or at an acceptable quality standard, could delay clinical trials, regulatory approvals or commercialization of ECC5004. If AstraZeneca’s manufacturing operations were disrupted for any reason, including regulatory action, equipment failure, natural disasters or supply chain interruptions, our ability to develop and commercialize ECC5004 could be materially and adversely affected. We may not be able to establish alternative manufacturing arrangements in a timely manner or at all, which could further delay the development and commercialization of ECC5004.

Disputes may arise between us and AstraZeneca or any future collaboration partner regarding the interpretation of agreement terms, the allocation of rights and obligations, the conduct of development activities or the ownership of intellectual property. Any such disputes could cause delays or termination of the relevant agreement, or result in costly litigation or arbitration that diverts management attention and resources. Any material and adverse changes to our relationship with AstraZeneca or future partners may affect the technological and financial resources available to us under the relevant arrangements, which could in turn adversely affect our research and development activities and business operations. While we may seek to form additional collaborations or strategic partnerships with other companies to maximize the value of our pipeline assets, there is no guarantee that we will be able to identify suitable partners, negotiate agreements on acceptable terms or maintain productive relationships once established. The failure to enter into or maintain such partnerships could limit our ability to develop and commercialize our drug candidates, and could materially adversely affect our business, financial condition and prospects.

**We have incurred a net loss and experienced net cash outflows from operating activities, and there is no assurance that it will achieve or maintain profitability or positive operating cash flows in the future.**

Investment in the development of biotech products is highly uncertain as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. We have not generated any revenue from commercial product sales to date, and we continue to incur significant research and development costs, and other expenses related to our ongoing operations. As a result, we have incurred net losses of US\$44.6 million in 2025.

Our net losses during the Track Record Period were primarily attributable to expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials. In 2024 and 2025, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were US\$25.0 million and US\$36.8 million, respectively. See “Financial Information — Description of Selected Components of Consolidated Statements of Comprehensive Income” for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing these drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur net losses in the foreseeable future, and that these net losses may increase as we carry out certain activities relating to our development, including, but not limited to, conducting our ongoing and planned research and development activities, scaling up our business to meet the requirements for our R&D activities, clinical trials and potential commercialization, and hiring additional drug discovery, clinical, quality control and administrative personnel.

---

## RISK FACTORS

---

We had operating cash outflows of US\$15.4 million and US\$50.8 million in 2024 and 2025, respectively. We cannot guarantee that we will achieve positive cash flow in the future. The size of our future net losses will depend, among other factors, on the rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter.

**If we are unable to obtain and maintain adequate intellectual property protection for our drug candidates and TRANDD workflow system in relevant jurisdictions our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected.**

Our commercial success depends, to a certain extent, on our ability to protect our proprietary TRANDD workflow system and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights. We seek to protect the drug candidates and technology that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions. See “Business — Intellectual Property” for details of our intellectual property. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biotech companies generally involves complex legal and factual questions, and can be frequently litigated. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not be granted with approvals that effectively prevent third parties from commercializing competitive technologies and drug candidates. The patent examination process may require us or our business partners to narrow the scope of our or our business partners’ current and future patent applications, which may then limit the scope of patent protection that could be obtained.

Even if patents are issued on these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates, or that we may not be successful in preventing unfair competition by third parties throughout the world. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. Our competitors may also be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner. For details, see “— Risks Relating to Our Intellectual Property Rights.”

**We are subject to the risks of doing business globally, which may materially and adversely affect our business and results of operations.**

Our operations are primarily located in the United States and China, coupled with the conduct of clinical trials in various jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, such as changes in a specific country’s or region’s political and cultural climate or economic condition, unexpected changes in laws and regulatory requirements in local jurisdictions and compliance with tax, employment, immigration and labor. Efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert

---

## RISK FACTORS

---

our management’s attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies. The occurrence of any one or more of these risks of doing business internationally, alone or in the aggregate, could materially adversely affect our business and results of operations.

**We may need to obtain additional financing to fund our operations. If we are unable to obtain sufficient financing on terms acceptable to us or at all, we may be unable to complete the development and commercialization of our drug candidates.**

Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. In 2024 and 2025, our total expenses, comprising research and development expenses and general and administrative expenses, were US\$26.8 million and US\$52.9 million, respectively.

To date, we have funded our operations primarily through equity financing, payments received under our collaboration and licensing arrangements and debt financing. For example, we entered into a working capital loan with a PRC bank with a term of one year. For details, see Note 26 to the Accountant’s Report set forth in Appendix I to this document. We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approvals, and we may need to obtain additional financing to fund our operations. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or commercialization for one or more of our drug candidates, and in turn will adversely affect our business prospects.

### RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

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

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

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. In addition, some of our competitors may have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors’ drug candidates, which may further delay our clinical trial enrollments.

---

## RISK FACTORS

---

Subject enrollment for our clinical trials may be affected by a variety of factors, including but not limited to the total size and nature of the relevant patient population, perceived risks and benefits of the drug candidate under study, and our resources to facilitate timely subject enrollment in clinical trials. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

**Results of preclinical studies and early phases of clinical trials may not be predictive of future trial results.**

The results of earlier studies and trials and non-head-to-head analyses of our drug candidates may not be predictive of the results of later-stage clinical trials. There can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, genetic differences, other medications or pre-existing medical conditions, and patient adherence to the dosing regimen. Furthermore, as our drug candidates are developed through preclinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives. Also, for non-head-to-head analyses, the results from clinical trials of one drug cannot be directly compared to those of another. Consequently, such findings may not accurately reflect the overall data. We may adjust our clinical development strategy from time to time based on our evaluation of emerging data to maximize the value of our entire product portfolio. We cannot guarantee that our specific plans will always efficiently anticipate regulatory and market trend shifts or be successfully implemented.

**The data and information we gather or otherwise rely on in our research and development process could be inaccurate or incomplete, which could harm our trial results, reputation and prospect.**

We collect, aggregate, process, and analyze data and information from preclinical studies, clinical trials and other research and development programs. Because data in the healthcare industry is fragmented, inconsistent in format, and incomplete, the overall quality of data is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and data issues and errors are frequently discovered. If mistakes are made in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

In addition, we rely on third parties, including our collaborators, to collect, monitor and manage data for some of the ongoing preclinical and clinical programs for our drug candidates and have limited control over their activities. If there are any inaccuracies, mistakes or incompleteness in the preclinical and clinical data of any of our collaborators, our clinical development activities may be negatively impacted as a result.

**We may be unable to successfully develop or market our drug candidates or may experience significant regulatory delays, if safety, efficacy or other issues arise from any of our drug candidates or from any drugs or medical treatment used, or intended to be used, in combination with our drug candidates.**

We plan to develop certain of our drug candidates for use as a combination therapy. For instance, ECC4703 is being explored in combination with ECC0509 to address both metabolic and inflammatory-fibrotic pathways implicated in MASH, and ECC4703 is additionally being evaluated in combination with a GLP-1 RA for obesity/overweight. We may also seek to develop our drug candidates in combination with other drugs in the future. If safety or efficacy issues arise with such treatments or drugs that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the

---

## RISK FACTORS

---

applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any drugs we use in combination with, we may not be able to complete clinical development of our drug candidates as a combination therapy on our current timeline or within our current budget, or at all.

In addition, we generally have no influence over the availability and pricing of such drugs. If other biotech companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. Such events would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

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

The global biotech market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made significant efforts to develop our core technologies and our proprietary TRANDD workflow system which allows us to continuously develop an integrated pipeline of drug candidates. In 2024 and 2025, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were US\$25.0 million, and US\$36.8 million, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our TRANDD workflow system and drug candidates, and harm our business and prospects.

### RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

**Issued patents could be found invalid or unenforceable if challenged in court or administrative proceedings, potentially harming our competitive position.**

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may be issued in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Defendant counterclaims alleging invalidity or unenforceability are commonplace; a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way

---

## RISK FACTORS

---

that they no longer cover and protect our drugs or drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art 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 our drugs or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

**Obtaining and maintaining our patent protection depends on compliance with various requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

The China National Intellectual Property Administration (the "CNIPA") and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. For instance, periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent, and such non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Such non-compliance events may include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA for confidentiality examination; otherwise the patent right will not be granted, if an application is later filed in China.

**If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed.**

We rely upon patents and other intellectual property rights to protect our drug candidates and technologies. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. The scope of patent protection we obtain, if any, may not exclude others from commercializing products that are similar or the same as our products. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. For example, in the PRC, the term of an invention patent is generally 20 years from the date of filing, and in the United States, the term of a patent is generally 20 years from the earliest non-provisional patent application filing date. Even if patents that cover our drug candidates, their manufacture or use are obtained, once the patent term expires, we may be subject to competition from competitive drugs, including biosimilars.

Because of the amount of time required to develop new drug candidates, test them in clinical trials and conduct regulatory review of any marketing application we submit, the period of commercial exclusivity for any approved drug candidate may be substantially shorter than the patent life. As a result, our patents and patent applications may not provide sufficient rights to exclude others from commercializing products that are similar or the same as our products. Even if patents are issued in respect of our patent applications, we may not have the right to exclude others from making, using, selling, offering for sale or importing products that are the same as or similar to our products, if we do not obtain an exclusive license from any such third-party co-owners of these patents or patent applications. These co-owners may license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co-owners of our patents and patent applications in order to enforce these patents against third parties, and any such co-owners may not cooperate with us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Even if we are eligible to seek certain patent term extensions, we cannot guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and they may refuse to grant extensions or grant more limited extensions than we request. We may

---

## RISK FACTORS

---

not be granted an extension because we failed to exercise due care during the testing phase or regulatory review process, failed to apply within the applicable periods, failed to apply prior to expiration of the relevant patents or failed to otherwise satisfy applicable requirements. Moreover, the length of the extension may be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights with respect to such product would be shortened and our competitors might obtain approval to sell competing products sooner than anticipated. Furthermore, during any patent term extension period, the scope of our exclusionary rights may be limited or may not cover competing products or uses of such products. Therefore, if granted, our revenues from the applicable drug candidates may be reduced, possibly materially.

Manufacturers of generic drugs or biosimilars may challenge the scope, validity or enforceability of our patents in court or at the patent offices, and we may not be successful in enforcing or defending these intellectual property rights, and as a result may not be able to exclusively develop or market the relevant products, which would have a material adverse impact on any potential sales. After our issued patents or patents that may be issued from our pending patent applications expire, we will not be able to assert such patents against potential competitors and our business and results of operations may be adversely affected. On the other hand, if we launch a drug candidate prior to the expiration of any competitive product patents, we may face potential patent infringement claims.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, certain of our employees were previously employed at other biotech companies, including our competitors or potential competitors. Some of these employees might have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We are not aware of any material threatened or pending claims related to these matters or concerning our senior management, but in the future we may be subject to claims that we or these employees or consultants have used or disclosed intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject

---

## RISK FACTORS

---

to injunctive or other equitable relief, which could prevent us from developing and commercializing our drug candidates, or at least delay the development or commercialization process. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

**Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages.**

As intellectual property rights have limitations, they do not necessarily protect us from all potential threats in our competition with other biotech companies. For example, others may be able to manufacture drugs that are similar to our drug candidates or apply similar technology that is not covered by the patents we own or in-license, now or in the future. Also, third parties may independently develop similar drugs through methods or means that do not technically infringe, misappropriate or otherwise violate our intellectual property rights, particularly if the scope of protection afforded by our intellectual property rights is limited by the laws and regulations of certain jurisdictions or pursuant to court judgments or other legal proceedings.

**RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES**

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

As of the Latest Practicable Date, we had not commercialized any drug candidates. Accordingly, we have limited experience in manufacturing drugs 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 drug candidates will not occur in the future. We also face certain risks in relation to the CDMOs that we or our partners engage for manufacturing activities.

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 certain future products, a batch or several related 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.

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

The quality of our products, including drug candidates we used for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes, the quality and reliability of equipment used, the capabilities of the CDMOs we engage and our ability to ensure that they adhere to our quality control and quality assurance protocol. We cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

---

## RISK FACTORS

---

**We have no track record with limited experience in launching and marketing approved drugs, and we may not be able to successfully create or increase market awareness of our drugs or sell our products, which will materially affect our ability to generate sales revenue.**

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

We will have to compete with other biotech companies to recruit, hire, train and retain marketing and sales personnel, but may be unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates. We may also pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates. There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

**Our drug candidates, once approved, may fail to achieve the degree of market acceptance, and the actual market size of our drug candidates might be smaller than expected.**

The commercial success of our drug candidates, upon regulatory approval, depends upon the degree of market acceptance each of such products achieves. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to, the clinical indications for which our drug candidates are approved, physicians, hospitals, medical treatment centers and patients considering our drug, efficacy and safety of our drug candidates, the prevalence and severity of any side effects, and the cost of treatment in relation to alternative treatments. Once approved, if any drug candidates that we commercialize 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 significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

**The size of the potential market for our current or future drug candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our current or future drug candidates may be smaller than our estimates.**

Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates. Furthermore, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are aiming for. 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. While we may seek approval for our drug candidates as an early-line therapy for certain

---

## RISK FACTORS

---

indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

**Counterfeit drugs and the illegal and/or parallel imports, compounding pharmacies and direct-to-consumer approaches with competing drugs may reduce demand for our drug candidates and compromise reputation, which could adversely affect our business.**

The illegal importation of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in the PRC and other countries where we commercialize our products. In certain therapeutic areas such as obesity/overweight, market dynamics are further complicated by the growing presence of the compounding pharmacies and/or direct-to-consumer distribution channels in certain parts of the world, which may offer alternative formulations or unapproved therapies that potentially reduce demand for our approved drugs and creating challenges related to patient acquisition, pricing, and market share. These could contribute to price erosion, fragmentation of the patient base and increased difficulty in establishing brand loyalty, all of which could negatively impact our commercial performance of any approved drugs, market share and long-term financial condition.

Furthermore, cross-border imports from lower-priced markets into higher-priced markets, which are known as parallel imports, could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower-priced biosimilar products of our future approved products or competing products from outside the jurisdictions in which we operate, conduct our clinical trials and perform our contractual obligations. Any future legislation or regulations that increase consumer access to lower priced drugs from outside the jurisdictions in which we operate, conduct our clinical trials and perform our contractual obligations could have a material adverse effect on our business.

Counterfeit drug products distributed or sold may be manufactured without proper licenses or approvals or be fraudulently mislabeled with respect to their contents or manufacturers. As counterfeit drugs or products in many cases resemble the authentic drugs, yet are generally sold at lower prices, any counterfeiting of our products could reduce the demand for our future approved drug candidates. Counterfeit drugs are unlikely to meet our or our collaborators' rigorous manufacturing and testing standards, and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit drugs.

**Negative results from off-label prescribing in metabolic therapies could damage the reputation of our drug candidates.**

Off-label drug use is the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. While regulatory authorities including the FDA, NMPA, and other comparable agencies strictly enforce regulations against the promotion of off-label use, physicians may legally prescribe drugs for unapproved uses under certain circumstances. Though a recognized aspect of medical practice, the prescription of our drug products outside their approved indications, patient populations, or dosing parameters could lead to potential risks arising from insufficient safety/efficacy data, regulatory compliance challenges, reimbursement issues, and the need for enhanced monitoring and documentation. Off-label use could also render our products less effective or entirely ineffective and may cause unexpected adverse drug reactions or other events. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, business operations and financial conditions. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates.

---

## RISK FACTORS

---

**Even if we or our partners are able to commercialize our drug candidates, we may face uncertainties from drug reimbursement practices, unfavorable drug pricing policies or regulations, or pricing reductions due to market conditions, which could harm our business.**

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. The pricing of drugs and biologics in the relevant jurisdiction is subject to governmental regulations, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the National Healthcare Security Administration of China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the “NRDL”), or provincial or local medical insurance catalogues for the National Medical Insurance Program (the “PRDL”) regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. In the U.S., there is no uniform policy of medical insurance coverage and reimbursement for drugs. In China, the average period for innovative drugs to be included in the NRDL or the PRDL has shortened from five to two years. Nevertheless, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

**Guidelines, recommendations and studies published by various organizations could disfavor our drug 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’ drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug products, either directly or indirectly relative to our competitive drug products, could result in current or potential decreased use of, sales of, and revenue from one or more of our drug products. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our drug products,

---

## RISK FACTORS

---

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.

### RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

**We work with various third parties to develop our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.**

We have relied on and plan to continue to rely on third-party CROs and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs and we control only certain aspects of their activities.

We and our CROs are required to comply with the applicable good clinical practice (“GCP”), good laboratory practice (“GLP”) and other regulatory regulations and guidelines enforced by the NMPA, the FDA and other comparable regulatory authorities for all of our drug candidates in clinical development. In addition, our clinical trials must be conducted with drug candidates or products manufactured under current good manufacturing practice (“cGMP”) requirements. The CROs we engage may not always perform to our standards, may not produce results in a timely manner or may fail to perform at all. We cannot control whether or not such CROs will devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If we or any of our CROs fail to comply with the applicable GCP, GLP, cGMP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Failure to comply with these regulations may lead us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Similarly, if other third parties fail to meet expected deadlines, timely transfer to us any requisite information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a sub-standard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, the clinical trials of our drug candidates may be compromised, delayed, prolonged, suspended or terminated, or our data may be rejected by the NMPA, the FDA, or other comparable regulatory authorities.

Because we rely on third parties, our internal capacity to perform these functions is limited. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. In addition, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines.

**We engage third parties to manufacture our drug products for clinical development and future commercial sales. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels.**

We expect to rely on third parties to manufacture most of our drug candidates. Our anticipated reliance on contract manufacturers or other third parties exposes us to certain risks. These contract manufacturers or third parties may have little or no experience with manufacturing our drug candidates, and they may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs. They may not be able to execute our or the relevant manufacturing procedures and other logistical support requirements appropriately. The contract

---

## RISK FACTORS

---

manufacturers or third parties are also subject to ongoing periodic unannounced inspections by comparable regulatory authorities for corresponding regulatory requirements; however, we or our licensees or third parties do not have control over contract manufacturers' compliance with these regulations and requirements. Raw materials and components used in the manufacturing process, particularly those for which we or licensees or third parties have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects. Products and components from our or our licensees' or third parties' contract manufacturers may be subject to additional customs and import charges, which may cause us to incur delays or additional costs as a result.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the NMPA, FDA or other comparable regulatory authorities, result in higher costs or adversely impact the commercialization of our drug candidates.

**If our business partners fail to maintain the necessary permissions, licenses or certificates, for the development, manufacturing and commercialization of our products, our business could be materially affected.**

Our business partners, such as CROs, CDMOs, suppliers or licensing partner, on whom we may rely on to develop, manufacture, market, sell and distribute our drug candidates, may be subject to requirement of obtaining and maintaining necessary permits, licenses and certificates in their operations. Our business partners may also be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such events may result in the loss or non-renewal of the relevant permits, licenses and certificates. If our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Any changes in the standards used by governmental authorities in considering whether to renew or reassess our business partners' licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business partners' operations, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our business, financial condition and results of operations.

**If we cannot maintain or develop clinical collaborations and relationships with principal investigators, key opinion leaders ("KOLs"), physicians and other industry experts, our results of operations and prospects could be adversely affected.**

Our relationships with principal investigators, KOLs, physicians and other industry experts play an important role in our research and development and marketing activities. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. If we are unable to develop and maintain our relationships with industry participants as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

---

## RISK FACTORS

---

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

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

We are a clinical-stage biotechnology company with a limited operating history. We have not yet demonstrated an ability to successfully obtain marketing approvals for, or commercialize, our drug candidates. To date, we have no products approved for commercial sale and have not generated any revenue from product sales.

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

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

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

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

**Our financial performance and results of operations may be adversely affected by fair value changes of our other financial assets at amortized cost.**

As of December 31, 2024 and 2025, we recorded other financial assets at amortized cost of US\$92.4 million and US\$87.5 million, respectively. We measure assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest at amortized cost. These financial assets at amortised cost are subject to credit risks. We assess on a forward-looking basis the expected credit loss associated with our financial assets carried at

---

## RISK FACTORS

---

amortized cost. There was no impairment losses for the years ended December 31, 2024 and 2025. For details, see Notes 4 and 22 to the Accountant’s Report in Appendix I to this document. Any failure or distress of banks or financial institutions with which we have a commercial relationship, or any events involving limited liquidity, defaults, non-performance or other adverse developments that affect the financial services industry in general (or any concerns or rumors about events of these kinds) may cause a substantial decrease in the value of our other financial assets at amortised cost, which may in turn adversely affect our results of operations and financial condition.

**We have granted, and may continue to grant, certain awards under our Equity Incentive Plan, which may result in increased share-based payment expenses.**

We have adopted our Equity Incentive Plan for the purpose of granting share-based compensation awards to employees, officers, or directors to incentivize their performance and align their interests with ours. In 2024 and 2025, we incurred US\$1.6 million and US\$2.7 million of share-based compensation expenses relating to share options granted under our Equity Incentive Plan, respectively. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the arrangements under our currently effective employee stock option plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this [REDACTED].

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

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. We recorded net foreign exchange gains of US\$0.4 million and losses of US\$1.2 million in 2024 and 2025 and net foreign exchange. There is no assurance that we will continue to incur foreign exchange gains in the future or our foreign exchange losses will not incur in the future. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

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

---

## RISK FACTORS

---

### RISKS RELATING TO OUR OPERATIONS

**The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could delay or prevent the successful development of our drug candidates and result to a material and adverse effect on our business and results of operations.**

As a global clinical-stage biotechnology company, our success is highly dependent on the expertise, recruiting and retaining qualified scientific, technical, clinical, sales and marketing personnel has been and will also be critical to our success in the future. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the biotech industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced senior management or key scientific and clinical personnel in the future. The departure of one or more of our senior management or key scientific and clinical personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

**We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business, which could adversely affect our business, financial conditions, results of operations and reputation.**

From time to time, we may be involved in inspections, claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, privacy protection, environmental and safety matters, breach of contract, employment or labor disputes and intellectual property rights. Any inspections, claims, disputes or legal proceedings initiated by us or brought against us, our management or directors, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, inspections, claims, disputes or legal proceedings against us, our management or directors may be due to actions taken by our counterparties, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

---

## RISK FACTORS

---

**We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties. If our third-party collaborators fail to comply with applicable anti-bribery laws, our reputation may be adversely affected and we could be subject to penalties and significant expenses.**

We are subject to anti-bribery laws in the United States, China and other jurisdictions in which we conduct our business. For example, we are subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"), which generally prohibits us from making improper payments to non-U.S. official for the purpose of obtaining or retaining business. We are also subject to anti-bribery laws in China that generally prohibit us and any of our intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We may be unable to prevent, detect or deter all such instances of misconduct by third parties. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery or other misconduct involving employees and third parties that had any material adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in the future. Failure to comply with the applicable anti-bribery laws could disrupt our business and lead to severe criminal and/or civil penalties, including imprisonment, criminal and civil fines, loss of relevant licenses or permits, suspension of our ability to conduct our business operations and others. Other remedial measures could include further changes or enhancements to our procedures, policies and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business and financial condition. We could also be adversely affected by any allegation that we violated any applicable anti-bribery laws. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business, results of operations and reputation.

**Product liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.**

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our drug candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in, among others, decreased demand for our drug candidates, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, and costs to defend the related litigation.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations. See "— We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources, which may negatively impact our R&D progress and overall operations" for more details.

---

## RISK FACTORS

---

**Our information technology systems, or those used by our business partners, may fail or suffer security breaches, which could materially and adversely affect our business, financial condition, results of operations and prospects.**

Our internal computer systems and those of our current and any future third-party vendors, collaborators, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. As we continue to implement and integrate new systems and technologies to support our growth and operations, we may face additional risks related to system transitions, data migration, and the establishment of appropriate controls and procedures.

Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations. Additionally, any failures in our systems or inadequacies in our control could result in operational inefficiencies or compliance issues. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

We could also be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our company, our third-party vendors, and clinical sites.

**Changes in geopolitical relationships, barriers to trade or escalation of trade disputes, including the imposition of trade restrictions and sanctions, could negatively affect demand for our products and services, and consequently could have a material adverse effect to our business, financial condition and results of operation.**

Our operations are subject to the risk of deterioration in the political and economic relations among countries and sanctions and export controls administered by the government authorities in the countries in which we operate, and other geopolitical challenges. We cannot predict whether the countries in which we operate, or may operate in the future, would become subject to new or additional trade restrictions and sanctions, including the type or effect of such restrictions and sanctions imposed by the United States or other governments. We cannot assure you that we, our research partners, our suppliers and customers, or the global value chains we plan to serve will not be impacted in the future. Any impacts may result in our customers seeking other suppliers for the products and services that we offer, and we may be unable to recapture and/or replace such customers. We may also have to adjust or even terminate our collaborations with our research and other business partners, which could disrupt our research and development and commercialization strategies. Further, any increased customs restrictions and tariffs or quotas, or the imposition of additional duties and other charges on imports and exports could change the way we and our customers conduct business, increase our costs, or impede the timely delivery of our products. This could have a negative effect on our business, financial condition, results of operations and prospects.

In particular, the United States government's attitude towards Chinese service providers in pharmaceutical and biotechnology industries may directly or indirectly affect our business operations. The United States has recently passed legislation, namely the BIOSECURE Act (the "**BIOSECURE Act**"), to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of

---

## RISK FACTORS

---

concern”, or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology service or equipment. For details, see “Regulatory Overview — Overview of Laws and Regulations in the United States — Recently Passed Law by the U.S. Government: The BIOSECURE Act”.

On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the National Defense Authorization Act (“NDAA”) for the year of 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. The Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a “biotechnology company of concern” (“BCC”); entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense’s annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process.

There is no guarantee that the legislation would not apply to or impact certain biotechnology equipment or services that we procure or use. As a result, any continued use of such biotechnology equipment or services provided or produced could affect our ability to continue our development or the third parties that we may contract with, which may, in turn, affect our business operations. Moreover, because the provisions remain subject to change, the potential scope, timing and impact of any final legislation are uncertain and could be more restrictive than currently anticipated.

Consequently, we may need to re-evaluate or adjust our established supply chains now that the BIOSECURE Act has become law. The need to re-evaluate our supply chain contracts may impose additional costs and operational complexities on our business, including, among other things, an examination and potential modification to existing personnel and expertise, and examination of our existing contracts, and a re-assessment of our current suppliers in order to identify possible alternative sources of supply. We may not be able to identify alternative sources of supply with competitive prices and terms and satisfactory quality in a timely manner, and any disruption to our established supply chains may lead to delays in procurement, production, and delivery, all of which could have a material adverse effect to our business, financial condition and results of operation.

### **Increased labor costs could result in exceeding expenses, slow our growth and affect our profitability.**

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially adversely affect our results of operations.

### **Potential acquisitions or strategic partnerships may increase our capital requirements, cause dilution to our Shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.**

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. See “Business — Our Strategies — Maximize the Value of Our Assets Through

---

## RISK FACTORS

---

Accretive Partnerships” for more details. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, such as increased operating expenses and cash requirements, and the assumption of additional indebtedness or contingent or unforeseen liabilities.

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

We are a relatively small company, operating in China and the U.S. and working on a rich and expanding pipeline of drug candidates. We had a total of 57 full-time employees as of December 31, 2025. Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially adversely affect our business, financial condition, results of operations and prospects.

**We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources, which may negatively impact our R&D progress and overall operations.**

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. However, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

**Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.**

Negative publicity about us, our business and our management could threaten the perception of our brands. Our reputation could be adversely affected by negative publicity regarding our clinical trials, study results, regulatory interactions, drug candidates, or relationships with business partners. Additionally, any misconduct by our clinical investigators, business partners, or other third parties involved in our development programs could result in negative media coverage. Any such negative publicity, regardless of veracity, could damage our reputation, subject us to government or regulatory investigations, divert our management’s attention, or cause us to incur additional other resources. We may not be able to conclusively refute each of the allegations within a reasonable period of time, or at all. As a result, our ability to advance our clinical programs, attract partners, retain talent, and raise capital may be adversely affected, and the price of our Shares may decline.

**We are subject to risks associated with leasing space.**

As of the Latest Practicable Date, we leased one property in the United States for office use, and one property for research and development in Shanghai. The lessors of our leased properties may have valid title or the legal rights to such leased properties but may not have complied with all the necessary property leasing procedures. In addition, if our leases expire, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such

---

## RISK FACTORS

---

offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases with respect to the properties on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

As of the Latest Practicable Date, the leased property in Shanghai had not been registered and filed with relevant land and real estate management departments in China. Failure to complete the lease registration will not affect the validity of these lease agreements, but the competent housing authorities may order us to register the lease agreements in a prescribed period of time and impose a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease if we fail to complete the registration within the prescribed time frame.

In addition, our leased property in Shanghai has been mortgaged by the property owner to secure third-party obligations. Under the Civil Code of the PRC, if the mortgagor defaults on its obligations, the mortgagee has the right to request a court-ordered auction or sale of the mortgaged property and to receive repayment from the proceeds with priority. If the mortgagee exercised its rights and the mortgaged property is sold or otherwise disposed of, our right to continue using such leased property may be adversely affected, and we may be required to vacate the premises. Although the property owner has provided a written undertaking to indemnify us for any losses arising from such circumstances, there can be no assurance that we will be able to recover all losses or that such indemnity will be honored in a timely manner, if at all. As of the Latest Practicable Date, no mortgagee has exercised its rights with respect to our leased property, and there are no ownership disputes regarding such properties. However, if we are required to relocate due to enforcement of a mortgage, although we believe suitable alternative properties are available, any relocation could result in disruption to our operations and could have a negative impact on our business, results of operations or financial condition.

**We may be subject to various factors beyond our control, which may have a material adverse effect on our business, financial condition and results of operations.**

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. The occurrence of a disaster or a prolonged outbreak of an epidemic illness, or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

### RISKS RELATING TO GOVERNMENT REGULATIONS

**All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated and are subject to change. Any failure to comply with relevant regulations and industry standards could negatively impact our reputation and our business, financial condition, results of operations and prospects.**

The biotech industry is subject to comprehensive government regulation and supervision. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions. The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislations may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes

---

## RISK FACTORS

---

in government regulations, policies or in practices relating to the biotech industry 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, failure to comply with the applicable regulatory requirements in the jurisdictions we operate or target to operate may subject us to administrative or judicial sanctions, such as regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, fines, or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our reputation and our business, financial condition, results of operations and prospects.

**If we are unable to obtain regulatory approval from the NMPA, FDA and other comparable regulatory authorities without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be materially and substantially affected.**

The time required to obtain relevant regulatory approvals for our drug candidates from competent authorities is uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We cannot guarantee that we will be able to obtain regulatory approvals for our other existing drug candidates or any drug candidates in the future. Our drug candidates could fail to receive the regulatory approvals from competent authorities for many reasons, such as disagreement with the design or implementation of our clinical trials, and failure of our clinical trial results to meet the level of statistical significance required for approval. The applicable competent authorities may require more information to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

**Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses.**

If the NMPA, the FDA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to other conditions of approval. It is also possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things, restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory recalls. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business and financial condition.

---

## RISK FACTORS

---

**We may be subject to applicable anti-kickback, false claims laws, or similar healthcare and security laws and regulations in relevant jurisdictions, which could adversely affect our business.**

Law enforcement authorities are increasingly focusing on enforcing anti-kickback, false claims laws or similar healthcare and security laws and regulations. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our business and results of operations. Furthermore, we are subject to anti-bribery laws in all jurisdictions in which we conduct our business that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages, such as the FCPA of the United States. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs.

As we expand our operations globally, we may also become subject to similar laws and regulations from other jurisdictions. There are ambiguities as to what is required to comply with any of these laws and regulations, and if we fail to comply with such requirements, we could be subject to penalties and other negative consequences. If any of the physicians or other third parties with whom we do business are found to be not in compliance with the applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, which may also adversely affect our business.

**We are subject to environmental protection, health and safety laws and regulations. Failure to comply with these laws and regulations could subject us to fines or penalties or incur costs that could have a material adverse effect on our business.**

We and certain third parties we work with, such as our CROs, CDMOs and business partners, are subject to numerous environmental, health and safety laws and regulations. We generally contract with third parties for the disposal of these materials and wastes and we cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and could incur significant costs associated with civil or criminal fines and penalties. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities.

**We are subject to registration, review and other requirements of the regulatory authorities for cross-border sales or licensing of technology as well as operations related to data safety.**

China has adopted management and administration measures of the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology, requiring either approvals by or registration with the relevant PRC governmental authorities. We have registered technology export contracts. In the future, we may also enter into agreements with CROs in the United States regarding technical

---

## RISK FACTORS

---

support in relation to the development of drug candidates, which may be deemed to constitute the export of technology under applicable regulations. As a result, such transfers may be required to be registered with applicable PRC governmental authorities.

We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we may be required, as applicable, to obtain approval from the relevant governmental authority who will conduct genetics and data safety review. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities. According to the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), 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 Chinese 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. If we are unable to obtain necessary approvals or fail to obtain such approvals in a timely manner, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects.

**We are subject to laws, regulations and obligations related to data privacy and security and cross-border data transferring, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.**

We are subject to the relevant local, state, national and international data privacy and protection laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the jurisdictions in which we may operate and conduct our clinical trials, as well as contractual obligations. Moreover, the landscape of cybersecurity and data privacy and security laws is constantly evolving. See “Regulatory Overview — Laws and Regulations on Information Security and Data Protection” for more details. We cannot guarantee if these rules or regulations promulgated will impose additional compliance requirements and the measures we have taken or will take in the future will always be effective or fully satisfy the relevant regulatory requirements under the relevant laws and regulations, including obtaining such approval, filing and other administrative measures in a timely manner, or at all. Complying with new laws and regulations could increase the costs or require us to change our business practices in a manner materially adverse to our business. Additionally, to the extent we are found by the applicable regulators to be not in compliance with these laws and requirements, we may be subject to fines, regulatory orders to suspend our operations or other regulatory and disciplinary sanctions, which could adversely affect our business, operations and financial performance.

**Changes in laws, regulations and policies relating to the biotech industry in all jurisdictions where we operate may result in additional compliance risks and costs.**

There have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the biotech industry and the healthcare system. For example, in China, the NMPA has revised the Drug Administration Law, implemented the Marketing Authorization Holder regime, and adopted numerous measures in recent years aimed at accelerating review while simultaneously heightening post-marketing surveillance and pharmacovigilance obligations. In the United States, the FDA has continued to refine its expectations with respect to oral small molecule drugs, which may include new expectations for real-world evidence, risk evaluation and others. In addition, the Inflation Reduction Act of 2022 introduced a Medicare drug price negotiation program that allows the federal government to directly negotiate prices for certain

---

## RISK FACTORS

---

high-expenditure drugs covered under Medicare. Notably, oral small molecule drugs become eligible for price negotiation seven years after their initial FDA approval, which may reduce the potential lifetime revenue for our drug candidates, particularly if they are selected for early negotiation.

Although none of our drug candidates had been commercialized as of the Latest Practicable Date, these legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug candidates in the future. Moreover, because these laws and regulations are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

### **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. The uncertainties, tensions and political concerns among various countries and regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. Such trade or political uncertainties and tension may negative affect our business or the business operations of our partners or third parties. 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 relevant foreign countries or regions. Any uncertainties, tensions and political concerns between 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 relevant 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.

While we have not started commercialization of our drug candidates, any rising trade and political uncertainties and 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 uncertainties and 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 drug 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

---

## RISK FACTORS

---

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 be classified as a “PRC resident enterprise” for PRC enterprise income tax purposes and our income may be subject to PRC tax under the relevant PRC laws.**

Under the Corporate Income Tax Law of the PRC (the “EIT Law”), an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Under the Circular of the State Taxation Administration (the “STA”) on Issues Concerning the Identification of Chinese-Controlled Enterprises Registered Overseas as Resident Enterprises on the Basis of Their De Facto Management Bodies (《國家稅務總局關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by the STA on April 22, 2009 and partially abolished in December 2017, or Circular 82, provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore, under which an offshore enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its “de facto management body” in China and will be subject to PRC enterprise income tax on its global income under certain circumstances. On July 27, 2011, the STA 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 clarifies certain issues related to determining PRC resident enterprise status, including which the competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Additional implementing regulations or guidance may be issued determining that we or any of our subsidiaries incorporated out of the PRC is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that we or any of our subsidiaries incorporated out of the PRC is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. See “Financial Information — Description of Selected Components of Consolidated Statements of Comprehensive Income — Income Tax Expenses” for more details on our income tax rates.

**Governmental regulations on currency exchange may affect us.**

The Circular of the SAFE on Foreign Exchange Administration of Equity Financing and Round-Trip Investments by Domestic Residents via Special Purpose Vehicles (《國家外匯管理局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》) (“Circular 37”) requires PRC residents to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities, and to update the registration upon any significant changes with respect to the PRC individual shareholder, such as the increase or decrease of capital contributions, share transfer or exchange, or mergers or divisions. Pursuant to the Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments will be filed with qualified banks instead of SAFE. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, as well as liability under PRC law for circumventing applicable foreign exchange restrictions.

---

## RISK FACTORS

---

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

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of the SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities. If we fail to obtain such approvals or complete registrations or report procedures, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments.

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

As a Cayman Islands holding company, we may rely on dividends and other distributions on equity that may be paid by our subsidiaries for our cash and financing requirements. If any of our subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to conduct our business or financial condition.

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

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

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

---

## RISK FACTORS

---

### **There might be uncertainties in affecting service of legal process, enforcing foreign judgments against us or our Directors and senior management personnel in the PRC.**

We are a holding company incorporated in the Cayman Islands. Certain of our Directors and senior management personnel reside in mainland China. Therefore, there are uncertainties for [REDACTED] to directly effect service of legal process upon us or our Directors and senior management personnel in the PRC.

On January 18, 2019, the Supreme People’s Court and the Hong Kong SAR 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 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 SAR and the mainland China. The new arrangement does not include the requirement for a choice of court agreement in writing by the parties. The new arrangement, which came into effect on January 29, 2024, supersedes the original arrangement. Under the new arrangement, judgments rendered by Hong Kong courts that comply with the provisions of the new arrangement can generally be recognized and enforced in the PRC even if the parties in the dispute have not entered into a written choice of court agreement. However, we cannot guarantee that all judgments from Hong Kong courts will be recognized and enforced in the PRC. The recognition and enforcement of a specific judgment are subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

### **We are a Cayman Islands exempted 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 company is incorporated as an exempted company under the laws of the Cayman Islands. The rights of shareholders and the responsibilities of our directors are governed by Cayman Islands law and our amended and restated memorandum and articles of association. The Cayman Islands has a less developed body of company case law compared to jurisdictions such as the United States or Hong Kong. As a result, there may be fewer judicial precedents to provide guidance on the interpretation of shareholder rights, fiduciary duties, and corporate governance matters. This could limit the ability of shareholders to obtain effective judicial remedies in the event of disputes, including those relating to minority shareholder protections, director misconduct, or enforcement of fiduciary duties. Additionally, Cayman Islands courts may not recognize or enforce judgments obtained in other jurisdictions, which could further complicate the enforcement of shareholder rights. Shareholders may therefore face greater challenges in protecting their interests compared to [REDACTED] in companies incorporated in jurisdictions with more established legal frameworks.

### **RISKS RELATING TO THE [REDACTED]**

#### **No public market currently exists for our Shares; an active [REDACTED] market for our Shares may not develop and the [REDACTED] and [REDACTED] of our Shares may decline or become volatile which could lead to substantial losses to [REDACTED].**

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of our negotiations with the [REDACTED] (for themselves and on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following [REDACTED]. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our Shares will develop, especially during the period when certain portion of our Shares may be subjected to lock-up, or if it does develop, that it will sustained following the [REDACTED], or that

---

## RISK FACTORS

---

[REDACTED] of the Shares will rise following the [REDACTED]. In addition, future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our Shares.

**You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.**

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

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

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we have not yet adopted a dividend policy with respect to future dividends. Therefore, you should not rely on an [REDACTED] in our Shares as a source for any future dividend income. Our Board has discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiary, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors.

**We may allocate the [REDACTED] from this [REDACTED] in ways that you and other Shareholders may not agree.**

Our management will have broad discretion in the application of the [REDACTED] from this [REDACTED], including for any of the purposes described in the section headed “Future Plans and Use of [REDACTED]” for more details. Because of the number and variability of factors that will determine our use of the [REDACTED] from this [REDACTED], their ultimate use may vary substantially from their currently intended use. Our management might not apply the [REDACTED] in ways that ultimately increase the value of your [REDACTED], and the failure by our management to apply these funds effectively could harm our business.

**Certain industry facts, statistics and forecasts in this document that were obtained from various government publications have not been independently verified.**

Certain industry facts, forecasts and statistics in this document relating to the biotech industry in and outside China are obtained from various government publications, and we can guarantee neither the quality nor reliability of such source materials. However, neither we, the Joint Sponsors, [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from official governmental sources. Therefore, we make no representation as to the accuracy of such facts, forecast and statistics. 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 biotech industry in and outside China may be inaccurate, and you should not place undue reliance on it. 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.

## RISK FACTORS

---

**You should read the entire document carefully and should not rely 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 certain information that does not appear in this document. We have not authorized such disclosures and do not accept responsibility for its accuracy or completeness. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the information, and any content inconsistent with this document should not be relied upon.